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Examining the Recommendation for 45 minutes of Therapy Following Stroke

by

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Abstract

Faculty of Environmental and Life Sciences

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Most people receive Occupational Therapy and/or Physiotherapy as part of stroke rehabilitation. The Royal College of Physicians recommends a minimum of 45 minutes of each therapy required, every day. This recommendation is based on expert consensus, underpinned by limited evidence that more therapy achieves better outcomes. The Sentinel Stroke National Audit Program (SSNAP) monitors achievement of the 45 minute guideline; currently it is achieved for 37% and 34% of people considered appropriate for Occupational Therapy and Physiotherapy respectively. Reasons for non-achievement are unclear. This study examined the recommendation for a minimum of 45 minutes of therapy after stroke, using multiple and mixed methods.

A Cochrane review analysed the effect of time spent in rehabilitation on activity limitation and impairment after stroke. To our knowledge, this is the first systematic review with meta-analysis, investigating the effect of time spent in rehabilitation after stroke, to control for type of rehabilitation within included studies. It found that 'more time in therapy is better' is false, but 'a lot more therapy' might lead to better outcomes. The Cochrane review concluded that there is insufficient evidence to recommend a specific minimum amount of therapy after stroke.

Therapist focus groups explored why some people do not receive the recommended minimum amount of therapy. Findings were used to inform a Delphi study to gain consensus from therapists on reasons why a person might not receive a minimum of 45 minutes of therapy. Collectively, these studies found issues with the suitability of the guideline for some people after stroke. Some people are not able to consistently tolerate this amount of therapy, but the SSNAP audit lacks sensitivity to account for this variability. Other people require more than 45 minutes of daily therapy; this study found that they may not receive it. Non-delivery of the guideline is not only due to its suitability, but also due to lack of resources. There is insufficient therapy time to deliver the recommended minimum amount due, in part, to the organisation of stroke care, but also due to lack of therapy personnel.

Findings from these studies, together with those of other published literature, contributed to a discussion regarding whether the 45 minute guideline is fit for purpose. It concluded that, although the guideline has increased the amount of therapy received, it does not meet all the requirements of a good clinical guideline according to literature sources. Therefore, this research identifies that the 45 minute guideline and its measurement via the SSNAP audit would benefit from review.

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List of Accompanying Materials

1. Detailed Risk of Bias assessments for Cochrane review:

https://apps.ccbs.ed.ac.uk/csrg/cochranestrokedocuments/Risk_of_Bias_Assessments_FINAL .pdf

Research Thesis: Declaration of Authorship

Print name: Beth Alice Clark

Title of thesis: Examining the Recommendation for 45 minutes of Therapy Following Stroke

I declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
7. Parts of this work have been published as:-

Clark B, Whitall J, Kwakkel G, Mehrholz J, Ewings S and Burridge J (2017) Time spent in rehabilitation and effect on measures of activity after stroke. *Cochrane Database of Systematic Reviews* (3)

Signature: ..... Date: 30/09/2021

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Definitions and Abbreviations

Definitions

Stroke	An acute, vascular injury to the central nervous system (Sacco et al. 2013)
Therapy	Physiotherapy and/or Occupational Therapy
Occupational Therapy	An intervention that enables people to overcome barriers that prevent them from undertaking the occupations (activities) that are important to them (Royal College of Occupational Therapists 2019)
Physiotherapy	An intervention that assists in the restoration of movement and function following illness or injury (Chartered Society of Physiotherapy 2018)
Rehabilitation	"Any non-pharmacological, non-surgical intervention that aims to improve activity after stroke" (Clark et al. 2017 p.2)
45 minute guideline	The recommendation that "People with stroke should accumulate at least 45 minutes of each appropriate therapy every day, at a frequency that enables them to meet their rehabilitation goals, and for as long as they are willing and capable of participating and showing measurable benefit from treatment". (Intercollegiate Stroke Working Party 2016 p.25)

Abbreviations

NICE	National Institute for Health and Care Excellence
OT	Occupational Therapy/ Therapist
PT	Physiotherapy/Physiotherapist
RCP	Royal College of Physicians
SLT	Speech and Language Therapy/Therapist
SSNAP	Stroke Sentinel National Audit Programme

Chapter 1 Introduction to thesis

1.1 Introduction

This research examines the evidence for and implementation of "the 45-minute guideline" in stroke rehabilitation. This guideline, recommended by both the National Institute for Health and Care Excellence (NICE), and the Royal College of Physicians (RCP), provides guidance for the minimum amount of time that people with stroke should spend in therapy. The most recent iteration of the guideline states:

> "People with stroke should accumulate at least 45 minutes of each appropriate therapy every day, at a frequency that enables them to meet their rehabilitation goals, and for as long as they are willing and capable of participating and showing measurable benefit from treatment". (Intercollegiate Stroke Working Party 2016 p.25)

The RCP produces guidelines to support continuous quality improvement in stroke care, by providing guidance, based on the best available evidence (Intercollegiate Stroke Working Party 2016). Despite acknowledgement that there is little evidence to support a minimum recommendation for amount of therapy (Intercollegiate Stroke Working Party 2016), it is assumed that 45 minute guideline was introduced to increase quality of therapy provision post-stoke and reduce unwarranted variation.

In England, Wales and Northern Ireland, the achievement of the guideline is audited by the Sentinel Stroke Audit Programme (SSNAP). Recent findings from this audit shows that the 45 minute guideline was achieved for 37% of people for Occupational Therapy and for 34% of people for Physiotherapy (Bahalla et al. 2021). Reasons for non-achievement are not known.

The motivation for this research project stems from my personal experience as an Occupational Therapist in clinical practice. I have experienced the guideline as a therapist, providing therapy to individuals post-stroke and as a team leader, introducing the guideline into clinical practice and reporting amount of therapy provided. In these roles, my concern was: Is the 45 minute guideline beneficial to people with stroke and useful to therapists? It was this question that resulted in further exploration of published literature and the development of the research questions addressed in this study.

This chapter introduces topics relevant to the area of research and consider the motivation for this project. It will also introduce the structure of the research project and the content of this thesis.

1.2 Stroke and its impact

A stroke is an acute, vascular injury to the central nervous system (Sacco et al. 2013). Of all strokes, 87% are ischemic, caused by a clot or embolus disrupting the blood flow in the brain. A further 13% are caused by a spontaneous haemorrhage, either intracerebrally (10%) or in the sub-arachnoid space (3%). Risk factors for stroke include being overweight/obese, high blood pressure, high cholesterol, diabetes and physical inactivity (Mozaffarian et al. 2015). Stroke is a significant global health issue. In 2016, there were approximately 13.7 million first-ever strokes and more than 80 million stroke survivors worldwide (Johnson et al. 2019). An estimated 152,000 people in the UK suffer a stroke every year (Townsend et al. 2012). The number of people living with stroke is increasing, due to reducing stroke mortality and a growing and aging population (Johnson et al. 2019). This results in increasing demands on stroke rehabilitation services (Stinear et al. 2020).

Damage caused to the brain by a stroke can lead to disorders of movement, cognition, vision, behaviour and perception (either alone or in any combination), often resulting in significant disability. Indeed, stroke is the second most common cause of lost disability adjusted life years (DALYs) (Johnson et al. 2019). In 2010, 102 million DALYs were lost globally following stroke (Feigin et al. 2014). In the UK, 37% of people discharged from hospital following stroke required

assistance with activities of daily living (ADL) such as washing and dressing (Royal College of Physicians 2014). Such disability results in significant societal cost, due to loss of paid employment and care requirements (Mozaffarian et al. 2015; Patel et al. 2020). Improved rehabilitation outcomes following stroke would reduce the impact of disability on quality of life for people with stroke and their carers' (Lewthwaite et al. 2018; Oyewole et al. 2020) and national economies (Patel et al. 2020).

1.3 Rehabilitation therapy following stroke

Occupational Therapy and Physiotherapy are mainstream broad-based interventions that 80% and 85% (respectively) of people with stroke receive as part of inpatient stroke unit care (Royal College of Physicians 2014) and following hospital discharge. Physiotherapy assists in the restoration of movement and function, following illness or injury (Chartered Society of Physiotherapy 2018) and Occupational Therapy (OT) enables people to overcome barriers that prevent them from undertaking the occupations (activities) that are important to them (Royal College of Occupational Therapists 2019). These professions contribute to post-stroke recovery including, but not limited to, increased independence in activities of daily living (ADL), community reintegration, improved postural control and mobility (Legg et al. 2006; Langhorne et al. 2011; Shing 2011; Pollock et al. 2014a).

1.4 The 45 minute guideline: implementation and audit

The 45 minute guideline was introduced in 2008 (Intercollegiate Stroke Working Party 2008). It was developed by the guideline development group of the Intercollegiate Stroke Working Party, which includes representatives from England, Wales, and Northern Ireland, of professional bodies, 3rd sector organisations, and patients.

The wording of the guideline indicates that there is flexibility regarding how therapy can be delivered. It states that people should "accumulate at least 45 minutes of each appropriate

therapy" and that therapy should be delivered "at a frequency that enables (people) to meet their rehabilitation goals" (Intercollegiate Stroke Working Party 2016 p.25). This suggest that therapists should distribute therapy throughout the day to suit the person receiving rehabilitation. The guideline also states that support staff can deliver therapy, under the guidance of a registered therapist.

Guideline authors acknowledge that the recommended minimum of 45 minutes is based on expert consensus, underpinned by research evidence that more therapy improves outcomes after stroke (Intercollegiate Stroke Working Party 2016). Chapter 2 reviews this research evidence and suggests that there are confounding variables within these studies, that calls into question their ability to underpin the 45 minute guideline.

The RCP describe the 45 minute guideline as "therapy intensity" post-stroke. The term "intensity" potentially refers not only to the number of minutes of therapy provided but characteristics related to the content of therapy. This could include number of repetitions performed within treatment sessions (Scrivener et al. 2012; Abdullahi et al. 2021), physiological effort exerted, measured by heart rate (Globas et al. 2012; Hornby et al. 2019), muscle resistance (Lamberti et al. 2017; Hogg et al. 2020) and/or walking speed (Hunnicutt et al. 2016; Bowden et al. 2020), or combinations of both repetitions and physiological effort (Hornby et al. 2015; Klassen et al. 2020). Intensity could also be defined as appropriate task challenge (Pollock et al. 2014c; Woodbury et al. 2016; Hayward et al. 2021), neither too easy nor too difficult. The RCP guidelines only dictated amount per session (45 minutes), session frequency (every day, previously five days-a-week) and duration (for as long as they are willing and capable of participating and showing measurable benefit). By focusing only on these time-based recommendations, important aspects related to the content of therapy and the interaction between the therapist and the person with stroke could be overlooked.

Since 2013, SSNAP has audited achievement of the guideline. Although the guideline recommends 45 minutes of therapy every day, its achievement is audited, based on provision of therapy five days-a-week for people identified as appropriate for therapy. Once a person has been identified as being appropriate for therapy, they are considered appropriate for a minimum of 45 minutes of therapy, five days per week (Intercollegiate Stroke Working Party 2021). The RCP guidelines state that rehabilitation should be a "pervasive activity" (Intercollegiate Stroke

Working Party 2016 p.25). However, only rehabilitation provided by a therapist or therapy assistant is recorded by the SSNAP audit (Intercollegiate Stroke Working Party 2021). This approach does not account for the time a person may spend in therapist-directed rehabilitation outside of therapy, which may include independent or family-supported practice, or activity undertaken with nursing staff. The guideline does not specify that its recommendations are for people in the acute/subacute stages following stroke, however, the SSNAP audit only applies to inpatient and early supported discharge services.

1.5 Research Questions

Exploration of relevant published literature, described in chapter two, identified gaps in current understanding. This included lack of a clear evidence for the 45 minute guideline, including lack of clarity regarding the effect of time spent in rehabilitation. There is also limited understanding regarding how the guideline is implemented in clinical practice, including why it is not always achieved. This led to the development of the following research questions:

1. Does the evidence for effect of time spent in rehabilitation support guideline recommendations for therapy following stroke?

2. What factors determine whether someone receives the recommended minimum amount of therapy?

3. Is the 45 minute guideline fit for purpose?

1.6 Research Structure

Multiple and mixed methods addressed the research questions. The first question, which examined the underpinning evidence for the 45 minute guideline, was addressed by undertaking a Cochrane review. The second question, which considered the reasons why a person might not receive the recommended minimum amount of therapy, was address via focus groups and a Delphi study. Finally, the findings of the first two question, combined with relevant published literature, were synthesised, to address the third question. Please see figure 1 for a diagram of the research design, in the context of the research questions.

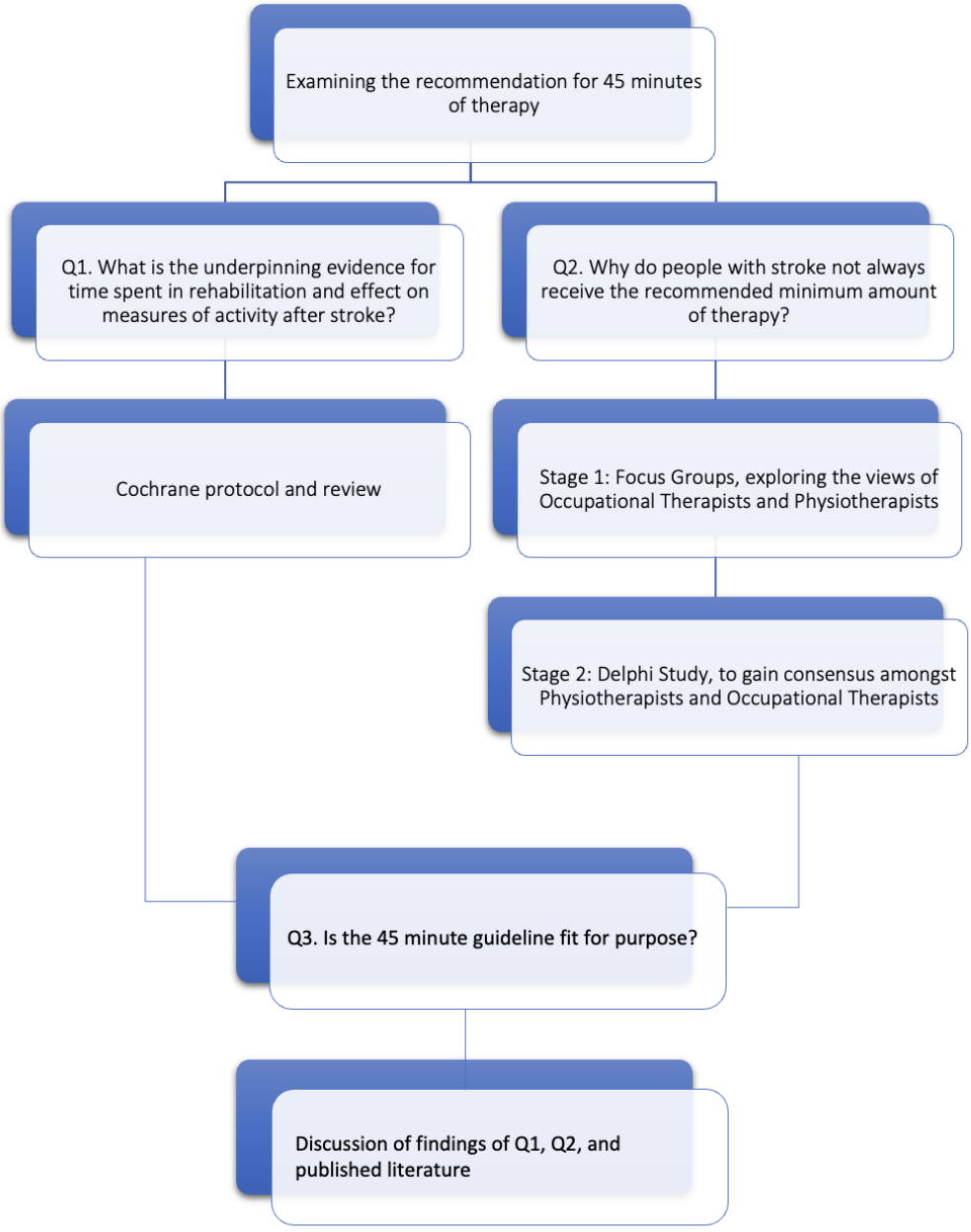

Figure 1 Research Design

1.7 Thesis Structure

This thesis follows the structure of a PhD by publication, where three of the chapters are in the form of research papers. The three research papers presented are the Cochrane review, the focus groups and the Delphi study. These papers address the first two research questions. Their

findings are synthesised in the discussion, to describe how they collectively contribute to an enhanced understanding of this guideline, its fitness for purpose and the implications this has for future guideline development and implementation.

The included chapters are as follows:

Chapter 2 – Background to Study. A narrative review of the literature is presented. The key findings of the literature are summarised and the research questions for this study proposed.

Chapter 3 – Study Design. The design of this programme of work, its' methodological underpinning and methods employed are described in this chapter

Chapter 4 – Time spent in rehabilitation and measures of Physical Activity after Stroke. This chapter presents a Cochrane systematic review and meta-analysis, accepted for editorial approval by the Cochrane Stroke Group in September 2021.

Chapter 5 - Why do some people with stroke not receive the recommended 45 minutes of Occupational therapy and Physiotherapy? Findings from therapist focus groups. This chapter presents the findings from focus groups, intended for publication in the BMJ Open.

Chapter 6 - Why do some people with stroke not receive the recommended 45 minutes of Occupational therapy and Physiotherapy? Consensus from a Delphi Study. This chapter presents findings from a Delphi study, intended for publication in the BMJ Open.

Chapter 7 – Discussion. A discussion of this programme of research is provided, drawing together the two research strands and addressing the third research question. Limitations of this study and future research required are considered.

Chapter 8 – Conclusions. Conclusions to this piece of research are offered.

1.8 Terminology and writing style in this thesis

1.8.1 Collective noun for people who have had a stroke

In healthcare and healthcare research, there is an ever-increasing awareness of terminology used to describe people with a health condition, aiming to use language that is positive and empowering. The growing culture of patient and public involvement (PPI) and co-production in healthcare means that people with health conditions are involved in discussions about language used. In considering the collective noun used to describe people who have had a stroke in this

research, the use of language by stroke-related third sector organisations was reviewed. Both the Stroke Association (Stroke Association 2021) and Different Strokes (Different Strokes 2021) discuss 'stroke survivors'. This term was discussed with members of a local stroke support group. Whilst they were predominantly comfortable with 'stroke survivors' as a collective noun, some were vocal in their objection. They felt that the term 'stroke survivor' caused their stroke to define them, to the potential exclusion of other roles and identities. They preferred to term themselves 'a person who has had a stroke', believing that this left more space for the other parts of themselves. In order to be inclusive, the terms 'stroke survivor' and 'people who have had a stroke' (sometimes abbreviated to 'people' or 'person') are interchangeable as the collective noun in this research.

1.8.2 Writing styles in this thesis

Predominantly, the writing style follows the traditional convention of writing in the third person. However, the Cochrane review uses the first-person plural, to follow the Cochrane writing convention. There are times when the thesis uses the first person. This is to demonstrated reflexivity, position myself openly as the researcher and to acknowledge my subjectivity in relation to the research topic.

1.9 Summary

This chapter has highlighted the rationale for undertaking this doctoral study. An overview of the PhD research questions and methods presented and a summary of this thesis outlined. The next chapter provides the background to this study, based on published research.

Chapter 2 Background to Study

2.1 Introduction

This chapter presents the background to this study, based on a narrative review of relevant literature. It will begin by exploring clinical guidelines, including their development and purpose, benefits and limitations. The development of the guideline under investigation is explored; including how its achievement is monitored and its effect on clinical practice. Attention will then turn to literature relevant to the first research question, considering the underpinning evidence for the 45 minute guideline. Initially, neuroplasticity and learning principles are examined to provide a plausible theoretical underpinning for guidelines suggesting specific time spent in therapy. Then research evidence for time spent in therapy is considered. The literature related to the second research question is then contemplated. This question explores why people with stroke do not always receive the recommended minimum amount of therapy, as such literature regarding therapist decision-making and effect of resource availability is examined. Finally, the key findings of the literature and research questions are presented.

The narrative review was carried out using DelphiS (the University of Southampton interface, powered by EBSCOhost, which enables cross-searching of databases) to search relevant key concepts (see table 1). Any source type was considered, from the conception of the database until present. Titles and, where required, abstracts, were screened for relevance, and articles were included in the review if they were relevant to one or more of the key concepts. If there was considerable literature for a key concept, the search would focus on the most up-to-date information. A snowballing strategy was used, where reference lists of relevant papers were scanned for possible further relevant material (Greenhalgh and Peacock 2005). Active searching for new literature on any one of the key concepts stopped, when saturation was reached, and further literature was not adding new or novel information. This process built over time, as further relevant literature was published and added to this review.

Table 1 Narrative review - key concepts searched

Key Concepts searched in literature
Clinical Guidelines
Clinical guidelines in stroke
Neuroplasticity and stroke
Therapy intensity and stroke
Therapist decision-making in stroke
Stroke rehabilitation delivery

The exception to the narrative method described, is the exploration of the underpinning evidence for the guideline in published literature (section 2.3.2). This followed the same systematic method undertaken for the Cochrane review, described in chapter four, but identifying systematic reviews with or without meta-analysis as opposed to Randomised Controlled Trials.

2.2 Clinical Guidelines

2.2.1 The Role of Clinical Guidelines in Healthcare

Clinical guidelines are defined as: "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." (Field and Lohr 1990 p.38). Since this definition, there has been a proliferation of clinical guidelines (Woolf et al. 1999; Scalzitti 2001). Broughton and Rathbone (2001) state that guidelines differ from protocols, which are a ridged sequence of activities to be followed, allowing little or no flexibility. They also differ from care pathways, which are locally agreed practice, based on guidelines and evidence. Guidelines should not be considered specific instructions, addressing a topic in fine detail (Twaddle 2005), nor should they be used to mandate practice (Hurwitz 1999). Instead, they require the clinician to use their judgment and interpretation (Hurwitz 1999; National Institute for Health and Care Excellence 2014) and staunch adherence should be discouraged, in favour of a critical approach (Hurwitz 1999). Service users can also employ guidelines, as a focus for discussion (Broughton and Rathbone 2001) and the National Institute for Health and Care

Excellence (2014) state that service users and carers should be involved in their development.

National clinical guidelines are commonly developed by specific organisations, such as the National Institute for Health and Care Excellence (NICE) or the Scottish Intercollegiate Guidelines Network (SIGN). Such organisations have published guidance to support the process of guideline development (National Institute for Health and Care Excellence 2014; Scottish Intercollegiate Guidelines Network 2015). Consensus in the literature is that guidelines should be developed by a multidisciplinary group of individuals, preferably including lay members (Shekelle et al. 1999; Scalzitti 2001; Twaddle 2005; National Institute for Health and Care Excellence 2014; Scottish Intercollegiate Guidelines Network 2015). The National Institute for Health and Care Excellence (2014) states that guidelines should be based on "the best available evidence" (p.5), so guideline development often commences with a systematic review of relevant literature (Shekelle et al. 1999; Scalzitti 2001; Twaddle 2005; National Institute for Health and Care Excellence 2014; Scottish Intercollegiate Guidelines Network 2015). The strength of the evidence used is often graded in guidelines (Shekelle et al. 1999) and, as research evidence alone rarely provides all the information required (Twaddle 2005), is supplemented with expert opinion (Twaddle 2005; National Institute for Health and Care Excellence 2014) or formal consensus (Scalzitti 2001; Twaddle 2005).

Service users, healthcare professionals and health care systems benefit from guidelines (Woolf et al. 1999). For service users, clinical guidelines enhance the quality of care (Feder et al. 1999; Woolf et al. 1999; Scalzitti 2001; Twaddle 2005; National Institute for Health and Care Excellence 2014) by consolidating evidence (Scalzitti 2001; National Institute for Health and Care Excellence 2014). This reduces the discrepancy between research and clinical practice (Cabana et al. 1999; Hurwitz 1999; Woolf et al. 1999; Twaddle 2005) and unacceptable variations in practice both locally and nationally (Cabana et al. 1999; Woolf et al. 1999; Broughton and Rathbone 2001). Guidelines also increase public awareness, which can influence policy, by highlighting areas that have previously been underfunded or overlooked (Woolf et al. 1999).

Healthcare professionals benefit from guidelines, as they provide clear recommendations to follow (Woolf et al. 1999; Twaddle 2005). Guidelines provide a framework against which quality can be measured (Woolf et al. 1999; Broughton and Rathbone 2001), aid commissioners' decision

making (Broughton and Rathbone 2001) and support quality improvement programmes (Woolf et al. 1999). Researchers also benefit from guidelines, as they identify gaps in knowledge (Woolf et al. 1999).

Healthcare systems also benefit from guidelines. As healthcare costs continue to rise and pressure on systems increases, guidelines can support by increasing efficiency and enhancing value for money (Woolf et al. 1999). Additionally, demonstrating adherence to guidelines can improve an organisation's public image. Woolf et al. (1999) argue that potentially, the economic benefits of clinical guidelines may be their primary source of their appeal.

Disadvantages of clinical guidelines arise when the recommendations given are wrong. They could be wrong for individual service users, or wrong in general. (Woolf et al. 1999) give three potential causes for guidelines giving incorrect recommendations:

1. The scientific evidence on which guidelines are based is lacking. Evidence may not have been fully considered, could be misleading or insufficient (Broughton and Rathbone 2001). Studies may be of poor quality, subject to bias or lack generalizability (Woolf et al. 1999). In some cases, there may be very little evidence to support clinical guidelines and the evidence there is may be of limited relevance, but it is included, as it is the only evidence available (Hurwitz 1999). This could lead to ineffective or potentially harmful practices (Woolf et al. 1999).
2. Those who assist in the development of guidelines are biased. Guidelines are developed by a group or committee (Shekelle et al. 1999; Twaddle 2005; National Institute for Health and Care Excellence 2014; Scottish Intercollegiate Guidelines Network 2015) but if group members are biased, the guidelines could include error (Woolf et al. 1999; Broughton and Rathbone 2001; Scalzitti 2001). Lack of resource availability and/or user representation can also introduce error into guideline development groups (Broughton and Rathbone 2001).
3. The motivation for guideline development could lead to error. Guidelines may be developed to cut costs or to serve the specialist interest of individuals (Woolf et al. 1999). If this is the case, then the guidelines may give incorrect recommendations.

The literature discusses other issues with guidelines: Conflicting guidelines could cause confusion for service users and clinicians (Broughton and Rathbone 2001). Too much emphasis could be

placed on guidelines, when they are not able to address all issues and uncertainties in clinical practice (Feder et al. 1999). There is concern that guidelines may limit practitioners' ability to exercise and/or develop their clinical reasoning skills (Hurwitz 1999; Broughton and Rathbone 2001). This could be damaging to healthcare professionals (HCPs), simplifying the often-complex judgments required of them. Additionally, HCPs could be exposed to the appraisal of managers and auditors, based only on guideline adherence, when there could have been extenuating circumstances (Woolf et al. 1999).

2.2.2 Use of Clinical Guidelines in Stroke Rehabilitation

The Royal College of Physicians (RCP) first published the National Clinical Guidelines for Stroke in 2000, with regular updates since. These guidelines contain many recommendations regarding the management of stroke targeting medical management, nursing care, therapies and other health care professionals. The 45 minute guideline is one of many recommendations given but as it is the recommendation under investigation in this research project, it is the only one considered here.

The first edition of the RCP guidelines (Intercollegiate Stroke Working Party 2000) acknowledged the debate about the amount of therapy a person requires after stroke, and recommended that people should see a therapist each working day and "should receive as much (therapy) as can be given and they find tolerable" (Intercollegiate Stroke Working Party 2000 p.26). The guideline didn't specify an amount, but stated that local standards should be agreed. The recommendations given in the second edition of the guideline (Intercollegiate Stroke Working Party 2004) were similar. It stated that people should "undergo as much therapy appropriate to their needs as they are willing and able to tolerate" (Intercollegiate Stroke Working Party 2004 p.24). The National Stroke Strategy (Department of Health 2007), a seminal document in the development of stroke services, also alluded to the importance of amount of therapy, by suggesting that stroke rehabilitation should be "started early after stroke and provided with sufficient intensity" (Department of Health 2007 p.36).

The first of the RCP guidelines to suggest a minimum amount of therapy was the 3rd edition

published in 2008: “Patients should undergo as much therapy appropriate to their needs as they are willing and able to tolerate and in the early stages they should receive a minimum of 45 minutes daily of each therapy that is required” (Intercollegiate Stroke Working Party 2008 p.39). The evidence cited for this recommendation was two systematic reviews of randomised controlled trials (RCTs) and three RCTs (Langhorne et al. 1996; Kwakkel et al. 1997; Partridge et al. 2000; Slade et al. 2002; Bhogal et al. 2003). The 45 minute recommendation was re-iterated in the NICE Quality Standard for stroke (National Institute for Health and Clinical Excellence 2010). In this iteration, there was no mention of 45 minutes being a minimum requirement in the ‘early stages’, but that “Patients with stroke are offered a minimum of 45 minutes of each active therapy that is required, for a minimum of 5 days a week, at a level that enables the patient to meet their rehabilitation goals for as long as they are continuing to benefit from the therapy and are able to tolerate it.” (National Institute for Health and Clinical Excellence 2010 p.22). The 4th edition of the RCP guidelines for stroke (Intercollegiate Stroke Working Party 2012a) gave a similarly worded recommendation, but evidenced differently. The previously quoted Systematic Review and RCT evidence, was replaced with ‘consensus’. Potentially this is because such studies don’t provide clear conclusions about the minimum amount of therapy, below which there is no benefit (Foley et al. 2012b; Intercollegiate Stroke Working Party 2012a).

In 2012, a joint meeting between the Intercollegiate Stroke Working Party (ICSWP) and The Stroke Research Network was hosted by the Royal College of Physicians. It was an “Intensity of therapy after stroke consensus meeting”, which brought together stroke service therapy leads with policy makers and academics to discuss the 45 minute guideline. In this meeting, therapy leads were encouraged to consider the 45 minutes as a ‘starting-point’, a “reasonable and achievable target” (Intercollegiate Stroke Working Party 2012a p.33). The meeting also provided feedback from a survey undertaken prior to the event of 276 delegates, predominantly Physiotherapists, Occupational Therapists and Speech and Language Therapists. This survey had canvased opinion regarding the minimum amount of therapy time that should be given as a guideline. The consensus was that, for Occupational Therapy and Physiotherapy, it should be 45 minutes. The 45 minute guideline has since been re-iterated in the NICE Guidelines for Stroke Rehabilitation in Adults (National Institute for Health and Care Excellence 2013) and the 5th edition of the RCP guidelines for Stroke (Intercollegiate Stroke Working Party 2016). The only further significant change, in the most recent edition, was the recommendation that therapy should be provided for a minimum of 45 minutes every day, as opposed to the previously stated five days-a-week.

The guideline development group of the Intercollegiate Stroke Working Party wrote the RCP guidelines. This group includes representatives from England, Wales, and Northern Ireland, of professional bodies, 3rd sector organisations, and patients. The Scottish Intercollegiate Guideline Network (SIGN) have developed their own guidelines for stroke rehabilitation (Scottish Intercollegiate Guidelines Network 2010), which do not provide a specific recommended minimum amount of time that a person should spend in rehabilitation. However, there are other stroke guidelines that do provide recommendations for amount of time spent in therapy. The Australian Stroke Foundation, Clinical Guidelines for Stroke Management recommends a minimum of two hour of active practice (physiotherapy and occupational therapy) per day (Stroke Foundation 2021). The Canadian Best Practice guidelines for rehabilitation recommends that people receive a minimum of three hours of task-specific therapy, five days per week (Teasell et al. 2020). These guidelines provide different recommendations to each other and the RCP guidelines, despite having access to the same research evidence for time spent in therapy. This suggests that the evidence does not provide a clear answer regarding the optimal minimum amount of time for therapy, so guideline authors create recommendations based on their interpretation of the available evidence as well as what is reasonable and feasible for delivery.

2.2.3 Auditing Stroke Guideline Achievement

Clinical Guidelines are a tool that assists in quality improvement. Another tool for quality improvement in healthcare is clinical audit. There is a significant link between guidelines and audit, in that audit requires defined standards (such as clinical guidelines) to benchmark services (Limb et al. 2017) and guideline adherence should be measured via audit (Feder et al. 1999).

Auditing of stroke services commenced in 1998, with the National Sentinel Stroke Audit (NSSA), undertaken every two years until 2010 (Royal College of Physicians 2011). The 2010 report included a supplementary report on therapy intensity (Intercollegiate Stroke Working Party 2012b), which audited the achievement of the 45 minute guideline. Prior to this, amount of therapy provided did not featured in the NSSA. The Sentinel Stroke National Audit Plan (SSNAP) superseded the NSSA in 2012. SSNAP is an ongoing, prospective audit, collecting a minimal data set on all stroke patients in England, Wales and Northern Ireland (Royal College of Physicians 2013). SSNAP collects data regarding the amount of therapy provided by Physiotherapy, Occupational Therapy and Speech and Language Therapy. This is benchmarked against the

amount recommended in the guidelines and individual therapies are given an alphabetized score (A – E), dependent on their compliance with the guideline. These scores contribute to an overall 'SSNAP Level' for the organisation. Again, trusts are rated from A to E, with A being the most desirable score (Royal College of Physicians 2013). Presently, the standard audited is 45 minutes of therapy, five days a week, not the seven days a week, suggested by the 5th edition of the RCP guideline. Although the guideline does not specify that its recommendations are for people in the acute/subacute stages following stroke, therapy input is only audited in inpatient and early supported discharge (ESD) services.

Hurwitz (1999) argues that clinical guidelines should not be used to mandate practice. However, when the achievement of a guideline is monitored and reported (as is the case with SSNAP measuring the achievement of the 45 minute guideline), there could be the perception, that the guideline has become a mandate. This perception may be amplified when achievement of the guideline is a published indicator of the quality of the care within the stroke service of an organisation, as it is with SSNAP. Theoretically, this could lead to trust managers having greater concern for guideline achievement than guideline suitability. However, if achievement of this guideline were not measured, then therapy services and individual therapists may not prioritize its achievement.

Public reporting of the SSNAP audit data provides opportunity to review achievement of the 45 minute guideline locally, regionally and nationally. Comparison of the most recent national data of the 45 minute guideline to the earliest available data demonstrates improvement over time (Bahalla et al. 2021). Superficially, this suggests that the guideline is achieving the objective of improving quality of care. However, improved guideline achievement may reflect therapists changing the way they provide therapy, in order to increase amount of therapy time. Therefore, the assumption that improved achievement of the guideline has led to improved quality of therapy following stroke may be false. For example, therapists may seek to increase the amount of therapy they provide to individuals by using group work, where they can treat several individuals at the same time. Limited evidence suggests that group work is no superior to individual therapy in respect of outcomes (Renner et al. 2016). Therefore, any such changes in clinical practice are likely made with the motivation of enhanced guideline achievement. Such changes in practice may be reflective of the requirement within the National Health Service (NHS), to achieve more with less (Appleby et al. 2014). Despite improvement in achievement of the guideline, recent figures suggest that 63% and 66% of people are not receiving the minimum

Occupational Therapy and Physiotherapy (respectively) recommended (Bahalla et al. 2021). The reasons for this are unclear, but feasibly could relate to the guideline not being suitable or issues with guideline delivery.

2.2.4 The effect of the guideline and SSNAP on stroke services

There is emerging research evidence for the effect that the guideline and its measurement have on clinical practice (Clarke et al. 2018; Taylor et al. 2018). Clarke et al. (2018) have noted benefits, including the potential for it to enhance quality of therapy provision. Having a target or standard to direct therapy is considered beneficial and SSNAP data has been used to inform business cases to increase therapy provision. The guideline has had an impact on both therapists and therapy delivery. Clarke et al. (2018) noted that SSNAP shaped delivery of rehabilitation, with therapists focused on increasing the number of minutes provided to improve SSNAP scores, not to provide people with more therapy. Practice has changed to improve performance ratings, including the increased use of group work, some of which has questionable therapeutic benefit (Clarke et al. 2018). Taylor et al. (2018) note that therapists make daily decisions regarding the appropriateness of the guideline for people on their caseload and some decisions are based on resource availability. Such changes in practice led to Taylor et al. (2018) discussing that teams may be 'hitting the target, but missing the point'.

Despite adapting their practice to accommodate the guideline, some therapists do not believe that SSNAP results are reflective of the quality of stroke services (either locally or nationally) and there is rivalry and mistrust between services in relation to the data (Taylor et al. 2018). Additionally, there is a reported discomfort amongst therapists about using a numerical target to evaluate therapy performance (Clarke et al. 2018). There is a lack of clarity regarding what should be recorded as therapy and measurement inconsistency between teams, with only some teams aware of the comprehensive SSNAP guidance (Clarke et al. 2018; Taylor et al. 2018). Drawing on the work of Lipsky and Power, Taylor et al. (2018) frames therapists working in the context of the 45 minute guideline as 'street level bureaucrats' in an 'audit society', suggesting that therapists are required, as individuals, to make influential decisions about the people they are treating, within the context of the nationally audited, consensus-based guideline recommendation. In some instances, therapists report conflict between their judgement that some people can only

tolerate shorter therapy sessions and the impact that this will have on their organisation's guideline achievement (Clarke et al. 2018). This suggests that 45 minutes is not always interpreted as a guideline (based on the definition earlier in this chapter) and is considered a mandate. Potentially the auditing of the guideline has effected this change.

As well as affecting therapists, the guideline appears to have affected managers and commissioners, with achievement of the 45 minute 'target' dominating the thinking of managers and senior therapists (Clarke et al. 2018) and the suggestion that it encourages commissioner-centred care, as opposed to patient centred care (Taylor et al. 2018). Further evidence for this is found in study of stroke survivors' views of the guidance. People receiving services varied in the amount of therapy they wanted, with some wanting more than 45 minutes and some less. For many, they were more concerned about the content of the therapy and being treated as individuals (Taylor et al. 2018).

2.3 Underpinning Evidence for the 45 minute guideline

2.3.1 Neuroplasticity and Learning Principles

To understand how amount of time spent in therapy influences stroke recovery, it must be considered in the context of what is known about the re-organisation of the stroke-damaged brain. Following stroke, return of activity may result from three types of recovery: restitution, substitution and compensation (Dobkin and Carmichael 2005).

Restitution is the recovery of the functioning of neural tissue, which occurs relatively independently of physical and cognitive stimuli. There is insufficient evidence to support the possibility of influencing restitution by specific rehabilitation interventions (Buma et al. 2013). It is influenced by other factors, such as the resolution of diaschisis. Diaschisis is the sudden loss of the function of an area of the brain remote from, but neurologically linked to the damaged area (Kwakkel et al. 2004a). Another influence is the recovery of penumbral tissue: vulnerable tissue between the area of evolving ischemia and normally perfused tissue (Kwakkel et al. 2004a). Penumbral tissue may be damaged by over-activity in the days following acute stroke (Turton and

Pomeroy 2002; Kleim and Jones 2008). Therefore, theoretically there is an amount of therapy that may harm a person very soon after acute stroke. Growing evidence indicates that rehabilitation, particularly intensive rehabilitation, could be harmful in the first 24 hours (Coleman et al. 2017).

Substitution is experience-dependent neuroplasticity, which relies on external stimuli, such as practice. Neuroplasticity is the brain's ability to modify and re-organise neurons and neural connections in order to promote learning (Kleim and Jones 2008). In the context of stroke rehabilitation, non-damaged areas of the brain adapt to adopt the functions of damaged areas. According to Levin and colleagues (2009), restitution and substitution combined is termed 'recovery' since they do not distinguish between recovery of the neural pathways or substitution by another part of the brain.

Regardless, a type of learning that promotes substitution is the "Hebbian Learning Rule" (1949). Hebbian Learning is concerned with an increase in synaptic efficacy, due to persistent, repetitive firing of the pre-synaptic cell, causing stimulation of the post-synaptic cell, leading to increased synaptic strength (Robertson and Murre 1999). Hebbian Learning is supported by experimental evidence concerning Long-term Potentiation and the opposite process, Long-term Depression (Turton and Pomeroy 2002). From a therapist's perspective, it could be interpreted that the time spent in therapy may determine the frequency of synaptic stimulation; therefore more time spent in therapy could increase synaptic strength, provided it included repetition. The requirement for repetition is supported by Kleim and Jones (2008).

Another consideration in the neurophysiological aspects of motor re-learning is the organisation of the sensory and motor cortex. Studies have shown that the cortex is flexible and adapts to re-learning (Nudo et al. 1996) but if an area of the cortex is not stimulated then that part of the cortex is appropriated by other functions (Kleim and Jones 2008). With advances in neuro-imaging, it is recognised that, although there is a global segregation of body parts in functional maps of the primary motor cortex, the representation of individual movements is widely distributed, hence the potential for functional re-learning (Nudo 2003). A greater amount of use results in greater cortical representation (Kleim and Jones 2008), but excessive training of one function may be at the expense of other functions (Nudo et al. 1996; Nudo 2003; Kleim and Jones 2008). This again provides support for an increased amount of time spent in therapy post-stroke.

Despite the suggestion that an increased amount of time spent in repetitive therapy may be beneficial, research points to other potentially important aspects of stroke rehabilitation. Kleim

and Jones (2008) identify that, whilst repetition is influential, the relative importance of the task undertaken, variability of training and providing a challenge will also influence plasticity. Other authors describe further influential factors in the re-learning of motor skills, such as the use of explicit versus implicit learning (Boyd and Winstein 2003; Boyd and Winstein 2004). The presence of a meaningful context has been shown to enhance motor learning (Ma et al. 1999; Wu et al. 2000). There is evidence that extrinsic feedback enhances motor-learning following stroke (van Vliet and Wulf 2006) and that people benefit more from random practice of variable exercises than they do blocked practice (Hanlon 1996). Wulf et al. (2010) discuss additional influences on learning, such as learning through observation, and internal vs. external focus of attention and self-controlled practice. Mount et al. (2007) discuss research related to the impact of errorless learning vs. trial and error learning, whilst Levack et al. (2006) suggest that specific, difficult goals may enhance performance. Finally, research suggests that an enriched environment enhances recovery (Janssen et al. 2010). None of these motor-learning factors have been directly tested to support a recommendation for a specific amount of motor practice for the recovery of motor function. However, their existence indicates that simple repetition is not the only answer when designing treatment programmes. There are other aspects of providing therapy that are also important to consider when treating people with stroke, which have led to a multitude of different types of therapy.

The final category of recovery is compensation: a person may learn new strategies to undertake tasks. This could include the development of an alternative movement pattern to complete the task, termed “adaptive compensation” or include the use of equipment, environmental adaptations or another limb, termed “substitutive compensation” (Levin et al. (2009). It is argued that this type of recovery also relies on neuroplasticity, as the brain is required to adapt in order to learn new skills (Kleim and Jones 2008; Krakauer et al. 2012). Similar arguments can be made about the benefit of an increased amount of time spent in therapy to facilitate compensation as were made for facilitation of substitution but, again, no direct evidence exists to support a specific minimal amount/frequency.

Levin and colleagues (2009) suggest that different categories of recovery require different measurement. Compensation is measured at the activity level of the International Classification of Functioning, Disability and Health (ICF). Recovery of normal function requires the addition of measurement at the body structures/functions level to differentiate from compensation. Levin et al. (2009) acknowledge that discriminating between recovery and compensation at a participation

level is challenging. A lack of well-designed RCTs, which utilize appropriate outcome measures in the early stages post-stroke, results in limited understanding of the interplay between different types of recovery (Buma et al. 2013). Evident in the literature, however, is the non-linear trajectory of stroke recovery. Whilst there is evidence to suggest that recovery is still detectable six-months post acute stroke (Horgan et al. 2009), the majority of recovery takes place within the first 3-months (Wade et al. 1983; Horgan et al. 2009). Potentially, the majority of stroke recovery is achieved within the first four weeks (Duncan et al. 1992; Kwakkel et al. 2004a) particularly for those with less impairment. This emphasizes the importance of ensuring that therapy is targeted in the early stages, stressing the need for clinical guidelines based on sound evidence.

In summary, the literature regarding neuroplasticity and learning principles provides some mechanistic evidence that a greater amount of time spent in therapy after the first 24-hours may enhance neurological recovery. However, it also points to other potentially important aspects of treatment that require consideration when planning therapy intervention, such as relative task importance, variability of training, level of challenge and the environment, that are not explored in the current NICE and RCP guidelines for therapy. Evidence for the recommended minimum amount and frequency of therapy is now considered with reference to research literature.

2.3.2 Published Literature

The impact of therapy on stroke recovery has been described as a “Black Box” (Ballinger et al. 1999), with contents that vary and are difficult to characterise (DeJong et al. 2005). However, there is evidence that the amount of time spent in therapy following stroke benefits recovery (Langhorne et al. 1996; Kwakkel et al. 1997). Studies suggest that the amount of time spent in therapy may be more important than the nature of the therapy itself. Phase 2 and 3 randomised controlled trials that have compared an experimental treatment with a ‘dose-matched’ traditional treatment have failed to find significant differences between the two treatment groups (Dromerick et al. 2009; Lo et al. 2010; Winstein et al. 2016). However, in the area of stroke rehabilitation, evidence suggests that ‘more is better’ is an over-simplification. For example, the AVERT trial (Langhorne et al. 2017b) found that a higher dose of therapy provided very early after stroke was associated with less favourable outcomes at 3 months. Similarly, Dromerick et al. (2009) found that an increased amount of Constraint Induced Movement Therapy early after

stroke had a negative effect on ADL outcomes. Both these studies suggest that a greater amount of time spent in therapy very early after stroke may be detrimental. Furthermore, the ICARE study (Winstein et al. 2016) found that a usual care low-dose group did as well as two higher-dose groups at the one-year endpoint, suggesting that a greater amount of therapy may make little difference long after the intervention is finished.

To methodically examine evidence for the amount of therapy following stroke, systematic reviews examining the effect of time spent in therapy are appraised. Systematic reviews, particularly when combined with meta-analysis are considered high quality evidence in healthcare (Devereaux and Yusuf 2003). The findings of nine systematic reviews with meta analyses are presented, a summary of these studies can be found in Appendix A.

All nine studies were published between 1996 and 2017, and include between seven (Langhorne et al. 1996; Cooke et al. 2010a) and 34 (Lohse et al. 2014) studies. Combined, there are a total of 65 unique studies represented in these papers. With the exception of one paper (Keith et al. 1995, a retrospective cohort study in Kwakkel et al. 1997), all included studies are Randomised or Quasi-Randomised controlled trials. The outcomes explored varied between the papers, but included morbidity/mortality, activity of daily living, neuromuscular and functional outcomes. Interventions included were either Physiotherapy or combined Physiotherapy and Occupational Therapy. All of the papers included meta-analyses and one also included a meta-regression. A variety of methods were used to perform the meta-analyses including measures of Standard Mean Difference (SMD), Standard Deviation Units (SDU), Odds Ratio (OR) and Hedges g.

The quality of the papers was assessed using the AMSTAR-2 (A MeaSurement Tool to Assess systematic Reviews, Shea et al 2017). This is a 16-item checklist, developed to assist in the quality appraisal of systematic reviews of randomised and non-randomised trials. It is a popular tool for the critical appraisal of such papers and has been developed with scientific rigour. It does not provide a summary score for each paper, but rather assesses the papers against 16 criteria, which are either fulfilled, partially fulfilled, not fulfilled or not applicable. A copy of the tool can be found in Appendix B. Appendix C provides an overview of the fulfilment of the items in the AMSTAR-2 for the included systematic reviews.

The nine papers report mixed findings regarding the effect of an increased amount of time in therapy. Some studies that pooled impairment/neuromuscular and activity/functional outcomes (Lohse et al. 2014) have shown positive results. However, Langhorne et al. (1996) found no significant results for pooled measured of impairment and disability. They did find that the risk of death or deterioration was significantly lower in experimental groups (OR 0.54 95% CI 0.3 – 0.85), but this finding is limited by a wide confidence interval. Small, but statistically significant differences in favour of additional treatment has been found for ADLs (Kwakkel et al. 1997; Kwakkel et al. 2004b; Galvin et al. 2008). However, Sehatzadeh (2015) found no significant difference in ADLs (as measured by the Barthel Index). Likewise, Veerbeek at al (2011) found no statistically significant standard effect size for basic ADLs (measured by the Barthel Index SMD 0.11, 95% CI -0.12 – 0.34), but a moderate standard effect size (SMD 0.54 05% CI 0.20 – 0.88) for extended ADLs (pooled analysis of the Nottingham Extended ADL checklist and the Frenchay Activities Index). Additional therapy had a significantly beneficial effect on walking speed according to two meta-analyses (Kwakkel et al. 2004b; Veerbeek et al. 2011), but this was not the case for a third (Cooke et al. 2010a). For the majority of papers exploring such outcomes, the effects on motor impairment and upper limb recovery appear to not be beneficial (Kwakkel et al. 2004b; Galvin et al. 2008; Cooke et al. 2010a). However, this was not the case for Sehatzadeh (2015) and Cooke et al. (2010a), who found positive findings for additional therapy for some measures of upper limb recovery.

The variations in the findings between these meta-analyses could be influenced by several factors. Firstly, the studies included in the meta-analyses were heterogenous in the amount of therapy provided. For example, in one study, included in six of the meta-analyses (Kwakkel et al. 1999), the mean difference in amount of therapy between the control and intervention group was 43.67 hours. However, in another study, which featured in seven of the meta-analyses (The Glasgow Augmented Physiotherapy Study Group 2004), the difference in amount of therapy between control and intervention was 13 hours. Schneider et al. (2016) noted that the significant heterogeneity found in their meta-analyses was partially explained by the amount of extra practice. They found that when sub-grouped into small (≤100%) or large (>100%) increases in amount of therapy, there was non-significant findings for the small increase group, but significant findings for the larger increase group (SMD 0.59, 95% CI 0.23 – 0.94).

Further explanation for the disparity in the findings could relate to the between-study differences in time-points at which measures were taken. For example, in one included study (Martinsson et

al. 2003), participants in the acute stage post-stroke were given five days of intensive treatment. In another study (Partridge et al. 2000), the treatment period was six weeks and in another (Kwakkel et al. 1999) it was 20 weeks. This difference means that measurements were taken at different time-points since stroke onset, meaning that recovery that was not as a result of therapy input could have also effected outcomes.

Heterogeneity between the meta-analyses may relate to the quality of included studies. Two of the meta-analyses (Langhorne et al. 1996; Sehatzadeh 2015) made no assessment of study quality. Of the remaining seven meta-analyses, only one (Galvin et al. 2008) explicitly stated the exclusion of studies on the basis of low methodological quality and none reported that they had undertaken sensitivity analyses to determine the effect of including studies at high risk of bias, despite this being the case.

A final factor that affected the outcomes of the meta-analysis is the quality of the studies themselves. The AMSTAR-2 summary (Appendix C) demonstrates that none of the systematic reviews established their methods prior to undertaking their review (Cooke at al 2010 reports that a protocol was written, but does not include the required detail to satisfy the question on the AMSTAR-2 tool). This means that studies could be susceptible to reporting bias. Additionally, none of the reviews used a comprehensive search strategy. All only included published work and many only included studies published in English. The final point noted is that all except one of the reviews (Lohse et al. 2014) did not use funnel plots to explore the possibility of publication bias (small study bias), which could have impacted their findings.

Irrespective of their findings, these systematic reviews with meta-analyses have other limitations, which reduce their ability to provide an evidence-base for the guideline. All have included studies in which the experimental and control interventions have differed in more than just the time spent in therapy. For example, four of the nine meta-analyses included a study by Sunderland et al. (1992). In this study, the “Enhanced Therapy” group not only received an increased amount of arm rehabilitation, but also received encouragement to actively participate in arm rehabilitation. Therefore, it is not possible to attribute the statistically significant recovery found in the “Enhanced Therapy” group to an increased amount of therapy time alone. Some of the meta-analyses included studies provided no intervention to the control groups (for example, Fang et al 2003), essentially measuring the effect of therapy vs. no therapy. Other potentially confounding

variables include studies in which the experimental and control groups were treated in different locations (Langhorne et al. 1996; Kwakkel et al. 1997).

Three meta-analyses explored the 'optimum amount' of therapy post-stroke. Kwakkel et al. (2004b) used a cumulative meta-analysis, finding a difference of at least 16 hours between experimental and control groups resulted in a significant difference in ADL scores. Lohse et al. (2014) used meta-regression to explore the effect of total scheduled therapy time on effect sizes. They found a small, overall benefit of additional therapy and a positive dose-response relationship between time scheduled for therapy and improvement on measures of function. Finally, Schneider et al. (2016) undertook a Receiver operating characteristic (ROC) curve analysis of false versus true benefit. This indicated that an extra 240% of rehabilitation is required to make certain a better outcome for activity measures. Whilst the findings of both Kwakkel et al. (2004b) and Schneider et al. (2016) suggest specific additional amounts required, both are relative and therefore cannot suggest an optimal dose of therapy. In summary, taken together, these meta-analyses suggest that the guideline for 45 minutes of therapy does not have a strong research evidence-base regarding an optimal minimum dose of therapy.

Prospective and retrospective observational cohort studies have also examined the effect of time spent in therapy after stroke (Saxena et al. 2006; Huang et al. 2009; Haines et al. 2011; Foley et al. 2012a; Wang et al. 2013; Yagi et al. 2017; Grimley et al. 2020). These studies have found that greater time spent in rehabilitation was associated with greater improvements in measures of ADLs. Indeed, the findings of such studies appear to provide more support for the benefit of additional time spent in rehabilitation than the systematic reviews of RCTs described above. The criticism of observational studies is that they can only indicate relationships between variables, they cannot establish cause and effect as this requires the randomisation of participants (Horn et al. 2005; Concato et al. 2010; Kersten et al. 2010). However, there are limitations to RCTs. Their strict control of variables has led to criticism that RCTs are artificial (Horn et al. 2005; Silverman 2009; Concato et al. 2010; Horn et al. 2012). Selection criteria limits the number of eligible participants, thus limiting their external validity (Horn et al. 2005; Silverman 2009; Kersten et al. 2010; Horn et al. 2012). In Stroke research, people with cognitive impairment and/or aphasia are commonly excluded from RCTs. Potentially, 44% of people have impaired cognition after stroke and approximately one third develop aphasia (Brady et al. 2016), suggesting that RCTs excluding these groups lack generalisability. Arguably, observational studies may provide a better reflection of clinical practice.

In the observational cohort studies described above (Saxena et al. 2006; Huang et al. 2009; Haines et al. 2011; Foley et al. 2012a; Wang et al. 2013; Yagi et al. 2017; Grimley et al. 2020), potentially a greater amount of therapy was provided to people that were more available and/or suitable for therapy, which may represent those with increased potential for improvement and could explain the greater improvement seen with more therapy. This suggests that a greater amount of therapy may suit some people more than others. In the context of this research, it poses the questions, what are the characteristics of people suitable for more therapy, and why do some people not receive the recommended minimum amount?

2.4 Why Don't Some People with Stroke Receive 45 minutes of therapy?

2.4.1 Therapist Decision-Making

The most recent wording of the guideline is:

> "People with stroke should accumulate at least 45 minutes of each appropriate therapy every day, at a frequency that enables them to meet their rehabilitation goals, and for as long as they are willing and capable of participating and showing measurable benefit from treatment." (Intercollegiate Stroke Working Party 2016 p.25)

The wording states who the guideline is applicable to. People need to be "willing and capable of participating" and "showing measurable benefit from treatment". This requires therapist decision-making. According to Clarke et al. (2018), therapists use "clinical reasoning" to decide how much therapy a person receives. Clinical reasoning, despite being an essential skill in healthcare, is a complex and multi-faceted concept that defies a clear definition (Huhn et al. 2018). It is an integrated thinking and decision-making process, involving cognitive, narrative, contextual and emotional factors (Kozlowski et al. 2017; Huhn et al. 2018). In order to better understand how therapists in stroke services implement the 45 minute guideline, this section will

explore the evidence for how therapists decide which people with stroke are capable of participating in the recommended minimum amount of therapy. It will then explore evidence for how therapists decide that a person is showing measurable benefit from intervention.

The clinical presentation of people with stroke influences the planning of therapy (McGlinchey and Davenport 2015; Clarke et al. 2018). Issues such as post-stroke fatigue, clinical instability, reduced level of consciousness and cognitive impairment can impact therapy delivery (Hakkennes et al. 2011; Otterman et al. 2012; Taylor et al. 2015; Clarke et al. 2018; Longley et al. 2019). Other factors related to the stroke may also affect the delivery of the 45 minute guideline, such as the person's mood (Skidmore et al. 2010) and their motivation (McGlinchey and Davenport 2015; Taylor et al. 2015; Longley et al. 2019). In addition to these stroke-related reasons, social factors may affect the amount of therapy the person with stroke receives. Potentially, an individual's social support may affect access to rehabilitation after stroke (Taylor et al. 2015; Longley et al. 2019). Additionally, Taylor et al. (2015) identified that having English as a first language and individuals' and/or their families' ability to 'work the system' was influential in therapists' decision-making. The potential impact of these social aspects aligns with the theory that there is not only a deductive element to clinical reasoning, but also a social element (Fleming and Mattingly 2008). In addition to stroke-related and social factors, the person's tolerance of therapy may affect their rehabilitation (Foley et al. 2012a; McGlinchey and Davenport 2015), however, it is not clear how therapists assess therapy tolerance. Both McGlinchey and Davenport (2015) and Longley et al. (2019) report that therapists use their clinical experience to guide decision making in relation to stroke rehabilitation; decisions are made based on a person's perceived need, which is based on reflections of clinical practice (as opposed to evidence). This is supported by the finding that a substantial proportion of therapists do not use evidence in their clinical decision-making (Salbach et al. 2010) and that therapists display limited knowledge of the evidence that an increased amount of therapy may improve outcomes following stroke (Clarke et al. 2018).

Having decided who is capable of participating in the recommended amount of therapy, according to the guideline, therapists then have to decide which people with stroke are "showing measurable benefit from treatment" in order to continue. Improvement in rehabilitation thus far influences decisions regarding provision of future rehabilitation (McGlinchey and Davenport 2015, Longley et al. 2019), however, it isn't clear how therapists determine functional improvement. There is the suggestion that therapists use tacit knowledge to make such decisions, as opposed to

validated outcome measures (Clarke et al. 2018). Demain et al. (2006) explored research literature about the 'recovery plateau' following stroke; the point at which a person is perceived to no longer make functional gains. Demain and colleagues identified that different factors contribute to recovery plateau, rendering it a complex concept. These factors include patient motivation, the therapeutic relationship and resource availability.

An issue that isn't clear in the literature is whether therapists make similar clinical decisions under similar circumstances. It is possible that, if therapists use different criteria to judge a person's ability to participate in or benefit from therapy, then service provision may differ. Taylor et al. (2014) utilised SSNAP data to explore achievement of the guideline nationally and found that there was wide and unexplained variation between teams. Individual therapists drawing different conclusions regarding someone's appropriateness for therapy may explain such variation, in part. Additionally, different therapy services may have different criteria to guide therapists' decision making. Studies have identified considerable variations in practice regarding access to inpatient rehabilitation (Hakkennes et al. 2011). This may also be the case for the clinical decision making under investigation. Indeed, SSNAP has recently acknowledged the variability in rehabilitation delivery in both inpatient and community setting (Bahalla et al. 2021).

2.4.2 Resource Availability

The impact of resource availability effects both therapist decision-making and the delivery of the 45 minute guideline. Both Taylor et al. (2018) and Clarke et al. (2018), when investigating guideline delivery on stroke units found that resources could impact therapy delivery. Staffing establishment affects therapists' ability to provide the recommended amount of therapy, with a positive correlation between staff numbers and achievement of the 45 minute guidance (Clarke et al. 2018) and discharge planning can detract from rehabilitation (Clarke et al. 2018; Taylor et al. 2018). McGlinchey and Davenport (2015) found that staffing had a major influence on therapy provision and defined how physiotherapists would prioritise people for therapy, within the resources available. How therapists use their time (e.g. reducing the time spent in non-face-to-face clinical activities) has been shown to have a positive impact on the achievement of the 45 minute guideline (Clarke et al. 2018); potentially, British therapists spend more than 50% of their time in such activities (Putman and De Wit 2009). Therapy staffing is not the only resource that may impact therapy provision. Ensuring that people are ready for therapy is considered a nursing

responsibility and people not being ready for therapy impacts on provision (McGlinchey and Davenport 2015; Clarke et al. 2018). Therefore, if nursing resources are limited, people may not receive therapy as planned. The issue of resourcing is complex and does not only include number of therapists but skill-mix, service set-up, equipment and integration with other teams. With a state-funded National Health Service, under increasing financial pressure (Appleby et al. 2014), therapy teams are unlikely to receive additional resources in order to achieve the recommended amount of therapy. Clarke et al. (2018) notes that, of the stroke units studied, all had staffing levels lower than national recommendations.

2.5 Key Findings and Research Questions

The following key findings from the literature review identify gaps in current understanding:

- Clinical guidelines are only beneficial if their recommendations are correct. The guideline under investigation is based on consensus, underpinned by research evidence that compares different types of therapy, as well as different amounts. Further understanding of the research evidence for the effect of time spent in therapy after stroke is required.
- There are no systematic reviews with meta-analyses that investigate impact of amount of therapy, without comparing different types of therapy
- Audited achievement of the recommendation for a minimum of 45 minutes of daily therapy has shown improvement over time, but it is not achieved for everyone. Why?
- Guideline achievement is largely determined by therapists' implementation. There is limited evidence regarding how therapist make decisions about therapy allocation, specific to the delivery of the 45 minute guideline.
- Decision-making between therapists and services may differ, which may contribute to the variability reported in stroke rehabilitation.

Based on the above gaps in understanding, the following Research Questions were addressed in this study:

1. Does the evidence for effect of time spent in rehabilitation support guideline recommendations for therapy following stroke?

2. What factors determine whether someone receives the recommended minimum amount of therapy?

3. Is the 45 minute guideline fit for purpose?

The first two questions both relate to the suitability of the guideline; the first question concerned with the evidence for guideline and the second concerned with its implementation. The third question draws together the findings of the first two questions, to evaluate if the 45 minute guideline meets the requirements of clinical guidelines, as synthesised in the background literature.

Chapter 3 Study Design

3.1 Introduction

This section describes the methodology of this programme of research, considering the philosophical principles that inform the approach used (Green and Thorogood 2018). Initially the aims and objectives are considered. The philosophical assumptions of the research are then described. An overview of the research design is presented, with justification for the design chosen. Finally, consideration of governance and ethics is presented.

3.2 Aims and Objectives

Aims:

1. To evaluate whether research evidence supports the recommendation for 45 minutes of therapy, 5 days-per-week after stroke.
2. To determine why some people don't receive the recommended minimum amount of rehabilitation
3. To judge whether the 45 minute guideline meets the purpose of clinical guidelines, based on the purpose of clinical guidelines reported in the literature.

Objectives:

1. To conduct a systematic review with meta-analysis (using Cochrane methods) of the quantitative evidence for the effect of time spent in therapy following stroke.
2. To use therapist focus groups to explore why some people do not receive the recommended minimum amount of therapy after stroke and a Delphi study to establish consensus amongst Physiotherapists and Occupational Therapists for why a person with stroke would not receive a minimum of 45-minutes of therapy
3. To synthesis the findings of research questions one and two, with the findings of other relevant research, to argue for and against the 'fitness for purpose' of the 45 minute guideline

3.3 Philosophical Assumptions

This research project was undertaken from a pragmatist worldview, valuing both subjective and objective knowledge with primary emphasis on the research questions, not the methods used (Feilzer 2009; Creswell and Plano Clark 2018; Kaushik and Walsh 2019). Pragmatism bridges the gap between positivism (the world exists separate to our understanding of it) and constructivism (the world is created by our experience of it), with the belief that our experiences of the world are constrained by the nature of the world, but our understanding of the world is limited to our interpretation of it (Morgan 2013). A pragmatist worldview asserts that focus should be on research that solves real-world, practical problems and the methods used should be those that best suit the questions asked (Feilzer 2009; Teddlie and Tashakkori 2009; Morgan 2013; Creswell and Plano Clark 2018; Kaushik and Walsh 2019; Kelly and Cordeiro 2020). As such, research undertaken within a pragmatist framework employs either qualitative or quantitative methods, or both if required, supported by the view that the distinction between these two research traditions is convention, rather than an epistemological separation (Hanson 2008). As such, pragmatism is often associated with mixed and multiple method studies (Creswell and Plano Clark 2018; Kaushik and Walsh 2019).

Mixed methods research occurs when both qualitative data (from a constructivist tradition) and quantitative data (from a positivist tradition) are integrated to answer a research question (Doyle et al. 2009; Teddlie and Tashakkori 2009; Curry and Nunez-Smith 2015; Creswell and Plano Clark 2018). It is considered an alternative to the dichotomy of quantitative and qualitative research, bridging the gap between these two traditions (Doyle et al. 2009; Teddlie and Tashakkori 2009; Creswell and Plano Clark 2018). Indeed, one of the advantages of using a mixed methods approach is that it can harness the benefits and offset the weaknesses of either qualitative or quantitative methods used in isolation (Creswell and Plano Clark 2018). Other benefits include the ability to gain a greater depth and breadth of understanding of a phenomenon (Doyle et al. 2009; Teddlie and Tashakkori 2009; Curry and Nunez-Smith 2015; Creswell and Plano Clark 2018). This study adopted a mixed-methods approach harness such benefits, but also because it is suited to addressing complex and multi-faceted phenomenon in healthcare research (Curry and Nunez-Smith 2015), using the methods that best-suit the research questions (Creswell and Plano Clark 2018). The methods included and justification for their choice is described below.

A multiple methods study (also known as Quasi-Mixed methods, (Teddlie and Tashakkori 2009)) reports both qualitative and quantitative data without integration. Creswell and Plano Clark

(2018) stress that it is the combining of the data (not simply reporting finding of both qualitative and quantitative study) that defines mixed methods research.

3.4 Research Design

This is a multiple-methods, quantitative and mixed-method study design, to answer the first two research questions identified. Although data from the two research questions are not are not formally integrated, they are synthesised in chapter seven to address the third research question. See figure 2 for a diagram of the research design.

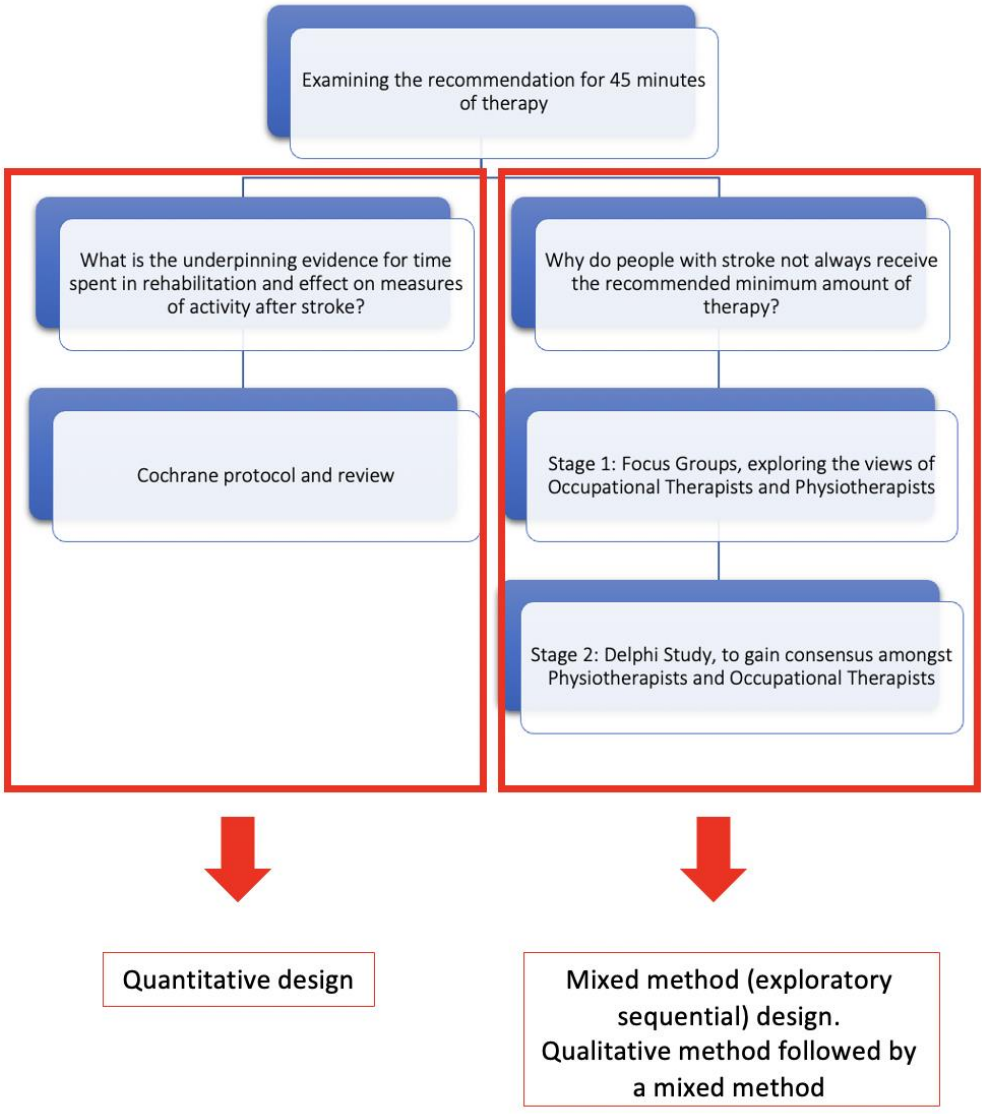

Figure 2 Diagram of the research structure and research design

3.4.1 Question One: What is the underpinning evidence for time spent in rehabilitation and effect on measures of activity after stroke?

A Cochrane review (systematic review with meta-analysis, following pre-determined, published standards) addressed this research question and the first study objective. A systematic literature review meticulously gathers all the relevant research evidence that addresses a specific research question and fits pre-determined selection criteria (Devereaux and Yusuf 2003; Akobeng 2005; Garg et al. 2008; Chandler et al. 2022). This facilitates the synthesis of high-quality research evidence, in which biases are limited by a systematic approach (Akobeng 2005; Garg et al. 2008), and allows researchers to explore the consistencies and differences of evidence across studies (Chandler et al. 2022). Systematic reviews often include Meta-Analyses, which is the use of statistical methods to quantitatively synthesize findings across studies (Uman 2011; Chandler et al. 2022). A meta-analysis can provide a more accurate estimate of true effect than any single study alone (Garg et al. 2008; Chandler et al. 2022).

To date, nine other systematic reviews with meta-analysis have consider the effect of time spent in rehabilitation. However, all nine include studies that vary not only in the amount of time spent in rehabilitation, but also the nature of the rehabilitation. Therefore, it is not certain if any difference found between groups is attributable to the amount of therapy received, as the content of the therapy may have also influenced outcomes. As such, it was reasoned that there were no systematic reviews with meta-analysis that considered the effect of time spent in rehabilitation, with all other important variables controlled.

Other methods could have been used to address Research Question One. However, within healthcare (and medicine, in particular), well conducted systematic reviews with meta-analysis are considered the highest quality level of evidence (Burns et al. 2011). Whilst this assumption could be disputed, systematic reviews with meta-analysis (and Cochrane reviews in particular) are considered useful sources of evidence for guideline development (National Institute for Health and Care Excellence 2014).

In accordance with the pragmatist standpoint of this study, a systematic review with meta-analysis was chosen, as it is an appropriate method to answer the question and, indeed, is a method that has been used to answer similar questions in the past. A Cochrane review was

specifically chosen, as it was considered likely to have a greater impact on future guideline development, supporting the pragmatist view that research should address real-world problems. The initial proposal for the Cochrane review was to synthesis RCTs and cohort studies which examined the effect of time spent in rehabilitation. However, the Cochrane Stroke Group favoured the exclusive inclusion of RCTs.

As this strand of the research project address question one, it was undertaken in parallel with the research activity undertaken to address question two. When the Cochrane review was completed, its findings were used to address research question three.

3.4.2 Question Two: Why do people with stroke not always receive the recommended minimum amount of therapy?

When planning research to address question two, different approaches were contemplated. Literature examined in chapter 2 revealed limited understanding about how therapists make decisions regarding therapy provision after stroke. Therapists themselves may be able to provide further information about the factors that influence their decision-making, therefore a method which asked therapists their views was required. There are many potential methods to gather the views of individuals including interviews, focus groups and observation. However, a consensus method would identify, not only reasons why a person may not receive the recommended minimum amount of therapy, but also which reasons were agreed by the majority of the participating therapists which reasons were not agreed by the majority. In addition, the guideline was determined via expert consensus, so a consensus method to determine why the guideline is not always achieved was considered an interesting parallel. Finally, it was felt that a consensus method, which included a large number of participants from across the UK, would support answering the third research question, is the 45 minute guideline fit for purpose? The fit between the methods used and the research questions aligns with the pragmatist standpoint of this programme of research.

Consensus methods are used to gain agreement in areas where there is uncertainty due to either a lack of, or conflicting, research evidence (Fink et al. 1984; Murphy et al. 1998; Black 2006; Tomasik 2010; James and Warren-Forward 2015). They collate the wisdom of participants, rather than create new knowledge (Murphy et al. 1998). Research literature identifies three main consensus methods: the Delphi method, the Nominal Group Technique (NGT) and the Consensus Development Conference (CDC) (Fink et al. 1984; Murphy et al. 1998; Black 2006; James and Warren-Forward 2015). The consensus method selected will depend on the evidence available (James and Warren-Forward 2015). If limited evidence is available, a Delphi Method or a NGT is more appropriate (Black 2006). However, if evidence is available but inconclusive or conflicting, a CDC is more appropriate (Halcomb et al. 2008). As there is limited evidence regarding how therapists make decisions about the amount of therapy provided to stroke survivors, a Delphi method or NGT were considered appropriate. These two methods are described, and justification given for the method chosen.

The Delphi method is a structured group communication technique, which uses a series of questionnaires administered in rounds. The first round commonly asks participants to suggest factors that should be considered by the group. Subsequent rounds ask participants to rate their level of agreement with statements given using Likert scales. After each round, the responses are summarised and sent back to the participants, indicating their individual position against the group's position. This process continues, until consensus is reached, normally after 2-3 rounds (Fink et al. 1984; Murphy et al. 1998; Powell 2003; van der Linde et al. 2005; Black 2006; Boulkedid et al. 2011). The benefits of a Delphi method are as follows: Firstly, the participants never meet; therefore individuals are not influenced by persuasive or dominant group members, thus reducing bias (Murphy et al. 1998; van der Linde et al. 2005; Black 2006; Boulkedid et al. 2011). Secondly, a large number of individuals can be included (Black 2006; Boulkedid et al. 2011). Thirdly, the process is not constrained by geography (Fink et al. 1984; Murphy et al. 1998; van der Linde et al. 2005; Boulkedid et al. 2011). Criticisms of the Delphi method include difficulty in distinguishing reasons for disagreement (Murphy et al. 1998; Black 2006) and reliance on questionnaire design and selection of an expert panel (James and Warren-Forward 2015). A Nominal Group Technique (NGT) is a committee decision-making process (Fink et al. 1984;

Murphy et al. 1998; James and Warren-Forward 2015). It involves 8-12 participants (Fink et al. 1984; Black 2006), who initially record their own ideas privately before ideas are shared and discussed in a facilitated meeting. Individuals then anonymously vote for their preferred option and statistical analysis applied to obtain a group judgment. Benefits of a NGT include allowing all members equal opportunity to generate suggestions in a formal, structured setting, therefore avoiding dominance of one or few individuals or ideas (Murphy et al. 1998; James and Warren-Forward 2015). Arguably, a NGT is less representative than a Delphi method, due to the smaller numbers of participants involved (Black 2006; James and Warren-Forward 2015).

Evidence suggests there are advantages and disadvantages to both a Delphi method and a NGT. Hutchings et al. (2006) conducted a study, including 213 heath care professionals, comparing the outcomes of Delphi methods and an NGT. They found that there was greater final consensus in the NGT (potentially because individuals were able to share the reasons for their opinions). However, there was greater between-group agreement in the Delphi method, indicating greater reliability, which may be due to the larger numbers involved (Fink et al. 1984). Hutchings et al. (2006) suggest that a 'hybrid' approach, combining the Delphi and NGT, may capture the benefits of both methods. They specifically suggested the use of a convened group (akin to a focus group), recorded and analysed using thematic analysis, followed by a postal stage. Therefore, to address the second research question (objective two) of this programme of research, a two-stage exploratory sequential mixed methods design (Creswell and Plano Clark 2018) was selected. In the first stage, therapist focus groups explored why some people do not receive the recommended minimum amount of therapy after stroke. The focus group findings, with findings from published literature were used to initiate stage two, a Delphi study to establish consensus amongst Physiotherapists and Occupational Therapists for why a person with stroke may not receive 45-minutes of therapy. This approach includes triangulation; utilising two methods to seek agreement within findings, to enhance validity (Doyle et al. 2009). Further detail regarding how the two stages were undertaken follow.

3.4.2.1 Stage 1: Focus Groups

In addition to contributing to the initiation of a Delphi study, focus were chosen to elicit rich data concerning how therapists decide how much therapy to provide to people after stroke.

Focus groups are an exploratory method, which utilise group interaction to elicit qualitative data (Barbour 2018; Green and Thorogood 2018). It's a social constructive approach, where individuals construct their knowledge through their interactions with others (Ivanoff and Hultberg 2006). They are suitable for studying the decision-making process (Barbour 2018), giving the researcher the opportunity to explore how participants view their reality (Ivanoff and Hultberg 2006). Focus groups are suitable for addressing sensitive topics, due to their perceived informality, and can encourage greater candour (Barbour 2018). The non-achievement of a national guideline could be considered a sensitive topic, which therapists might feel uncomfortable discussing in an individual interview. It's indicated that therapists use tacit knowledge in their decision-making (Clarke et al. 2018). Potentially, some decision-making relies on instinct and 'gut feeling'. Focus groups, therefore, were considered an appropriate method for gathering this data, where therapists could use the interaction with others to clarify the factors that influence their decision-making.

As described in chapter 5, the focus groups were undertaken with established therapy teams. The use of pre-existing groups as focus groups reduces the variability in terms of possible practical limitations to providing the recommended amount of therapy within groups. It is also beneficial in terms of familiarity within the group and potentially increases truthfulness (Barbour 2018).

The focus groups were analysed using reflexive thematic analysis, broadly following the process described by Braun and Clarke (2006), but adopting the principles of reflexive thematic analysis, as described by Braun and Clarke (2022). Such principles include, not only generating qualitative data, but positioning the data collection withing a qualitative research design, informed by qualitative principles. The focus groups did not seek to establish the 'right' answers, but to explore therapists views and experience, as socially constructed in the group process and acknowledging the effect that the researcher would have on this data collection and analysis. The data was analysed from an interpretivist philosophical perspective. Interpretivism is concerned with exploring meaning, using both the participants and the researchers understanding, recognising the impact that the social world and the researcher will have on each other (Snape and Spencer 2003; Green and Thorogood 2018). For this reason, it was considered appropriate for analysis of these focus groups.

3.4.2.2 Stage 2: Delphi Study

The findings of the focus groups, as well as published literature were used to design the first round of a Delphi study, to establish consensus amongst Physiotherapists and Occupational Therapists for why a person with stroke would not receive a minimum if 45-minutes of therapy and to determine if there was any lack of agreement amongst therapists regarding why some people do not receive 45 minutes of therapy. This first round was sent to participants who had consented to participate in the Delphi study; in this first round, participants were invited to suggest any further reasons why someone may not receive the 45 minute guideline, which were incorporated into the second Delphi round. Participants completed each round of the Delphi study via an electronic link, using survey software.

A Delphi study uses both qualitative and quantitative data (Hasson et al. 2000; Powell 2003; Keeney et al. 2006; James and Warren-Forward 2015) and, therefore, can be considered a mixed-method (Whitehead et al. 2020). In this Delphi study, the quantitative data is the Likert-scale responses to the Delphi statements and the qualitative data is the comments.

As this strand of the research project address question two, it was undertaken in parallel with the research activity undertaken to address question one. When the focus groups and Delphi study were completed, their findings were used to address research question three.

3.4.3 Question Three: Is the 45 minute guideline fit for purpose?

The purpose of clinical guidelines, as summarised in Chapter 2, was compared to the findings of this programme of research (Cochrane review, focus groups and Delphi study) and other relevant published research and data sources, to respond to this research question. It is this research question that links research questions one and two, as the findings of each contribute to the discussion regarding the suitability of the guideline in clinical practice and if it is, indeed, fit for purpose.

3.5 Demonstrating quality and rigor

3.5.1 Cochrane review

A systematic approach, which followed the guidance of the Cochrane Handbook for systematic reviews (Higgins et al. 2021c) was used. This included a comprehensive search of 11 electronic databases and 5 clinical trials registries, handsearching of key studies and citation reference searching. This was supported by the Cochrane Stroke Group's information specialist. Two authors judged studies' eligibility for inclusion and assessed the risk of bias in included studies, using a comprehensive tool. Data was extracted and inputted by one author, and check by another. Further information regarding these activities are detailed in the Cochrane review.

3.5.2 Focus groups and Delphi study

Consensus regarding criteria by which quality should be judged in qualitative studies is lacking (Mays and Pope 2000; Ballinger 2006; Green and Thorogood 2018). As an alternative to considering criteria, Ballinger (2006) proposes four 'considerations' for assessing the quality of qualitative research, which have been applied to the data collection and analysis of the focus groups and the qualitative element of the Delphi study. The four considerations are described below:

- *Coherence* considers the extent to which the elements of the study align. In this study, both the focus group and the Delphi method aligns with the pragmatist position of the study and with the research question that the focus groups and Delphi study contribute to addressing.
- *Evidence of Systematic and Careful Research Conduct* is demonstrated through the considered planning and execution of the focus groups and Delphi study, detailed in the this chapter and in chapters five and six. In the focus groups, care was taken to accurately record the expressed views of participants using a systematic approach including inductive analysis and in vivo coding. A coding framework was produced to demonstrate how codes were produced from the data and how they were organised into themes. This was not to support the analytical process, but to provide transparency. In the Delphi study, a systematic approach was taken to reviewing statements that didn't reach consensus and reviewing them for subsequent rounds. Details regarding this approach are supplied in an appendix, to provide transparency.

- *Convincing and relevant interpretation* considers the credibility of the research. Presentation and discussion of the focus group results in chapter five and the Delphi study results in chapter six demonstrate that the results are consistent with findings from other, similar studies, whilst also offering potentially new information. The focus groups were initially coded by BC and organised into themes/sub-themes. This was presented to a research supervision (JT), who discussed the codes, their interpretation, themes and sub-themes at length. The research supervisor challenged interpretations, when she felt they may not be substantiated by the data. The final presentation of themes and sub-themes is the result of this discussion.

  Delphi statement review was initially undertaken by BC, following the process outlined in chapter six. Statements for which there was not consensus were analysed, in relation to the comments that participants gave for their answer and statements were re-worded for the following round. The re-worded statements (with justification) were then presented to two research supervisors (JT and JB), who ensured that the re-worded statements were appropriate in light of the comments and level of agreement.
- Accounting for the *Role of the Researcher*, is considered in terms of my views and biases. In chapter one, I explained that the motivation for this research stemmed from my own clinical practice. I became a band 7 (advanced) Occupational Therapist in stroke in 2008, the same year the 45 minute guideline was first published. I was instrumental in the first audit of the 45 minute guideline in my organisation (2010) and I worked with my team to introduce this guideline into clinical practice. With my colleagues, I debated the guideline. We questioned its origins, its benefits and the effect it could have on clinical practice (from both therapists' and patients' perspective). Beginning this study, I had my own, formed views of the 45 minute guideline, combined with the motivation to learn and understand more. These views and experience will have influenced the findings of this research.

  In a Focus Group, the group facilitator actively contributes to the data being generated (Barbour 2018). The questions asked and the manner in which they were asked would have influenced the information participants gave. I made efforts to manage my effect on the data collection and analysis by maintaining a reflective diary throughout, using memos to note when I was potentially making judgments. However, despite having maintained awareness of this potential, my own preconceptions will have undoubtedly influenced this research to some extent. In addition, I was known to some of the research participants by virtue of the teams being local. I aimed to reduce the impact of this by

introducing myself as a researcher and through reassurance that confidentiality would be maintained but it is likely to have impacted the data collected.

In the Cochrane review and Delphi study I was not as close to the data collection. In the Delphi study, I did not meet participants face-to-face. However, the way that I presented the research to them (in the Participant information sheet, consent forms and in email communication) could have influenced their responses. Despite the perceived objectivity of a Cochrane review, decisions I made about the review objective and methods for data analysis, as well as the emphasis on the discussion, will have been influences by my views.

3.6 Governance, Ethics and Insurance

3.6.1 Informed Consent

Participants were given information sheets appropriate for the stage of study. Contact details were provided on the participant information sheet, had prospective participants wished to discuss any issues. All participants signed a consent form prior to participation.

3.6.2 Maintaining Confidentiality and Protecting Data

All paper-based data was stored behind two locks. Any electronic data was saved in a password-protected document. The University of Southampton Data protection policy and General Data Protection Regulations (GDPR) was followed.

Participants' confidentiality was maintained by avoiding use of personally identifiable information in data collection or analysis.

3.6.3 Right to withdraw

All participants retained the right to withdraw from the study, without explanation. They were informed that, should they withdraw, data they had already contributed to the study may be retained.

3.6.4 Ethical Approval & Insurance

Ethical approval was sought from the University of Southampton. In addition, ethical approval was required from Research and Development (R&D) of any hospital trust that employs therapists involved in the focus groups. Sponsorship and insurance was obtained from the University of Southampton.

Chapter 4 The effect of time spent in rehabilitation on activity limitation and impairment after stroke

4.1 Introduction to chapter

This chapter presents a Cochrane review, examining the effect of time spent in rehabilitation on activity limitation and impairment after stroke. It was undertaken to address the first research question: What is the underpinning evidence for time spent in rehabilitation and effect on measures of activity after stroke? This review received editorial approval from the Cochrane Stroke Review group in September 2021, and is awaiting publication. In accordance with Cochrane methodology, a protocol was published in March 2017, prior to commencement of the review (Appendix D). The full paper is presented here-in.

Title: The effect of time spent in rehabilitation on activity limitation and impairment after stroke

Authors: Clark B, Whitall J, Kwakkel G, Mehrholz J, Ewings S, Burridge J

4.2 Plain Language Summary

4.2.1 Review Question

Does more time spent in rehabilitation improve activity? What matters? Is it the total time spent in rehabilitation that is important, or is it the way rehabilitation is delivered (the schedule). Is it, for example, the amount of time spent per week? Or the frequency of sessions?

4.2.2 Background

Stroke rehabilitation helps people who have had a stroke to recover and resume their activities. Different countries have different guidelines about the amount of therapy they should receive. In England, a minimum of 45 minutes of each appropriate therapy, every day is recommended. In Canada the guidelines recommend more — three hours of task-specific training, five days per-week. Previous research has not found clear evidence in favour of one approach or the other: the effect of total time spent in rehabilitation; or the schedule by which it is delivered. The English recommendation of 45 minutes is based on the results of studies that compare different types of

rehabilitation as well as different amounts of the same type of rehabilitation — which is not the same thing. This is why our review compares only different amounts of the same type of stroke rehabilitation.

4.2.3 Study Characteristics

We included 21 studies amounting to 1,412 people with stroke. Each study had compared groups of people who had received different amounts of the same type of rehabilitation. Different types of rehabilitation were included, but the comparison within each study was always only different amounts of the same type. We included rehabilitation of the arm, leg, walking and general rehabilitation. In 16 studies, participants were in the first six months after stroke. In the remaining five studies participants were more than six months after stroke.

4.2.4 Search Date

We searched for studies up to June 2021

4.2.5 Key Results

We found that, for measures of activities involved in daily living (e.g. washing and dressing), activity measures of the arm (e.g. picking up an item) and activity measures of the leg (e.g. walking) there was neither harm to nor benefit for groups that received more rehabilitation compared with groups that received less. For measures of movement of the arm and leg (e.g. strength or range of movement), there *was* a benefit from receiving more rehabilitation. However, when we compared only the studies that had a bigger contrast between groups, there was a beneficial effect from additional therapy in terms of daily living activities, activity measures of the arm and leg; and movement measures of the arm. This suggests that people with stroke need a large amount of extra rehabilitation for it to make a difference in their recovery and ability to do everyday activities.

4.2.6 Quality of the Evidence

Quality of the evidence, which is measured by the quality of each of the studies included in the review, was either low or very low. We can therefore only draw tentative conclusions from the findings of this review. It also indicates that more, better quality, studies are needed.

4.3 Summary of findings

Table 2 Summary of findings table one (objective one – immediately after intervention)

More time compared to Less time in rehabilitation (Objective one - Outcomes immediately after intervention)						
Patient or population: rehabilitation vs Less time spent **Setting**: Any rehabilitation setting, including hospital, outpatients and patient's home **Intervention**: More time **Comparison**: Less time						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Less time	Risk with More time				
ADL Outcomes assessed with: Studies measured ADL outcomes using different scales. Higher scores indicate greater independence	-	SMD **0.13 higher** (0.02 lower to 0.28 higher)	-	864 (19 RCTs)	⨁⊖⊖⊖ VERY LOW[a,b,c]	As a rule of thumb, a SMD of 0.2 is considered a small effect. Therefore, this finding suggests that the average difference in mean scores between more therapy groups and less therapy groups is small. As the confidence interval for this outcome includes 0, there may be no

More time compared to Less time in rehabilitation (Objective one - Outcomes immediately after intervention)						
						difference for ADL measures when more time is spent in rehabilitation.
Activity measures of the Upper Limb (Upper limb activity) assessed with: Studies measured upper limb activity using different scales. Higher scores indicate greater activity	-	SMD **0.09 higher** (0.11 lower to 0.29 higher	-	426 (18 RCTs)	⨁⊖⊖⊖ VERY LOW[a,b,d]	As a rule of thumb, a SMD of 0.2 is considered a small effect. Therefore, this finding suggests that the average difference in mean scores between more therapy groups and less therapy groups is small. As the confidence interval for this outcome crosses 0, there may be no difference for upper limb activity measures when more time is spent in rehabilitation.
Activity measures of the Lower Limb (Lower limb activity) assessed with: Studies measured lower limb activity using different scales. Higher	-	SMD **0.25 higher** (0.03 lower to 0.53 higher)	-	425 (5 RCTs)	⨁⨁⊖⊖ LOW [a, b]	As a rule of thumb, a SMD of 0.2 is considered a small effect. Therefore, this finding suggests that the average difference in mean scores between more therapy groups and less therapy groups is small. As the confidence interval for this outcome crosses 0, there may be no

More time compared to Less time in rehabilitation (Objective one - Outcomes immediately after intervention)						
scored indicate greater activity						difference for lower limb activity measures when more time is spent in rehabilitation.
Motor impairment measures of the Upper Limb (Upper limb impairment) assessed with: Studies measured upper limb impairment using different scales. Higher scores indicate less impairment	-	SMD **0.32 higher** (0.06 higher to 0.58 higher)	-	287 (12 RCTs)	⨁⨁⊖⊖ LOW a, e	As a rule of thumb, a SMD of 0.2 is considered a small effect. Therefore, this finding suggests that the average difference in mean scores between more therapy groups and less therapy groups is small. As the confidence interval for this outcome does not crosses 0, there is a benefit for upper limb impairment measures when more time is spent in rehabilitation.
Motor impairment measures of the lower limb (Lower limb impairment)	-	SMD **0.71 SD higher** (0.15 higher to 1.28 higher)	-	51 (1 RCT)	⨁⊖⊖⊖ VERY LOW f, g	As a rule of thumb, a SMD of 0.5 is considered a moderate effect. Therefore, this finding suggests that the average difference in mean scores between more therapy groups and less therapy groups is moderate. As the confidence

More time compared to Less time in rehabilitation (Objective one - Outcomes immediately after intervention)						
assessed with: Measured by knee flexion peak torque						interval for this outcome does not crosses 0, there is a benefit for lower limb impairment measures when more time is spent in rehabilitation.
Serious Adverse Events/Death	48 per 1000	**57 per 1000** (24 to 136)	**RR 1.20** (0.51 to 2.85)	379 (2 RCTs)	⨁⨁⨀⨀ LOW a, b	There is no increased risk of serious adverse events or death when more time is spent in rehabilitation
*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **SMD:** Standardised mean difference; **RR:** Risk ratio						
GRADE Working Group grades of evidence **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect **Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different						

More time compared to Less time in rehabilitation (Objective one - Outcomes immediately after intervention)
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect **Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect
See interactive version of this table: https://gdt.gradepro.org/presentations/#/isof/isof_question_revman_web_417399834740907517
a. Several studies classified as 'some concerns' or 'high' risk of bias (downgraded by one level) **b.** 95% CI contains an effect size of no difference **c.** Two studies may have measured this outcome but have not reported it. A funnel plot shows some asymmetry, which may be indicative of publication bias. **d.** Five studies may have assessed this outcome but did not report findings. A forest plot for this outcome shows asymmetry, suggestive of non-reporting bias. **e.** One study assessed this outcome but does not reported findings and two further studies may have assessed this outcome but do not report findings **f.** Analysis only included one study, which was judged as High risk of bias. Therefore, finding considered at very serious risk of bias (downgraded by 2 levels). **g.** Two studies may have assessed this outcome but do not report findings

Table 3 Summary of findings table two (objective one – medium-term outcomes)

More time compared to Less time in rehabilitation (Objective one - medium term outcomes)						
Patient or population: rehabilitation vs Less time spent **Setting**: Any rehabilitation setting, including hospital, outpatients and patient's home **Intervention**: More time **Comparison**: Less time						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Less time	Risk with More time				
ADL Outcomes assessed with: Studies measured ADL outcomes using different scales. Higher scores indicate greater independence	-	SMD **0.01 higher** (0.15-lower to 0.16 higher)	-	673 (12 RCTs)	⨁⊖⊖⊖ VERY LOW a, b, c	As this finding is very close to 0, it suggests that the average difference in mean scores between more therapy groups and less therapy groups is close to nothing. Therefore, there is no difference for ADL measures when more time is spent in rehabilitation.

More time compared to Less time in rehabilitation (Objective one - medium term outcomes)						
Activity measures of the Upper Limb - Medium-term outcomes assessed with: Studies measured upper limb activity using different scales. Higher scores indicate greater activity	-	SMD **0.02 lower** (0.36-lower to 0.33 higher)	-	218 (9 RCTs)	⨁⊖⊖⊖ VERY LOW b, d, e	As this finding is very close to 0, it suggests that the average difference in mean scores between more therapy groups and less therapy groups is close to nothing. Therefore, there is no difference for activity measures of the upper limb when more time is spent in rehabilitation.
Activity measures of the Lower Limb - Medium-term outcomes assessed with: Studies measured lower limb activity using different scales. Higher scored indicate greater activity	-	SMD **0.1 higher** (0.3 lower to 0.49 higher)	-	243 (4 RCTs)	⨁⊖⊖⊖ VERY LOW b, d, f, g	As a rule of thumb, a SMD of 0.2 is considered a small effect. Therefore, this finding suggests that the average difference in mean scores between more therapy groups and less therapy groups is very small. As the confidence interval for this outcome crosses 0, there may be no difference for lower limb activity measures when more time is spent in rehabilitation.

More time compared to Less time in rehabilitation (Objective one - medium term outcomes)						
Motor impairment measures of the Upper Limb - Medium-term outcomes assessed with: Studies measured upper limb impairment using different scales. Higher scores indicate less impairment	-	SMD **0.02 lower** (0.39 lower to 0.35 higher)	-	115 (5 RCTs)	⨁⊖⊖⊖ VERY LOW b, d, h	As this finding is very close to 0, it suggests that the average difference in mean scores between more therapy groups and less therapy groups is close to nothing. Therefore, there is no difference for motor impairment measures of the upper limb when more time is spent in rehabilitation.
Motor impairment measures of the Lower Limb - Medium-term outcomes assessed with:	-	SMD **0.62 higher** (0.04 lower to 1.28 higher)	-	37 (1 RCT)	⨁⊖⊖⊖ VERY LOW b, i, j	As a rule of thumb, a SMD of 0.5 is considered a moderate effect. Therefore, this finding suggests that the average difference in mean scores between more therapy groups and less therapy groups is moderate. As the confidence interval for this outcome does not crosses 0, there is a

More time compared to Less time in rehabilitation (Objective one - medium term outcomes)						
Measured by knee flexion peak torque						benefit for lower limb impairment measures when more time is spent in rehabilitation.
Serious Adverse Events/Death - Medium-term outcomes	70 per 1000	**93 per 1000** (44 to 194)	**RR 1.32** (0.63 to 2.76)	344 (3 RCTs)	⨁⊖⊖⊖ VERY LOW a, b	There is no increased risk of serious adverse events or death when more time is spent in rehabilitation
*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **SMD:** Standardised mean difference; **RR:** Risk ratio						
GRADE Working Group grades of evidence **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect **Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different **Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect **Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect						

More time compared to Less time in rehabilitation (Objective one - medium term outcomes)
See interactive version of this table: https://gdt.gradepro.org/presentations/#/isof/isof_question_revman_web_421205526923794365.
a. More than half of the studies included in analysis have a high overall risk of bias. Therefore, finding considered at very serious risk of bias (downgraded by two levels) **b.** 95% CI contains an effect size of no difference **c.** Data from one included study is missing from this analysis. One study assessed this outcome but does not reported findings and seven other studies may have assessed this outcome but do not report findings. A funnel plot for this outcome shows asymmetry, which may indicate non-reporting bias. **d.** Several studies classified as 'some concerns' or 'high' risk of bias (downgraded by one level) **e.** Data from two included studies are missing from this analysis. Two studies assessed this outcome but do not reported findings and seven other studies may have assessed this outcome but do not report findings. **f.** I2= 58% **g.** Data from one included study is missing from this analysis. One study assessed this outcome but does not reported findings and one further study may have assessed this outcome but does not report findings. **h.** Data from one included study is missing from this analysis. Two studies assessed this outcome but do not reported findings and six other studies may have assessed this outcome but do not report findings. **i.** Only included study was a high risk of overall bias

More time compared to Less time in rehabilitation (Objective one - medium term outcomes)
j. One study assessed this outcome but does not reported findings and two other studies may have assessed this outcome but does not report findings.

Table 4 Summary of findings table three (objective two – long-term outcomes)

More time compared to Less time in rehabilitation (Objective one - long-term outcomes)						
Patient or population: rehabilitation vs Less time spent **Setting**: Any rehabilitation setting, including hospital, outpatients and patient's home **Intervention**: More time **Comparison**: Less time						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Less time	Risk with More time				
ADL Outcomes - Long-term outcomes	-	SMD **0.09 higher** (0.39 -	-	67 (1 RCT)	⨁⨁⊖⊖ LOW a	As a rule of thumb, a SMD of 0.2 is considered a small effect. Therefore, this finding suggests that the average difference in mean scores between more therapy group

More time compared to Less time in rehabilitation (Objective one - long-term outcomes)						
assessed with: Adelaide Activities Profile		lower to 0.57 higher)				and less therapy group is very small. As the confidence interval for this outcome includes 0, there may be no difference for ADL measures when more time is spent in rehabilitation.
Activity measures of the Lower Limb - Long-term outcomes assessed with: 6 minute walk test	-	SMD **0.16 higher** (0.32 - lower to 0.64 higher)	-	67 (1 RCT)	⊕⊕⊖⊖ LOW a	As a rule of thumb, a SMD of 0.2 is considered a small effect. Therefore, this finding suggests that the average difference in mean scores between more therapy group and less therapy group is small. As the confidence interval for this outcome includes 0, there may be no difference for activity measures of the lower limb when more time is spent in rehabilitation.
Motor impairment measures of the upper limb - Long-term	-	-	-	-	-	-

More time compared to Less time in rehabilitation (Objective one - long-term outcomes)						
outcomes - not reported						
Motor impairment measures of the lower limb - Long term outcomes - not reported	-	-	-	-	-	-
Serious adverse events/death - Long-term outcomes - not reported	-	-	-	-	-	-
*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **SMD:** Standardised mean difference						

More time compared to Less time in rehabilitation (Objective one - long-term outcomes)
GRADE Working Group grades of evidence **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect **Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different **Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect **Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect
See interactive version of this table: https://gdt.gradepro.org/presentations/#/isof/isof_question_revman_web_421205629766293495
a. Very serious imprecision, due to 95% CI containing an effect size of no difference and finding based on the results of only one study, with a relatively small number of participants (downgraded by 2 levels)

4.4 Background

This review explores the effect of time spent in rehabilitation after stroke. We acknowledge that 'time spent' is potentially an ambiguous term. For the purpose of this review, we consider 'time spent' to include

- The number of minutes of rehabilitation provided, per week;
- The frequency of rehabilitation provided per week (i.e. number of days per week on which rehabilitation was given);
- The time-period over which rehabilitation was provided, or rehabilitation duration;
- The total amount of time spent in rehabilitation (in minutes/hours).

The outcome of rehabilitation after stroke may be affected by how these different elements are combined. For example, the outcome of a certain number of minutes of rehabilitation provided over a shorter time-period may be different to the same number of minutes provided over a longer time-period. We acknowledge that, to some, 'time spent in rehabilitation' could be synonymous with 'rehabilitation intensity'. Whilst the term 'intensity' could be used to describe the time-related elements described above, it has also been used to describe alternative characteristics of rehabilitation, including number of repetitions performed within treatment sessions (Scrivener et al. 2012) and physiological effort exerted (Outermans et al. 2010). We will not explore these characteristics in this review. Other terms to describe 'time spent in rehabilitation' could be 'dose of rehabilitation' or 'amount of rehabilitation'.

4.4.1 Description of the condition

Stroke is a “neurological deficit attributed to an acute focal injury of the central nervous system by a vascular cause” (Sacco et al. 2013). It is a significant, global health issue. In 2016, there were approximately 13.7 million first-ever strokes and more than 80 million stroke survivors worldwide, with stroke being the second most common cause of lost disability adjusted life years (DALYs) (Johnson et al. 2019). In the UK alone, over 27,000 (37%) of people discharged from hospital between 2013 and 2014 required help with activities of daily living such as washing and dressing (Royal College of Physicians 2014) and between 2019 and 2020, 34% of people had not returned to independence by 6 months post-stroke (Bahalla et al. 2021). Such disability results in significant cost due to care requirements and loss of productivity (Mozaffarian et al. 2015; Patel et al. 2020). Better rehabilitation outcomes after stroke would reduce the impact of disability and dependence

on the quality of life of people with stroke and their carers (Lewthwaite et al. 2018; Oyewole et al. 2020), and national economies (Patel et al. 2020).

4.4.2 Description of the intervention

The intervention of interest in this study is stroke rehabilitation. Stroke rehabilitation is a multidimensional process, designed to optimise functional activity in people with stroke, where there are ongoing stroke-related impairments (Dobkin and Carmichael 2005; National Institute for Health and Care Excellence 2013). For the purpose of this review, we define rehabilitation as any non-pharmacological, non-surgical intervention that aims to improve activity after stroke.

There are many rehabilitation interventions to target different stroke-related impairments via a variety of methods. Previous Cochrane Reviews have explored physical rehabilitation (Pollock et al. 2014a), cognitive rehabilitation (Bowen et al. 2013; Chung et al. 2013; Loetscher et al. 2013; das Nair et al. 2016), telerehabilitation (Laver et al. 2013), virtual reality (Laver et al. 2015), acupuncture (Yang et al. 2016), electromechanical and robot-assisted arm training (Mehrholz et al. 2018), mirror therapy (Thieme et al. 2018), physical fitness training (Saunders et al. 2020), motivational interviewing (Cheng et al. 2015), constraint-induced movement therapy (CIMT) (Corbetta et al. 2015), repetitive transcranial magnetic stimulation (Hao et al. 2013), and repetitive task training (French et al. 2016). Whilst there is value in determining the efficacy of specific rehabilitation interventions, it is acknowledged that, in practice, the content of rehabilitation therapy is not clearly defined and varies between both therapists and services (Ballinger et al. 1999; DeJong et al. 2005). The relationship between type of therapy and response is unclear (Lohse et al. 2014), with therapists adopting an eclectic approach (Jette et al. 2005). Therefore, this review is adopting an 'intervention agnostic' approach, seeking to explore not if one type of rehabilitation is superior to another, but to explore the specific effect of time spent in rehabilitation.

Rehabilitation may be provided by a variety of professions (Pollock et al. 2014a). This review is not limited to any specific provider of rehabilitation; therefore, we will refer to providers of rehabilitation as 'service providers'.

4.4.3 How the intervention might work

In this review, the intervention is any non-pharmacological, non-surgical intervention that aims to improve activity after stroke and the research question focuses on the influence of time spent in any particular intervention. These interventions might work through neuroplasticity: the brain's ability to modify neuronal activity and reorganise neural connections. Neuroplasticity underpins

both recovery of and compensation for impaired motor function after stroke (Dobkin and Carmichael 2005; Kleim and Jones 2008; Levin et al. 2009; Buma et al. 2013; Nudo 2013). The differentiation between recovery, where survivors initially regain their pre-morbid kinematic/muscle activation patterns and compensation, where alternative kinematic/muscle activations are used to accomplish a task is thought to occur by around the first five to eight weeks after stroke (van Kordelaar et al. 2013; Kwakkel et al. 2015; van der Vliet et al. 2020).

Research points to many potentially important aspects of stroke rehabilitation that influence outcomes. Kleim and Jones (2008), in their review of the evidence for experience-dependent neural plasticity, identified that repetition, the relative importance of the task undertaken, and skill acquisition (as opposed to simply use) will influence plasticity. Other authors described further important aspects in the re-learning of motor skills, such as the use of explicit versus implicit learning (Boyd and Winstein 2003; Boyd and Winstein 2004). The presence of a meaningful context or goal has been shown to enhance motor learning (Ma et al. 1999; Wu et al. 2000). There is evidence that extrinsic feedback enhances motor-learning after stroke (van Vliet and Wulf 2006) and that stroke survivors benefit more from random practice of exercise than they do block practice (Hanlon 1996). Wulf et al. (2010) discussed additional influences on learning, such as learning through observation, and internal versus external focus of attention and self-controlled practice. Mount et al. (2007)discussed research related to the impact of errorless learning versus trial and error learning, whilst Levack et al. (2006) suggested that specific, difficult goals may enhance performance. Finally, research suggests that an enriched environment enhances recovery post-stroke (Janssen et al. 2010). The purpose of this review, however, is to explore the effect of the time spent in rehabilitation for activity level outcomes after stroke. Whilst it is acknowledged that other factors will influence outcomes, we assume that these other factors are similarly distributed in an intervention where only the time spent in rehabilitation is the variable of focus for this review.

Mechanistically, one type of learning that promotes neuroplasticity is Hebbian Learning (Hebb 1949). Hebbian (and anti-Hebbian) Learning is concerned with an increase in synaptic efficacy, due to repetitive firing of the pre-synaptic cell, causing stimulation of the post-synaptic cell, leading to increased synaptic strength (Nudo 2013). Evidence indicates that repetition is key to increasing synaptic efficacy (Kleim and Jones 2008; Nudo 2013). From a service provider's perspective, then, it could be deduced that the time spent in rehabilitation may determine the frequency of synaptic stimulation and therefore more time spent in repetitive rehabilitation should increase synaptic strength.

Behavioural experience, or the intervention itself, is one of the most important factors in the modulation of cortical function and structure (Nudo 2013). Behaviourally, there is a large body of evidence regarding motor learning (and re-learning) in non-disabled people (Wulf et al. 2010) and also in people with stroke (Kitago and Krakauer 2013) where the main principles of repetition, 'just right' challenge (Guadagnoli and Lee 2004) and graded feedback (Winstein and Schmidt 1990) closely align with the key principles of neuroplasticity (Kleim and Jones 2008), again supporting the premise that increased time spent in rehabilitation will provide more beneficial change in the performance outcomes of a task.

Several intervention studies also suggest that the time spent in rehabilitation after stroke is more important than the type of rehabilitation. A narrative review of CIMT found that CIMT compared with dose-matched bilateral arm training did not produce significant differences in overall effect sizes (Kwakkel et al. 2015). Phase 2 and 3 randomised controlled trials (RCTs) have found no significant differences in outcomes between CIMT and dose-matched 'traditional occupational therapy' (Dromerick et al. 2009), robot-assisted therapy and dose-matched intensive therapy (Lo et al. 2010), or structured task-oriented training and dose-equivalent usual care (Winstein et al. 2016). Taken together, these and similar findings indicate that, as long as the rehabilitation provided is of equal amounts, it does not matter very much what type or content of therapy is given. This has led to many studies comparing amounts of therapy for a given population as the factor of interest (as reviewed in a later section). However, 'more is better regardless' is almost certainly an oversimplified view of how rehabilitation interventions might work.

For example, in the recent ICARE study (Winstein et al. 2016), a usual-care low-dose group did as well as the two higher-dose-matched groups at the one-year end-point suggesting that dose of rehabilitation may not be the most important factor in recovery levels measured long after the intervention, although the three groups are confounded by having different types of intervention. Furthermore, Dromerick et al. (2009) found that providing a greater dose of CIMT, when given early after stroke, had a detrimental effect on outcomes related to activities of daily living. This suggests that time spent in rehabilitation interacts with stage of recovery and spontaneous recovery processes. These two studies both suggest that timing of an intervention may be important. A study in the chronic population, comparing bilateral rhythmic arm training and unilateral dose-matched therapeutic exercises, determined that the two interventions did not operate through the same neuroplastic mechanisms, despite eliciting similar outcomes at the impairment and activity level (Whitall et al. 2011). This finding indicates that type of rehabilitation and what the rehabilitation targets interacts with the underlying mechanisms in ways we do not completely understand yet.

Finally, all the intervention studies above have the problem of how to actually dose-match different types of rehabilitation so that they are truly equivalent in effort by the patient at any given amount. This is an almost impossible task. Given this problem, as well as the evidence just presented that the type of intervention may well be important after all, leads us to question whether it is valid to compare different amounts of time spent in rehabilitation with two different interventions. We pursue this point further below.

In summary, it is thought that rehabilitation interventions 'work' by influencing the recovery from and compensation for the neurological damage caused by stroke. The time spent in rehabilitation may be a factor in determining the effectiveness of this intervention for reducing activity limitation.

4.4.4 Why is it important to do this review?

Some clinical practice guidelines give recommendations for the amount of time that should be spent in rehabilitation:

- The Royal College of Physicians' National Clinical Guideline for Stroke recommends a minimum 45 minutes of each relevant rehabilitation therapy (occupational therapy, physiotherapy, and speech and language therapy), every day (Intercollegiate Stroke Working Party 2016)
- The Canadian Best Practice guidelines for rehabilitation states that patients should receive a minimum of three hours of task-specific therapy, five days per week, delivered by an interprofessional stroke team (Teasell et al. 2020)
- The Australian Stroke Foundation, Clinical Guidelines for Stroke Management states that a minimum of one hour of active practice of physical therapy (occupational therapy and physiotherapy) should be provided at least five days per week (Stroke Foundation 2021).

These guidelines all suggest minimum daily session duration (in terms of hours/minutes) of rehabilitation that should be provided and a suggested frequency of rehabilitation (in terms of days per week). They do not all make a recommendation for treatment duration (in terms of the length of time over which rehabilitation should continue).

The effect of time spent in rehabilitation post-stroke has been explored extensively, using systematic reviews with meta-analyses (Langhorne et al. 1996; Kwakkel et al. 1997; Kwakkel et al. 2004b; Galvin et al. 2008; Cooke et al. 2010a; Veerbeek et al. 2011; Lohse et al. 2014; Veerbeek et al. 2014), but none of these studies provide clear evidence for the aforementioned guidelines.

These meta-analyses include 71 unique studies. In at least 50 of these studies, the experimental and control interventions differed in not only the amount of rehabilitation provided, but also the type of rehabilitation. As previously mentioned, it may be that type of rehabilitation influences outcomes, as well as amount of time spent in rehabilitation. Arguably, therefore, conclusions regarding the effect of amount should not be drawn from studies comparing different types of rehabilitation.

Two meta-analyses explored the “optimum amount” of rehabilitation post-stroke. Kwakkel et al. (2004b) used a cumulative meta-analysis and, although their findings did not support a precise optimal amount of time spent in rehabilitation, no ceiling effect was found. Lohse et al. (2014) used meta-regression to explore the effect of total scheduled therapy time on effect sizes. They found a non-linear relationship between total amount of therapy and outcomes. This suggests that there may be an 'optimal amount' of therapy time, beyond which the benefits of additional therapy are limited. Taken together, these meta-analyses suggest that guidelines that include a specific minimum amount of rehabilitation are pragmatically-based, as opposed to evidence-based.

More recently, there is a Cochrane Review published that explores the effect of repetitive task training (RTT) on functional ability after stroke (French et al. 2016). They found evidence that RTT improves upper and lower limb function, but there was no effect for additional time spent in RTT. In their Cochrane Review 'Physical rehabilitation approaches for the recovery of function and mobility following stroke', Pollock et al. (2014a) undertook a subgroup analysis exploring the effect of dose of physical rehabilitation on functional recovery and the recovery of motor function after stroke. They concluded that evidence related to dose is limited. In addition, Pollock et al. (2014b)undertook a Cochrane Review of interventions for improving upper limb function after stroke. They found that certain interventions were effective at a higher dose, and identified the need for evidence related to dose of intervention, in order to inform future research and clinical practice.

As yet, there is no Cochrane Review exploring the effect of time spent in rehabilitation on activity after stroke. We consider our review important in order to determine if the increasing number of clinical guidelines that recommend a specific minimum amount of time spent in rehabilitation after stroke have an evidence base and, if so, this will be useful for future guideline development. Based on current guidelines and evidence, there is a strong push for technologies that enable additional practice, especially in the home and without additional staff. This requirement has intensified, due to the 2020 COVID-19 pandemic. A better understanding of the importance of

amount of time spent in rehabilitation will inform development of new technologies such as telerehabilitation and use of virtual reality.

4.5 Objectives

1. To assess the effect of more time spent in the same type of rehabilitation on activity measures in people with stroke
2. To assess the effect of difference in total rehabilitation time (in minutes) on recovery of activity in people with stroke
3. To assess the effect of rehabilitation schedule on activity in terms of:
    a) Average time (minutes) per week undergoing rehabilitation
    b) Frequency (number of sessions per week) of rehabilitation
    c) Total duration of rehabilitation.

4.6 Methods

4.6.1 Criteria for considering studies for this review

4.6.1.1 Types of studies

We have included randomised trials that compare different amounts of time spent, greater than zero, of the same rehabilitation intervention. These could be RCTs (participants are randomised to either an experimental group or a control group) or randomised clinical trials (participants are randomised to different experimental groups). We also would have included cluster-randomised trials and data from the first period of randomised cross-over trials were any found. We restricted the types of studies to randomised trials only, as they are considered high-quality sources of evidence in clinical practice (Devereaux and Yusuf 2003) and the method to establish causality (Horn et al. 2005; Concato et al. 2010; Kersten et al. 2010).

If studies included more than one treatment arm, one of which met the criteria for this review, we included the control group and intervention arm compliant with the criteria for this review. If studies included multiple intervention arms, we included all compliant with the criteria for this review.

4.6.1.2 Types of participants

Participants were adults (over 18 years), with a clinical diagnosis of stroke, caused by either infarct or haemorrhage (including subarachnoid haemorrhage), as defined by the study authors. Participants received rehabilitation in either an inpatient, outpatient, or community setting. We excluded studies that include participants with diagnoses other than stroke as the primary diagnosis, even if they included some participants with a primary diagnosis of stroke.

4.6.1.3 Types of interventions

We included trials that compare different amounts of time spent in the same type of rehabilitation. We defined rehabilitation as any non-pharmacological, non-surgical intervention that aims to improve activity after stroke.

To be eligible for inclusion, trials had to include two or more groups that varied in one or more of the following elements, in any combination:

- The number of minutes of rehabilitation provided, per week;
- The number of days per week on which rehabilitation was provided;
- The time-period over which rehabilitation was provided, or rehabilitation duration, measured in days, weeks or months.
- The total amount of time spent in rehabilitation (in minutes/hours)

To establish if time spent is related to outcomes, included studies varied only in the amount of time spent in rehabilitation between groups. We have included 'control' or 'usual care' groups, provided they received the same type of rehabilitation as the intervention group. We have excluded comparisons of intervention vs. no intervention (including trials in which only some participants received no intervention).

If studies clearly varied in the time spent in rehabilitation (as defined above), but did not report a specific time-related measurement, we included the study.

Co-interventions did not preclude inclusion, provided they were administered equally to both experimental and control groups.

4.6.1.4 Types of outcome measures

We included published outcome measures falling into ICF categories for activity and body structures/body functions (World Health Organisation 2001). We were primarily interested in

measures of activity, as these outcomes are likely to be most meaningful to stroke survivors and to indicate a reduction in the burden of care. We were also interested in measures of body structure/body function, as they indicate if an increased amount of time spent in rehabilitation facilitates recovery at this level.

4.6.1.4.1 Primary outcomes

For our three study objectives, we defined the primary outcome measure as ADL outcomes. We included any measure of ADL, including but not limited to (and in no specific order): Barthel Index, Frenchay Activity Index, Rivermead ADL Assessment, Nottingham Extended ADL, Functional Independence Measure.

4.6.1.4.2 Secondary outcomes

For our three study objectives, our secondary outcome measures were:

1. Activity measures of the upper limb (e.g. Action Research Arm Test, Jebsen Taylor Hand Function Test)
2. Activity measures of the lower limb (e.g. timed up-and-go, 6-minute walk test, walking speed and the Rivermead Mobility Index)
3. Motor impairment measures of the upper limb (e.g. Upper extremity Fugl- Meyer assessment, muscle strength, range of movement)
4. Motor impairment measures of the lower limb (e.g. muscle strength, range of movement)
5. Serious adverse events/death

For both primary and secondary outcomes, we were principally interested in measures taken immediately after intervention. However, we also undertook analysis of medium-term outcomes (two weeks to six months after treatment ended) and long-term outcomes (more than six months after treatment ended). The medium and long-term outcomes were analysed for objective one, but not for objectives two and three.

4.6.2 Search methods for identification of studies

See the 'Specialised register' section in the Cochrane Stroke Group module. We searched for trials in all languages and arranged for the translation of relevant articles where necessary.

4.6.2.1 Electronic searches

We searched the Cochrane Stroke Group trials register (last searched 7th June 2021) and the following electronic databases from their inception.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2020, Issue 7) in the Cochrane Library (searched June 2021) (Appendix E);
- MEDLINE (from 1946 to June 2021) (Ovid) (Appendix F)*;*
- Embase (from 1980 to June 2021) (Ovid) (Appendix G);
- CINAHL (Cumulative Index to Nursing and Allied Health Literature; from 1937 to June 2021) (EBSCO) (Appendix H);
- AMED (from 1985 to June 2021) (EBSCO) (Appendix I);
- PsycINFO (from 1987 to June 2021) (EBSCO) (Appendix J);
- Open Grey (www.opengrey.eu/) (July 2020) (Appendix K) (search not updated in June 2021, as the site has been archived);
- OTSeeker (www.otseeker.com/)(June 2021) (Appendix L);
  PEDro: Physiotherapy Evidence Database (www.pedro.org.au)(July 2021) (Appendix M);
- REHABDATA (National Rehabilitation Information Centre) (www.naric.com/?q=REHABDATA) (July 2021) (Appendix N);
- ProQuest Dissertations & Theses (www.proquest.com/) (June 2021) (Appendix O).

We developed the MEDLINE search strategy (Appendix F) with the help of the Cochrane Stroke Group Information Specialist and adapted it for the other databases. We searched for all relevant RCTs regardless of language or publication status (published, unpublished, in press or in progress).

We also searched the following trials registers and registries:

- ClinicalTrials.gov (www.clinicaltrials.gov/) (June 2021) (Appendix P);
- Stroke Trials Registry (www.strokecenter.org/trials/) (July 2018) (Appendix Q); (unable to update this search beyond July 2018, as the website was unavailable)
- EU Clinical Trials Register (www.clinicaltrialsregister.eu) (June 2021) (Appendix R);
- ISRCTN Registry (www.isrctn.com/) (June 2021) (Appendix S);
- World Health Organisation (WHO) International Clinical Trials Registry Platform (ICTRP) portal (www.who.int/ictrp/en/) (June 2021) (Appendix T).

4.6.2.2 Searching other resources

We hand searched the reference lists of all identified studies and systematic reviews for any further potentially eligible studies. In addition, we contacted key authors to obtain any missing or additional trial data.

We undertook reference searching using Web of Science Cited Reference Search for all included studies to identify any further relevant trials.

4.6.3 Data collection and analysis

4.6.3.1 Selection of studies

We collated the search results and removed duplicates prior to screening, using the method described by Bramer et al. (2016). One review author (BC) screened the titles of the studies retrieved via the searching process and excluded obviously irrelevant studies. Two review authors (BC and JB) then independently screened titles and abstracts of the remaining studies, excluding those that didn't meet the selection criteria. We retrieved the full-text articles for the remaining references and two review authors (BC and JW) independently screened the full-text articles and identified studies for inclusion, and recorded reasons for exclusion of ineligible studies. Where necessary, we contacted study authors for further information. We resolved any disagreements through discussion and, when required, consulted a third author (JB). We collated multiple reports of the same study, to ensure that no single study was duplicated in reporting. We recorded the selection process and completed a PRISMA flow diagram (Moher et al. 2009), a table of 'Characteristics of included studies', a table of 'Characteristics of excluded studies', a table of 'Characteristics of studies awaiting classification', and a table of 'ongoing studies'.

4.6.3.2 Data extraction and management

Two review authors (of BC, JB and JW), working independently, extracted data from each study. We used the “template for intervention description and replication” (TIDieR) checklist and guide (Hoffmann et al. 2014) to extract data from eligible studies. In addition to the 12 points on the TIDierR checklist, we also included information on study eligibility, the study participants, the outcomes measured (including time points) and a 'miscellaneous' section (which included information such as funding sources, key conclusions from the study authors, references to other relevant studies, correspondence required, and any other comments by the review author). We included detailed information on time spent in rehabilitation in section eight of the TIDieR checklist, entitled 'When and how much'. Prior to commencing data extraction, we piloted the

adapted TIDieR checklist to ensure the tool was extracting the data required and that review authors were using the tool comparably.

Where there were discrepancies in the data extraction, the two review authors who had extracted the data resolved them via discussion, with the option to involve the third review author if required.

4.6.3.3 Assessment of risk of bias in included studies

Two review authors (of BC, JB and JW), working independently, assessed risk of bias for all included study outcomes immediately after intervention at medium-term follow-up and at long-term follow-up (where reported) using the revised version of the Cochrane's tool for assessing risk of bias, the Risk of Bias 2 (RoB2) (Sterne et al. 2019; Higgins et al. 2021b). Any disagreements were resolved by discussion between the two review authors who had assessed risk of bias for the study outcome, with the option to involve the third review author. Using the Word version of the tool (9 October 2018), we assessed risk of bias according to the following domains:

1. Risk of bias arising from the randomization process
2. Risk of bias due to deviations from the intended interventions
3. Risk of bias due to missing outcome data
4. Risk of bias in measurement of the outcome
5. Risk of bias in selection of the reported result

Judgments were derived for each of the relevant study outcomes using the signalling questions outlined in the RoB 2 Guidance (Higgins et al. 2019). This resulted in a domain level judgment of low risk of bias, high risk of bias or some concerns. Domain level judgments contributed to an overall assessment of risk of bias for each included study outcome. All studies were included in the analyses, irrespective of their risk of bias.

In this review, we were interested in both the effect of assignment and the effect of adherence to intervention. We selected the effect of assignment to intervention as our primary interest, which contributes to the overall risk of bias judgement for each study outcome. We made this selection because our primary objective is to establish if more time spent in rehabilitation results in greater improvement by comparing assignment to more rehabilitation with assignment to less rehabilitation. The included RCTs are designed to test the effect of assignment. However, we acknowledge that adherence to the intended amount of intervention could affect outcomes. If participants assigned to more rehabilitation do not receive the intervention as intended, the difference in the amount of time between the more rehabilitation group and the less

rehabilitation group could be negligible. This leads to indirectness due to the intervention (Guyatt et al. 2011), increasing the likelihood of a study accepting the null hypothesis. For this reason, we also assessed the risk of bias pertaining to adherence to intervention. The judgements made do not contribute to the overall risk of bias, but are described and discussed and a sensitivity analysis undertaken to examine the effect of excluding studies at high risk of bias due to the effect of adherence to intervention (in addition to the sensitivity analyses described below).

When assessing study outcomes for risk of bias due to missing outcome data (domain 3), we used a threshold of 90% available participant data to return a judgement regarding the extent of missing data. This was because the included studies were small, which is common for rehabilitation studies.

The consensus decisions for the signalling questions for each risk of bias were entered into a Word version of the tool, aggregated into one document, saved as a PDF, and uploaded onto the Cochrane Stroke Group server.

4.6.3.4 Measurement of treatment effect

For continuous outcomes using different scales of measurement (ADL measures, upper and lower limb activity measures and upper and lower limb impairment measures), we calculated pooled standardised mean difference (SMDs) and 95% confidence intervals (CIs). We expressed dichotomous outcomes (SAE/Death) as risk ratios (RR) with 95% CIs.

4.6.3.5 Unit of analysis issues

We have not considered unit of analysis issues in relation to cluster-randomised trials as none were included.

In the event of studies that included multiple intervention groups, we included the groups that met the criteria for this review and excluded groups that did not. Where studies included multiple intervention groups that met the criteria for this review, we treated the group that received the least amount of therapy as the control group and 'split' this group (in terms of number of participants) to create multiple pair-wise comparisons for that study. The control group was split in order to avoid the double-counting of participants (Higgins et al. 2021a).

As outcome measures were pooled, If studies included more than one measure of the same category (e.g. if studies used more than one activity measure of the upper limb), we selected the

measure that reported the most data. If there were measures with equal amounts of data, we selected the measure listed first in the study.

If studies included more than one measurement within a time-point of interest (e.g. if they measured outcomes at both three months and six months post-intervention, both of which we would classify as medium term outcomes), we selected the first reported relevant outcomes within the time-point of interest only.

4.6.3.6 Dealing with missing data

We contacted study authors to obtain any outcome data missing from the included studies, which was not accounted for within the study report. If it was not possible to obtain missing data, we attempted to determine the reason for missing data from study authors, to establish if data are 'missing at random' or 'missing not at random'.

If data were 'missing at random', we analysed the available data and ignore missing data. If data were 'missing not at random', we planned to impute the last observation carried forward and conduct a sensitivity analysis to determine the effect of missing data.

The potential impact of missing data will be discussed later in the review.

4.6.3.7 Assessment of heterogeneity

We visually inspected the forest plots to determine the overlap in the CIs of the studies. Poor overlap is likely to indicate statistical heterogeneity (Deeks et al. 2021). In addition, we used the I^2 statistic to quantify heterogeneity in the study results (Higgins et al. 2003). If the I^2 result is greater than 50%, we considered this to represent substantial heterogeneity (Deeks et al. 2021).

Where substantial heterogeneity was found, we explored the possible reasons for this by examining the trials in terms of their design, risk of bias, clinical settings, interventions, and participants involved. We analysed possible sources of heterogeneity by undertaking subgroup analyses.

4.6.3.8 Assessment of reporting biases

We attempted to minimise the effect of reporting bias by using a comprehensive search strategy. Where meta-analyses included at least 10 studies, we used funnel plots of the primary and secondary outcomes to provide a visual inspection of whether treatment estimates are associated with the study size (Page et al. 2021).

In addition, we considered reporting bias in terms of unavailable data within included studies (unavailable due to the P value, magnitude or direction of the results). We assessed this by reviewing the outcomes measured by each study, in comparison to their protocol and any other available reports of the study (e.g. conference publications, PhD Theses etc.). We recorded any unreported outcomes, which likely were measured in the study (Page et al. 2021).

4.6.3.9 Data synthesis

We conducted meta-analyses using RevMan Web (The Cochrane Collaboration 2019) following the guidance provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks et al. 2021). One author (BC) entered the data into RevMan Web and a second author (SE) checked the accuracy of this. Disagreements were resolved through discussion. Analysis included all eligible study outcomes, irrespective of their risk of bias.

We used a random-effects meta-analysis, regardless of the level of heterogeneity between studies. If the studies are heterogeneous, then this is the appropriate model to use. However, if heterogeneity is low, a random-effects model will return very similar results to a fixed-effect model (Deeks et al. 2021).

To address the first objective, we undertook meta-analyses for each of our primary and secondary outcomes at out three time-points of interest (immediately after intervention, medium term follow-up and long-term follow-up).

To address the second objective of the review, we conducted subgroup analyses for each of our primary and secondary outcomes, immediately after intervention. We compared studies with a larger difference between arms (in terms of total time spent in rehabilitation) to those with a smaller difference between arms. We used a median split based on differences in amount of time spent in rehabilitation between arms to determine the subgroups. When there was an uneven number of studies, the position of the split was determined by how great the difference was between the middle studies, thereby grouping the studies that were most similar in terms of amount of therapy provided. In addition to this, we produced scatter plots of difference in total amount of time spent in rehabilitation plotted against the estimated treatment effect (SMD).

To address the third objective of this review, we conducted subgroup analyses for each of our primary and secondary outcomes, immediately after intervention. We compared studies with a larger difference between arms in terms of number of minutes of rehabilitation provided per week to those with a smaller difference between arms in terms of number of minutes of rehabilitation provided per week. In addition to this, we produced scatter plots of difference in

number of minutes spent in rehabilitation per week plotted against the estimated treatment effect (SMD).

Scatter plots were created using Microsoft Excel.

4.6.3.10 Subgroup analysis and investigation of heterogeneity

Where there was the required information, we stratified the studies to analyse possible sources of heterogeneity using the following characteristics.

- Time since stroke. This was to examine whether more time spent in rehabilitation had a different effect, dependent on stroke chronicity, by comparing:
    - Studies providing rehabilitation within the first six months since stroke
    - Studies providing rehabilitation after six months since stroke

- Hours of interventional therapy provided per week. This was to examine the effect of more time spent in therapy per-week on outcomes, by comparing:
    - Studies in which the experimental group received less than 5 hours of interventional treatment per week
    - Studies in which the experimental group received more than 5 hours (but less than 10 hours) of interventional treatment per week
    - Studies in which the experimental group received more than 10 hours (but less than 20 hours) of interventional treatment per week
    - Studies in which the experimental group received 20 hours or more of interventional treatment per week

- Type of intervention. This was to examine whether the type of intervention provided alters the effect of time spent in therapy (i.e. if more time spent in one type of therapy has a greater benefit than more time spent in a different type of therapy). The following two comparisons were made:
    - Upper limb therapy vs. other therapy
    - Electro-mechanical technology vs. No electro-mechanical technology

4.6.3.11 Sensitivity analysis

We performed the following sensitivity analyses for objective one at our primary time point of interest (immediately after intervention): removal high risk of bias studies, removal of studies at

high risk of bias due to the effect of adherence to intervention and removal of studies with both high risk of overall bias and high risk of bias due to the effect of adherence to intervention. The latter sensitivity analyses were performed as risk of bias due to the effect of adherence to intervention did not contribute to the overall risk of bias.

4.6.3.12 Summary of findings and assessment of the certainty of the evidence

We created a 'Summary of findings' table to present the findings of our first objective, using the seven outcomes identified: ADL, activity measures of the upper limb, activity measures of the lower limb, motor impairment measures of the upper limb, motor impairment measures of the lower limb and serious adverse events/death. We report the results of the outcomes measures immediately after intervention, which was our primary time point of interest.

For each outcome, we report the number of participants that contribute to the finding, the relative effect, direction of effect and the certainty of the evidence. We analysed the certainty of the evidence using the evidence grading system developed by the GRADE collaboration (Schünemann et al. 2013), described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann et al. 2021). Overall risk of bias (assessed by the RoB2 tool) contributed to the GRADE assessment.

4.7 Results

4.7.1 Description of studies

See Characteristics of included studies (Appendix U), Characteristics of excluded studies (Appendix V), Characteristics of studies awaiting classification (Appendix W) and Ongoing studies (Appendix X).

4.7.1.1 Results of the search

Searches, undertaken in June and July 2021, identified 44,728 unique records for screening. Following title screening, 43,236 were excluded, leaving 1,492 for title and abstract review. From these records, we reviewed the full text of 179 papers and identified 23 studies (46 records) that met the criteria for this review. Figure 3 outlines the study selection process.

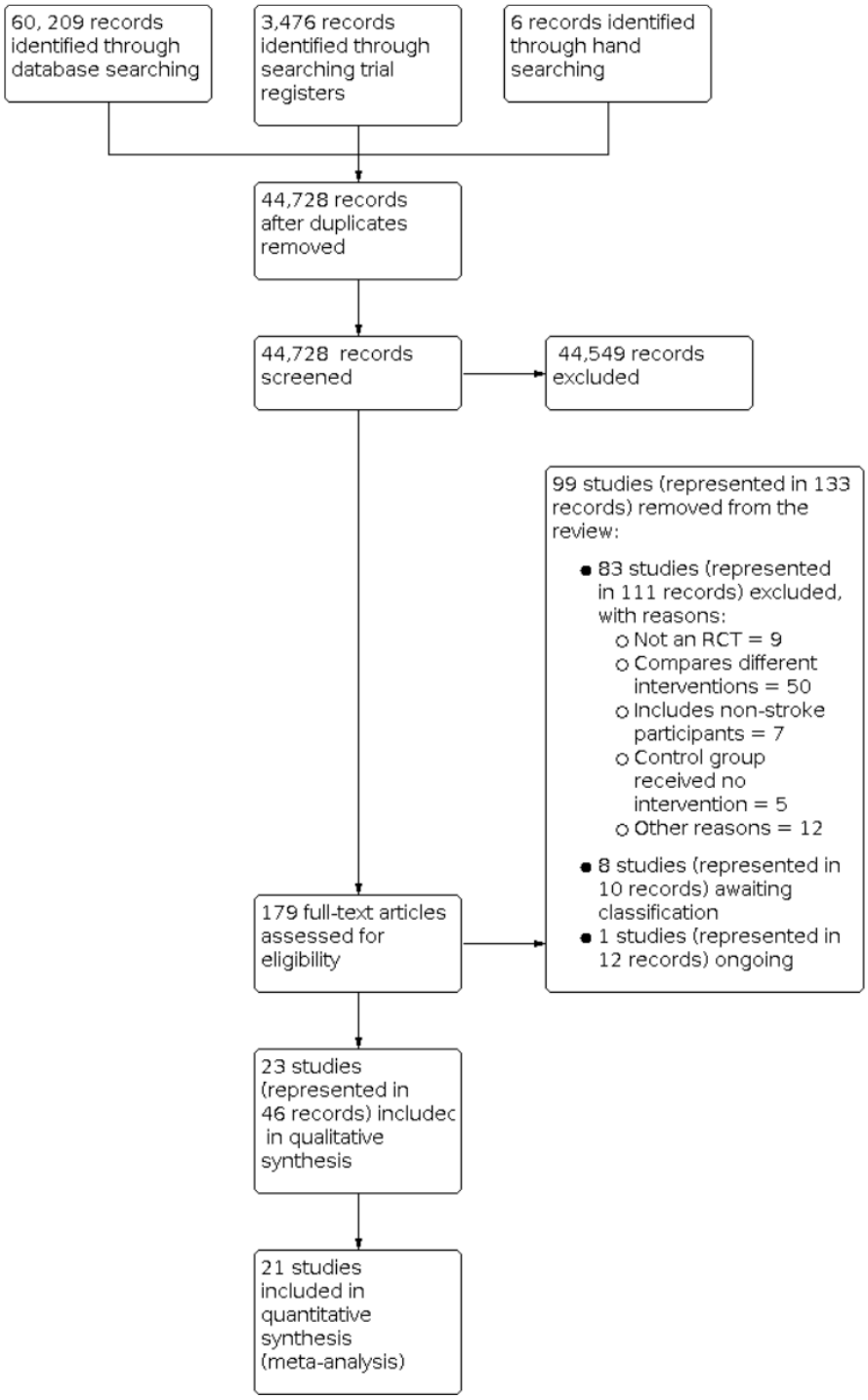

Figure 3 PRISMA Diagram

4.7.1.2 Included studies

Twenty-three studies, analysed data from 1,458 participants in study arms that met the criteria for this review (see Characteristics of included studies, Appendix U). Two studies were not included in the analysis because missing information could not be obtained from the study

authors (Page et al. 2011; Wang et al. 2011). Therefore, the quantitative synthesis comprised 21 parallel designed randomised clinical trials, which analysed 1,412 participants. Five studies included two or more intervention groups that met the criteria for this study (Hunter et al. 2011; Page et al. 2012b; Han et al. 2013; Lang et al. 2016; Winstein et al. 2019), therefore, 27 pair-wise comparisons are presented.

Each pair-wise comparison that has originated from the same study, can be separately identified (e.g. Lang 2016a, Lang 2016b, Lang 2016c). Please see the notes section for the respective studies in Characteristics of included studies for how these pair-wise comparisons were defined.

4.7.1.2.1 Time spent in rehabilitation and rehabilitation schedule

Time spent in rehabilitation varied between the 21 studies, see Appendix Y for a summary. Nineteen studies reported time (minutes) spent in rehabilitation. Seven report time allocated for therapy (Partridge et al. 2000; Wang et al. 2004; Dromerick et al. 2009; Hsu et al. 2010; Page et al. 2012b; Han et al. 2013; Winstein et al. 2019), but not amount of therapy delivered. We have presumed that time allocated was the same as time delivered as no issues concerning delivery were reported. The remaining 12 studies report average (mean or median) minutes of rehabilitation delivered. Two studies reported number of repetitions (Hsieh et al. 2012; Abdullahi 2018). In both studies, one intervention group received double the amount of repetitions as the other intervention group, which we took to represent a different amount of time spent in rehabilitation.

The difference in total minutes of rehabilitation between control and intervention groups ranged from 186 minutes (English et al. 2015) to 6160 minutes (Wang et al. 2004) with a median difference of 840 minutes. Minutes of rehabilitation provided per week, ranged from 90 (Ada et al. 2013) to 1,288 (Tong et al. 2019). Days per week on which rehabilitation was provided ranged from three (Ada et al. 2013) to seven (Hunter et al. 2011; English et al. 2015; Tong et al. 2019) but for 12 studies, rehabilitation was provided five days per week (Lincoln et al. 1999; Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Wang et al. 2004; Kowalczewski et al. 2007; Dromerick et al. 2009; Hsu et al. 2010; Hsieh et al. 2012; Page et al. 2012b; Han et al. 2013; Abdullahi 2018; Winstein et al. 2019). Duration of rehabilitation ranged from 2 weeks (Dromerick et al. 2009; Hunter et al. 2011; Tong et al. 2019) to 6 months (Smith et al. 1981; Wang et al. 2004).

Fifteen studies compared groups that received a different amount of rehabilitation per day (Lincoln et al. 1999; Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Donaldson et al. 2009; Dromerick et al. 2009; Cooke et al. 2010b; Hsu et al. 2010; Hunter et

al. 2011; Hsieh et al. 2012; Page et al. 2012b; Han et al. 2013; Lang et al. 2016; Abdullahi 2018; Tong et al. 2019; Winstein et al. 2019). Difference in minutes of rehabilitation per day between control and intervention groups ranged from 12 minutes (Lang et al. 2016) to 180 minutes (Winstein et al. 2019), with a median difference of 30 minutes. Two studies compared groups that received a different number of days per week of rehabilitation (Kowalczewski et al. 2007; English et al. 2015). Two studies compared more minutes of rehabilitation over more days with fewer minutes over fewer days (Smith et al. 1981; Wang et al. 2004). One study compared different durations of rehabilitation (Ada et al. 2013) and one study reported the amount of therapy provided over a three-week period, without specifying a schedule (Burgar et al. 2011).

4.7.1.2.2 Nature of intervention in studies

Nature of intervention in studies included physiotherapy (physical therapy) and/or occupational therapy (Smith et al. 1981; Lincoln et al. 1999; Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Wang et al. 2004; Donaldson et al. 2009; Cooke et al. 2010b; English et al. 2015), neuromuscular electrical stimulation (Kowalczewski et al. 2007; Hsu et al. 2010; Page et al. 2012b), robot assisted training (Burgar et al. 2011; Hsieh et al. 2012), constraint induced movement therapy (Dromerick et al. 2009; Abdullahi 2018), task-specific training (Lang et al. 2016; Winstein et al. 2019), mobilisation and tactile stimulation (Hunter et al. 2011), upper limb rehabilitation (Han et al. 2013), treadmill training (Ada et al. 2013) and mobilisation (Tong et al. 2019).

In grouping interventions, 13 studies provide upper limb rehabilitation (Lincoln et al. 1999; Kowalczewski et al. 2007; Donaldson et al. 2009; Dromerick et al. 2009; Hsu et al. 2010; Burgar et al. 2011; Hunter et al. 2011; Hsieh et al. 2012; Page et al. 2012b; Han et al. 2013; Lang et al. 2016; Abdullahi 2018; Winstein et al. 2019). Five studies provided general rehabilitation (Smith et al. 1981; Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Wang et al. 2004; English et al. 2015), two studies provided mobilisation training (Ada et al. 2013; Tong et al. 2019) and one study provided lower limb training (Cooke et al. 2010b). In an alternative grouping, six studies provided rehabilitation using electro-mechanical technology (Kowalczewski et al. 2007; Hsu et al. 2010; Burgar et al. 2011; Hsieh et al. 2012; Page et al. 2012b; Ada et al. 2013) and 15 studies did not use electro-mechanical technology (Smith et al. 1981; Lincoln et al. 1999; Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Wang et al. 2004; Donaldson et al. 2009; Dromerick et al. 2009; Cooke et al. 2010b; Hunter et al. 2011; Han et al. 2013; English et al. 2015; Lang et al. 2016; Abdullahi 2018; Tong et al. 2019; Winstein et al. 2019)

4.7.1.2.3 Participant characteristics

Characteristics of participants, including age, gender and time since stroke are summarised in Appendix Z.

4.7.1.2.4 Time since stroke

Sixteen studies included participants in the first 6 months following stroke (Smith et al. 1981; Lincoln et al. 1999; Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Wang et al. 2004; Kowalczewski et al. 2007; Donaldson et al. 2009; Dromerick et al. 2009; Cooke et al. 2010b; Hsu et al. 2010; Burgar et al. 2011; Hunter et al. 2011; Han et al. 2013; English et al. 2015; Abdullahi 2018; Tong et al. 2019). Five studies included participants more than 6 months post- stroke (Hsieh et al. 2012; Page et al. 2012b; Ada et al. 2013; Lang et al. 2016; Winstein et al. 2019).

4.7.1.2.5 Stroke severity or level of impairment

Comparison of stroke severity or level of impairment due to stroke was limited, due to variations in measurement.

Of the 21 studies, four included objective measurement of stroke severity. Three reported the National Institute of Health Stroke Scale (NIHSS) (Wang et al. 2004; Dromerick et al. 2009; Tong et al. 2019), one reported lesion volume (Winstein et al. 2019). Of studies that reported NIHSS scores, the mean scores were in the mild to moderate range of 5-14 (Brott et al. 1989). Winstein et al. (2019) reported lesion volume in cm^3. We were not able to use this information to classify stroke severity.

Of the 21 studies, fourteen included a measure of baseline physical impairment, 11 upper limb impairment, one lower limb impairment and two global physical impairment. Of the 11 that reported upper limb impairment, eight used the Fugl Meyer Upper Extremity (FM-UE). Using the Woytowicz et al. (2017) classifications, two studies had a moderate-mild mean FM-UE (Hsieh et al. 2012; Winstein et al. 2019), three were moderate-severe (Burgar et al. 2011; Page et al. 2012b; Abdullahi 2018) and three were severe (Kowalczewski et al. 2007; Hsu et al. 2010; Han et al. 2013). The remaining studies that report baseline upper limb impairment use myometer measurement (Lincoln et al. 1999; Donaldson et al. 2009) and the Upper Extremity Motricity Index (Hunter et al. 2011), which we were not able to classify. Cooke et al. (2010b) reported baseline lower limb impairment using myometer measurement. The two studies that used global measures of physical impairment used the Motricity Index (The Glasgow Augmented Physiotherapy Study

Group 2004) and the Fugl Meyer (full scale) (Wang et al. 2004). Participants studied by Wang et al. (2004) were classified as severe for motor impairments (Duncan et al. 1994). We were unable to categorically classify the Motricity Index.

Of the 21 studies, five studies did not include either measures of stroke severity or impairment (Smith et al. 1981; Partridge et al. 2000; Ada et al. 2013; English et al. 2015; Lang et al. 2016).

No studies reported non-physical measures of impairment. However, ten studies excluded participants with cognitive impairment (Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Kowalczewski et al. 2007; Dromerick et al. 2009; Burgar et al. 2011; Page et al. 2012b; Ada et al. 2013; Lang et al. 2016; Abdullahi 2018; Winstein et al. 2019). Seven studies excluded participants with communication impairment (The Glasgow Augmented Physiotherapy Study Group 2004; Donaldson et al. 2009; Dromerick et al. 2009; Hunter et al. 2011; Ada et al. 2013; Abdullahi 2018; Tong et al. 2019) and four studies excluded people with visual inattention/neglect (Kowalczewski et al. 2007; Donaldson et al. 2009; Dromerick et al. 2009; Abdullahi 2018). Definition of these impairments varied or were not clearly defined.

4.7.1.2.6 Rehabilitation setting

Fourteen studies provided rehabilitation in an inpatient setting (Lincoln et al. 1999; Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Wang et al. 2004; Kowalczewski et al. 2007; Donaldson et al. 2009; Dromerick et al. 2009; Cooke et al. 2010b; Hsu et al. 2010; Burgar et al. 2011; Hunter et al. 2011; Han et al. 2013; English et al. 2015; Tong et al. 2019). These were all studies of participants in the first 6 months following stroke. Five studies provided intervention in the community/outpatient setting (Smith et al. 1981; Page et al. 2012b; Ada et al. 2013; Lang et al. 2016; Abdullahi 2018). Both Smith et al. (1981) and Abdullahi (2018) studied participants as outpatients following their discharge from the inpatient setting, within the first 6 months after stroke. Ada et al. (2013), Lang et al. (2016) and Page et al. (2012b) were studies of participants more than 6 months following stroke. In Page et al. (2012b), participants were seen in their own homes, the other studies treated participants in outpatient/community settings. The remaining studies did not describe rehabilitation setting (Hsieh et al. 2012; Winstein et al. 2019), but as they are both of participants more than 6 months after stroke, it is expected that they were undertaken in outpatient/community settings.

4.7.1.2.7 Included groups from studies

We included all participant groups from six of the included studies (Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Wang et al. 2004; Kowalczewski et al.

2007; Han et al. 2013; Lang et al. 2016). Of the remaining 15 studies, not all participant groups met our study criteria and therefore, these participant groups were excluded from the analysis. In 12 studies, one intervention group received a different intervention, compared to two (or more) groups that received different amounts of the same intervention (Lincoln et al. 1999; Donaldson et al. 2009; Dromerick et al. 2009; Cooke et al. 2010b; Hsu et al. 2010; Burgar et al. 2011; Hunter et al. 2011; Hsieh et al. 2012; Page et al. 2012b; English et al. 2015; Abdullahi 2018; Tong et al. 2019). In the remaining three studies, a control group received no rehabilitation, compared to two intervention groups that received different amounts of the same treatment (Smith et al. 1981; Ada et al. 2013; Winstein et al. 2019).

4.7.1.3 Excluded studies

We excluded 83 studies (111 records) following full review (see Characteristics of excluded studies – Appendix V). Studies were excluded for various reasons including comparing different types of rehabilitation (not different amounts of the same rehabilitation), comparing rehabilitation with no rehabilitation and inclusion of non-stroke participants. Eight studies are awaiting classification (see Characteristics of studies awaiting classification – Appendix W). These are predominantly conference proceedings, for which we have been unable to obtain the required detail for inclusion. Eight studies are ongoing (see Characteristics of ongoing studies – Appendix X).

4.7.1.4 Risk of bias in included studies

Risk of bias assessments for each outcome, including all domain judgements and support for judgement, is at the side of all forest plots. To access further detailed risk of bias assessment data, please use the following link (https://apps.ccbs.ed.ac.uk/csrg/cochranestrokedocuments/Risk_of_Bias_Assessments_FINAL .pdf).

Risk of bias judgements within studies are generally consistent, with the following exceptions. In four studies, there was a greater risk of bias for follow-up measures, due to missing data (participants lost to follow-up) (Lincoln et al. 1999; Partridge et al. 2000; Donaldson et al. 2009; Burgar et al. 2011). In two studies the risk of bias differs within the study, due to the outcome measure used (Lincoln et al. 1999; Lang et al. 2016). In one study the risk of bias differs within the study, due to selection of the reported results (Winstein et al. 2019). In one study, the risk of bias differs within the study due to unexplained missing data for one outcome, but not the other (Cooke et al. 2010b).

For domain five (risk of bias in the selection of reported results), the majority of outcomes have been judged as having at least some concerns. In order to judge potential bias, study protocols,

written prior to the completion of the study are required. For 15 of the 21 studies either no protocol was available or the protocol was of insufficient detail to determine that the study was carried out as planned (Smith et al. 1981; Lincoln et al. 1999; Partridge et al. 2000; The Glasgow Augmented Physiotherapy Study Group 2004; Wang et al. 2004; Kowalczewski et al. 2007; Donaldson et al. 2009; Cooke et al. 2010b; Hsu et al. 2010; Burgar et al. 2011; Hunter et al. 2011; Hsieh et al. 2012; Page et al. 2012b; Han et al. 2013; Lang et al. 2016). In all cases, we contacted the study authors to aim to gather further information, but this information remained unavailable. A reason for the limited protocol availability may be due to the relatively recent practice of registering rehabilitation trials and publishing protocols.

As previously described, we have selected the effect of assignment to intervention as our primary interest, when considering the risk of bias due to deviations from intended interventions (domain 2). However, we are also interested in the risk of bias pertaining to adherence to intervention. The judgements made did not contribute to the overall risk of bias, but are herein described.

Both versions of this domain begin by asking if participants, carers and people delivering rehabilitation were aware of group allocation during the trial. Notably, none of the studies blinded for people delivering rehabilitation and just three studies report that participants were unaware of their group allocation (Partridge et al. 2000; Donaldson et al. 2009; Burgar et al. 2011). Lack of blinding of participants and personnel is common for rehabilitation studies due to the nature of interventions. This increased the likelihood of all studies being judged as high risk or some concerns for this domain.

Assessment of risk of bias for effect of adhering to the intervention was consistent within studies. Seven studies were judged as low risk of bias for effect of adhering to the intervention (Wang et al. 2004; Hsieh et al. 2012; Page et al. 2012b; Ada et al. 2013; Han et al. 2013; Lang et al. 2016; Winstein et al. 2019). The remaining 14 studies were judged as high risk of bias. In addition to the aforementioned lack of blinding, nine of these studies provided no information regarding co-interventions (Smith et al. 1981; Lincoln et al. 1999; Partridge et al. 2000; Kowalczewski et al. 2007; Donaldson et al. 2009; Cooke et al. 2010b; Hunter et al. 2011; English et al. 2015; Abdullahi 2018). Three studies provide no information about adherence to the intervention (Partridge et al. 2000; Dromerick et al. 2009; Hsu et al. 2010) and five studies describe issues with adherence to the intervention (Lincoln et al. 1999; The Glasgow Augmented Physiotherapy Study Group 2004; Burgar et al. 2011; Hunter et al. 2011; Tong et al. 2019) Three studies demonstrated more than one of these issues (Lincoln et al. 1999; Burgar et al. 2011; Hunter et al. 2011).

A brief summary of studies' overall risk of bias will be presented with the results of the meta analyses.

In addition to the risk of bias in included studies, we assessed this review's risk of bias due to missing results (non-reporting bias). Funnel plots are presented with the relevant analysis and a summary of potential non-reporting bias is presented in Appendix AA. A brief summary of any possible missing results is presented with the results of the meta-analyses for objective one. In addition, there were two studies we were unable to include, due to missing information that could not be obtained from study authors (Page et al. 2011; Wang et al. 2011).

There are eight potentially eligible studies that are 'awaiting classification' (please see Characteristics of studies awaiting classification – Appendix W). These studies did not include enough information to determine whether they meet the criteria for this review and, to date, we have been unable to gather any further information about them. If unbeknownst to us, some or all of these studies meet the criteria for this review, their non-inclusion would result in further non- reporting bias.

4.7.2 Effects of interventions

4.7.2.1 Objective One: To assess the effect of more time spent in the same type of rehabilitation on activity measures in people with stroke

Please see Summary of findings tables 2, 3 and 4, more time compared to less time in rehabilitation

We compared intervention groups that spent more time in rehabilitation with intervention groups that spent less time. Comparisons were undertaken for our primary and secondary outcome measures immediately after intervention, at medium term follow-up (two weeks to six months after intervention has ended) and long-term follow-up (more than 6 months after treatment has ended).

4.7.2.1.1 Comparison 1 — Outcomes measured immediately after intervention

Forest plots for the following outcomes are in Appendix BB

4.7.2.1.1.1 Analysis 1.1 — ADL Outcomes (Primary outcome)

There was no evidence of an effect for additional time spent in rehabilitation for ADL outcomes immediately after intervention (SMD 0.13, 95% CI -0.02 to 0.28; 14 studies, 864 participants; p = 0.09; I^2 = 7%; very low certainty of evidence). Measures used included the Functional

Independence Measure, Barthel Index, Motor Activity Log, Activities of Daily Living Index, Arm Motor Ability Scale and the Adelaide Activities Profile (Appendix BB – analysis 1.1).

Of the 19 comparisons included in this analysis, three were judged low overall risk of bias, nine were judged as having some concerns regarding risk of bias and seven were judged as high risk of bias.

With studies judged as high risk of bias removed, there remained no evidence of an effect. With studies judged as high risk of bias due to effect of adherence removed, there was evidence of an effect. This effect was lost when studies judged as high risk of overall bias and high risk of bias due to effect of adherence were excluded (Appendix CC).

Data from one included study is missing from this analysis. Smith et al. (1981)included an ADL measure, but report a change score. We contacted the study authors, but the raw data is no longer held.

Three studies may have assessed this outcome but did not report findings (Appendix AA). A funnel plot for this outcome (Appendix DD) shows asymmetry, which may indicate non-reporting bias.

4.7.2.1.1.2 Analysis 1.2 — Activity measures of the Upper Limb

There was no evidence of an effect for additional time spent in rehabilitation for activity measures of the upper limb immediately after intervention (SMD 0.09, 95% CI -0.11 to 0.29; 12 studies, 426 participants; p = 0.36; I^2 = 0%; very low certainty of evidence). Measures used included the Wolf Motor Function Test and the Action Research Arm Test (Appendix BB Analysis 1.2).

Of the 18 comparisons included in this analysis, one was judged low overall risk of bias, 13 were judged as having some concerns regarding risk of bias and four were judged as high risk of bias.

Sensitivity analyses to explore the impact of excluding studies judged high risk of bias demonstrated that there were no substantial changes from the original reported finding (Appendix CC).

Data from two included studies is missing from this analysis (Lincoln et al. 1999; English et al. 2015). These studies presented the data in an incomparable format, and we were unable to obtain raw data from the study authors.

Five studies may have assessed this outcome but did not report findings (Appendix AA). A funnel plot for this outcome (Appendix- EE) shows asymmetry, which may indicate non-reporting bias.

4.7.2.1.1.3 Analysis 1.3 — Activity measures of the lower limb

There was no evidence of an effect for additional time spent in rehabilitation for activity measures of the lower limb immediately after intervention (SMD 0.25, 95% CI -0.03 to 0.53; five studies, 425 participants; p = 0.08; I^2 = 48%; low certainty of evidence). Measures used included the six-minute walk test and the Rivermead Mobility Index (Appendix BB - Analysis 1.3).

Of the five comparisons included in this analysis, two were judged low overall risk of bias, two were judged as having some concerns regarding risk of bias and one was judged as high risk of bias.

With studies judged as high risk of bias removed, there remained no evidence of an effect. When studies judged as high risk of overall bias and high risk of bias due to effect of adherence were excluded, there was evidence of an effect (Appendix CC)

Two studies may have assessed this outcome but did not report findings (Appendix AA).

4.7.2.1.1.4 Analysis 1.4 — Motor impairment measures of the upper limb

An effect was found in favour of additional time spent in rehabilitation for motor impairment measures of the upper limb immediately after intervention (SMD 0.32, 95% CI 0.06 to 0.58; nine studies, 287 participants; p = 0.01; I^2 = 10%; low certainty of evidence). Measures used included the Fugl Meyer (upper extremity) and the Motricity Index (arm section) (Appendix BB - Analysis 1.4).

Of the 12 comparisons included in this analysis, one was judged low overall risk of bias, 10 were judged as having some concerns regarding risk of bias and one was judged as high risk of bias.

With studies judged as high risk of bias removed, there was no evidence of an effect. When studies judged as high risk of overall bias and high risk of bias due to effect of adherence were excluded, there was evidence of an effect (Appendix CC)

Data from one included study is missing from this analysis (Lincoln et al. 1999). This study presented the data in an incomparable format, and we were unable to obtain raw data.

One study assessed this outcome but did not report findings and three further studies may have assessed this outcome but did not report findings (Appendix AA).

To establish if the effect seen in this analysis represented a meaningful change to participants, we examined whether the change between baseline and outcome measures for each group within each study reached the Minimal Clinically Important Difference (MCID) for the outcome measure used. For studies that used the Upper Extremity Fugl-Meyer in the subacute stage, we used a MCID of 9 (Arya et al. 2011) and for studies that used the Upper Extremity Fugl-Meyer in the chronic stage, we used a MCID of 4.25 (Page et al. 2012a). For studies that used grip strength, we used a MCID of 5kg (Lang et al. 2008; Bohannon 2019). One study (two comparisons) used the arm section of the Motricity Index, for which we were unable to find a MCID.

Of the remaining 10 comparisons, four found a meaningful change in the 'more rehabilitation' group coupled with an absence of meaningful change in the 'less rehabilitation' group. This suggests that for four out of the 10 comparisons (Burgar et al 2011, Hsieh et al. 2012 and two comparisons from Han et al. 2013), the additional rehabilitation provided resulted in a clinically meaningful difference in a measure of upper limb impairment, which was not achieved for those in the group that received less rehabilitation. The remaining six comparisons either didn't find a clinically meaningful change for either group (three comparisons) or they found a clinically meaningful change for both groups (three comparisons). See Appendix FF for a summary.

4.7.2.1.1.5 Analysis 1.5 — Motor impairment measures of the Lower Limb

An effect was found in favour of additional time spent in rehabilitation for motor impairment measures of the lower limb immediately after intervention (SMD 0.71, 95% CI 0.15 to 1.28; one study, 51 participants; p = 0.01; I^2 = N/A; very low certainty of evidence). Measure used was peak knee flexion torque (Appendix BB - Analysis 1.5).

This study was at high risk of bias.

Sensitivity analyses related to risk of bias could not be performed, as this left no studies in the analysis.

Two further studies may have assessed this outcome but did not report findings (Appendix AA).

The study in this analysis used knee flexion peak torque to measure motor impairment of the lower limb. We were unable to find evidence for a MCID for knee flexion peak torque to determine if the effect seen in this analysis represented a meaningful change to participants.

4.7.2.1.1.6 Analysis 1.6 — Serious Adverse Events/Death

There was no evidence of an increased risk of serious adverse events or death for additional time spent in rehabilitation (RR 1.20, 95% CI 0.51 to 2.85; two studies, 379 participants; p = 0.68; I^2 = 0%; low certainty of evidence) (Appendix BB - Analysis 1.6).

Of the two comparisons included in this analysis, one was judged low overall risk of bias and one was judged as some concerns regarding bias.

As there were no studies at high risk of bias, there was no change to the result when studies at high risk of bias were removed. When studies judged as high risk of bias due to effect of adherence were removed, there were no remaining studies in the analysis (Appendix CC).

We have not detected any studies that may have planned to assess this outcome and have not reported findings.

4.7.2.1.2 Comparison 2 — Outcomes measured at medium term follow-up (two weeks to 6 months after intervention)

Forest plots for the following outcomes are in Appendix GG

4.7.2.1.2.1 Analysis 2.1 — ADL Outcomes

There was no evidence of an effect for additional time spent in rehabilitation for ADL outcomes at medium term follow-up (SMD 0.01, 95% CI -0.15 to 0.16; 10 studies, 673 participants; p = 0.94; I^2 = 0%; very low certainty of evidence) (Appendix GG - Analysis 2.1).

Of the 12 comparisons included in this analysis, two were judged low overall risk of bias, three were judged as having some concerns regarding risk of bias and seven were judged as high risk of bias.

Data from one included study is missing from this analysis. English et al. (2015) did not report follow- up measures for the FIM. This is available in a data repository, but payment is required to access it, and we don't have funding for this.

One study assessed this outcome but did not report findings and seven other studies may have assessed this outcome but did not report findings (Appendix AA). A funnel plot for this outcome (Appendix HH) shows asymmetry, which may indicate non-reporting bias.

4.7.2.1.2.2 Analysis 2.2 — Activity measures of the Upper Limb

There was no evidence of an effect for additional time spent in rehabilitation for activity measures of the upper limb at medium term follow-up (SMD -0.02, 95% CI -0.36 to 0.33; seven studies, 218 participant; p = 0.93, I^2 = 30%; very low certainty of evidence) (Appendix GG - Analysis 2.2).

Of the nine comparisons included in this analysis, one was judged low overall risk of bias, six were judged as having some concerns regarding risk of bias and two were judged as high risk of bias.

Data from two included studies is missing from this analysis. Lincoln et al. (1999) presented this data in an incomparable format and study authors no longer have the raw data. English et al. (2015) did not report follow-up measures for the WMFT. This is available in a data repository, but payment is required to access it, and we don't have funding for this.

Two studies assessed this outcome but did not report findings and seven other studies may have assessed this outcome but did not report findings (Appendix AA).

4.7.2.1.2.3 Analysis 2.3 — Activity measures of the lower limb

There was no evidence of an effect for additional time spent in rehabilitation for activity measures of the lower limb at medium term follow-up (SMD 0.10, 95% CI -0.30 to 0.49; four studies, 243 participants; p = 0.63; I^2 = 58%; very low certainty of evidence) (Appendix GG - Analysis 2.3).

Of the four comparisons included in this analysis, one was judged low risk of bias, two were judged as having some concerns regarding risk of bias and one was judged as high risk of bias.

Data from one included study is missing from this analysis. English et al. (2015) did not report follow- up measures for the 6MWT. This is available in a data repository, but payment is required to access it, and we don't have funding for this.

One study assessed this outcome but did not report findings and one further study may have assessed this outcome but did not report findings (Appendix AA).

4.7.2.1.2.4 Analysis 2.4 — Motor impairment measures of the upper limb

There was no evidence of an effect for additional time spent in rehabilitation for motor impairment measures of the upper limb at medium term follow-up (SMD -0.02, 95% CI -0.39 to

0.35; five studies, 115 participants; p = 0.90; I^2 = 0%; very low certainty of evidence) (Appendix GG - Analysis 2.4).

Of the five comparisons included in this analysis, one was judged low overall risk of bias, three were judged as having some concerns regarding risk of bias and one was judged as high risk of bias.

Data from one included study is missing from this analysis. Lincoln et al. (1999) presented the data in an incomparable format, and we were unable to obtain raw data.

Two studies assessed this outcome but did not report findings and six other studies may have assessed this outcome but did not report findings (Appendix AA).

4.7.2.1.2.5 Analysis 2.5 — Motor impairment measures of the Lower Limb

There was no evidence of an effect for additional time spent in rehabilitation for motor impairment measures of the lower limb at medium term follow-up (SMD 0.62, 95% CI -0.04 to 1.28; one study, 37 participants; p = 0.07; I^2 = N/A; very low certainty of evidence) (Appendix GG - Analysis 2.5).

This study was at high risk of bias.

One study assessed this outcome but did not report findings and two other studies may have assessed this outcome but did not report findings (Appendix AA).

4.7.2.1.2.6 Analysis 2.6 — Serious Adverse Events/Death

There was no increase in risk of serious adverse events or death for additional time spent in rehabilitation at medium term follow-up (RR 1.32, 95% CI 0.63 to 2.76; three studies, 344 participants; p = 0.46; I^2 = 2%; very low certainty of evidence) (Appendix GG - Analysis 2.6).

Of the three comparisons included in this analysis, two were judged as having some concerns regarding risk of bias and one was judged as high risk of bias.

There did not appear to be any studies that measured this outcome but did not report findings (Appendix AA).

4.7.2.1.3 Comparison 3 — Outcomes measured at long term follow-up (more than 6 months after intervention)

Forest plots for the following outcomes are in Appendix II

4.7.2.1.3.1 Analysis 3.1 — ADL Outcomes

There was no evidence of an effect for additional time spent in rehabilitation for ADL outcomes at long term follow-up (SMD 0.09, 95% CI -0.39 to 0.57; one study, 67 participants; p = 0.71; I^2 = N/A; moderate certainty of evidence) (Appendix II - Analysis 3.1).

This study was overall low risk of bias.

4.7.2.1.3.2 Analysis 3.2 — Activity measures of the lower limb

There was no evidence of an effect for additional time spent in rehabilitation for activity measures of the lower limb at long term follow-up (SMD 0.16, 95% CI -0.32 to 0.64; one study, 67 participants; p = 0.52; I^2 = N/A; moderate certainty of evidence) (Appendix II - Analysis 3.2).

This study was at low risk of bias for all domains.

No studies report activity measures of the upper limb, motor impairment measures of the upper and lower limb and SAE/Death at long term follow-up (more than 6 months after intervention)

4.7.2.2 Objective Two: To assess the effect of difference in total rehabilitation time (in minutes) on recovery of activity in people with stroke

We conducted subgroup analyses of the primary and secondary outcomes immediately after intervention. We compared studies with a larger difference between study arms (in terms of total time spent in rehabilitation) to those with a smaller difference between study arms. We used a median split based on differences in amount of time spent in rehabilitation between arms to determine the subgroups. When there was an uneven number of studies, the position of the split was determined by how great the difference was between the middle studies, in terms of time spent in rehabilitation, thereby grouping the studies that were most similar in terms of amount provided.

In addition to these subgroup analyses, we produced scatter plots of difference in total amount of time spent in rehabilitation (i.e. difference between study intervention groups in terms of total

interventional minutes received over the duration of the study) plotted against the estimated treatment effect (Standardised Mean Difference). Due to insufficient data points on the scatter plots we were unable to draw a line of best fit and the descriptive analysis given is tentative. Forest plots for these analyses are in Appendix JJ.

4.7.2.2.1 Analysis 4.1 — ADL Outcomes

The test for subgroup differences showed a significant difference between results of studies with larger (900 – 6,160 minutes) vs. smaller (186 – 852 minutes) difference in total minutes of rehabilitation between treatment arms for ADL outcomes, immediately after intervention ($p = 0.02$) (Appendix JJ - Analysis 4.1). This was in favour of a larger difference in amount.

Analysis of the scatter plot for this outcome (Figure 4) is limited by the small number of data points. Tentatively, it suggests a small positive association between difference in total amount of rehabilitation and ADL outcomes. There were two studies that were exceptions. (Dromerick et al. 2009) found a large but non-significant benefit in favour of the control group. This study examined the effect of different amounts of constraint induced movement therapy early after stroke. They suggested that the effect seen could be due to fatigue or injury due to over training. Finally, Page et al. (2012b) found a much greater benefit than all other studies.

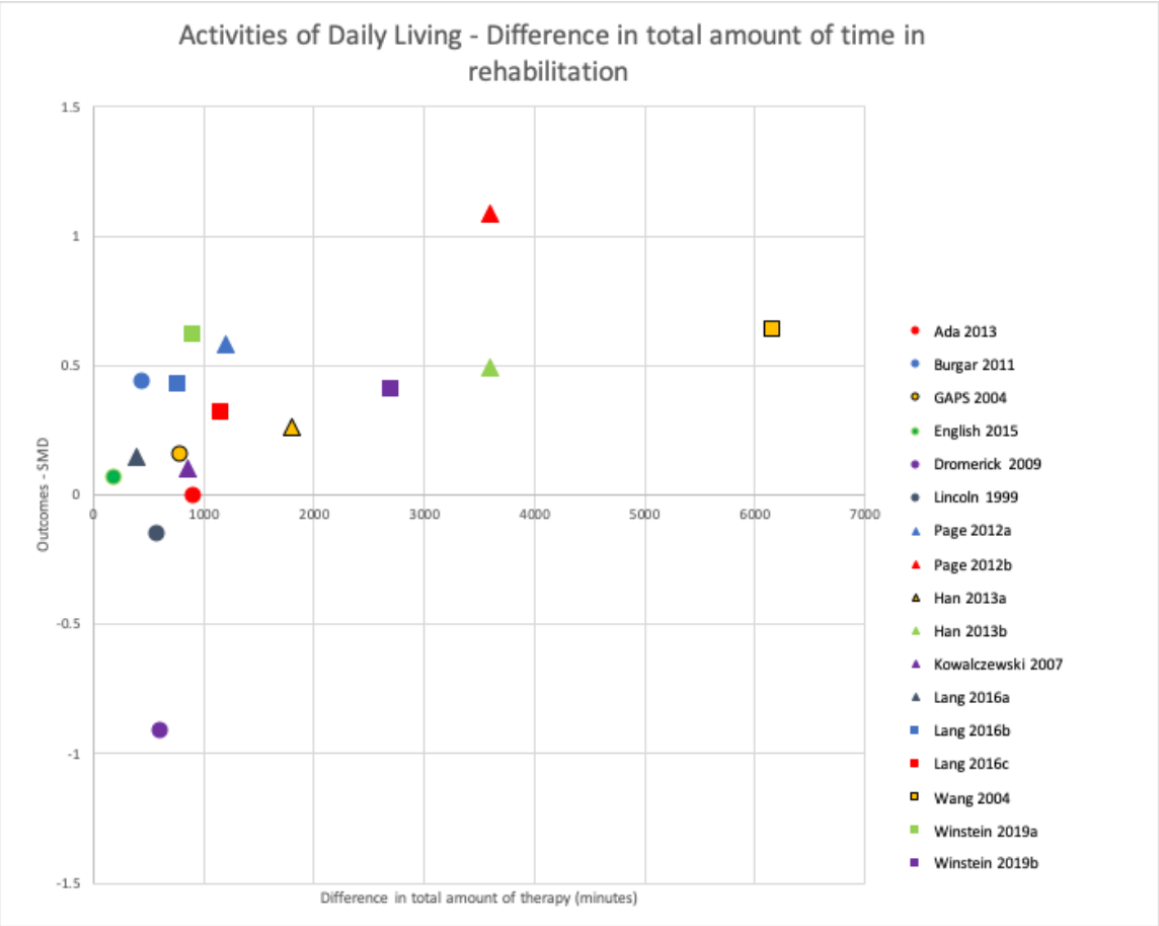

Figure 4 Scatter diagram plotting difference in total minutes of rehabilitation against outcomes (SMD) for activities of daily living, immediately after intervention

4.7.2.2.2 Analysis 4.2 — Activity measures of the Upper Limb

The test for subgroup differences shows that there is a significant difference between results of studies with larger (852 – 3,600 minutes) vs. smaller (198.8 – 762 minutes) difference in total minutes of rehabilitation between treatment arms for activity measures of the upper limb, immediately after intervention ($p = 0.04$) (Appendix JJ - Analysis 4.2). This was in favour of a larger difference in amount.

Analysis of the scatter plot for this outcome (Figure 5) is limited by the small number of data points, but suggests a positive association between difference in total amount of rehabilitation and improved activity measures of the upper limb. There are three outlying studies. Kowalczewski et al. (2007) found a relatively large but non-significant effect in favour of additional therapy, despite a relatively smaller difference in total amount of therapy. This study provided different amounts of FES exercise therapy to two groups; one received intervention daily

and one received intervention weekly. Winstein et al. (2019) found a non-significant effect in favour of control, despite a large difference in amount of time spent in therapy. Their study investigated the effect of an accelerated skill acquisition program for people in the chronic stage following stroke. There were baseline imbalances in this group that would favour the null hypothesis for this study. Finally, Dromerick et al. (2009) found a large but non-significant benefit in favour of the control group, as reported in analysis 4.1.

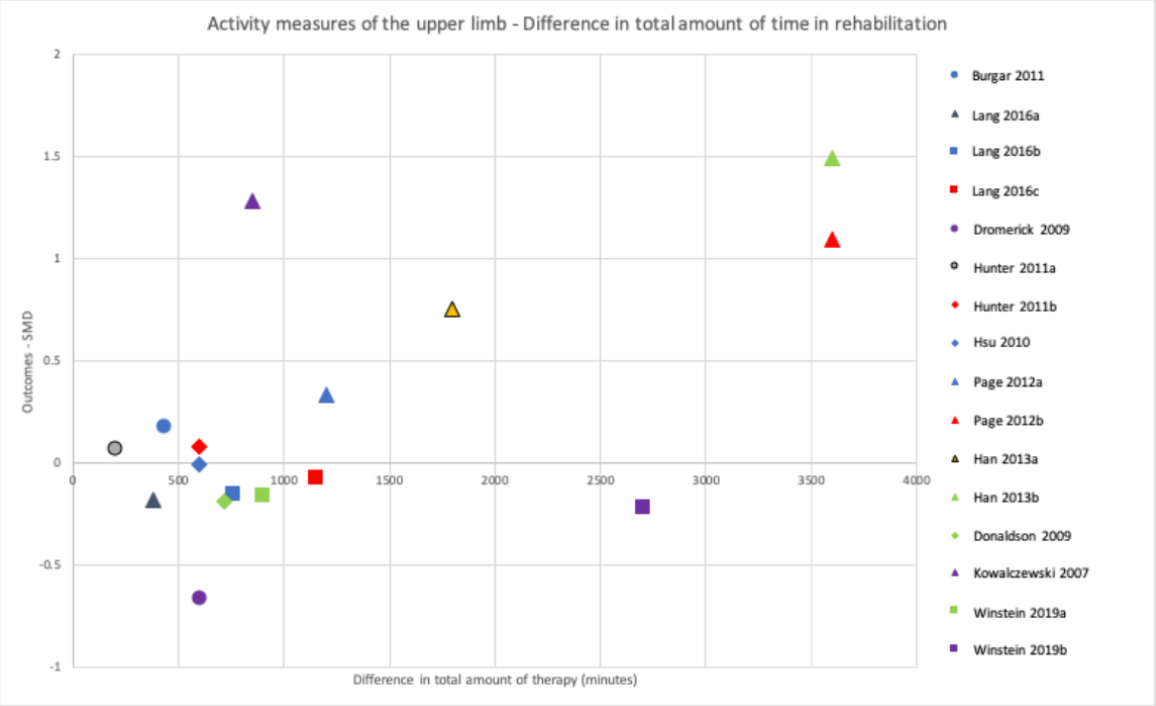

Figure 5 Scatter diagram plotting difference in total minutes of rehabilitation against outcomes (SMD) for activity measures of the upper limb, immediately after intervention

4.7.2.2.3 Analysis 4.3 — Activity measures of the lower limb

The test for subgroup differences shows that there is no significant difference between results of studies with larger (828 – 900 minutes) vs. smaller (186 – 780 minutes) difference in total minutes of rehabilitation between treatment arms for activity measures of the lower limb, immediately after intervention ($p = 0.41$) (Appendix JJ - Analysis 4.3).

The scatter plot for this comparison can be seen in Figure 6. Due to the lack of data points, it is not possible to draw any meaningful conclusions from these data.

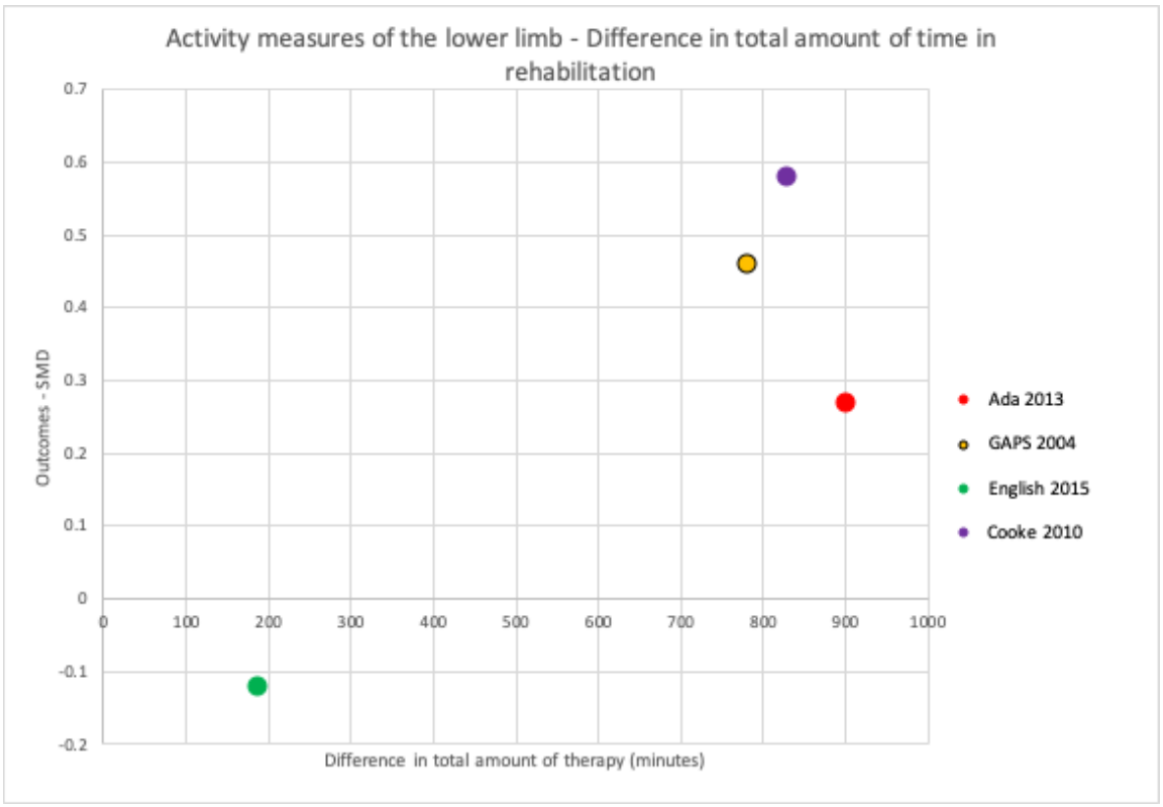

Figure 6 Scatter diagram plotting difference in total minutes of rehabilitation against outcomes (SMD) for activity measures of the lower limb, immediately after intervention

4.7.2.2.4 Analysis 4.4 — Motor impairment measures of the Upper Limb

The test for subgroup differences shows that there is no significant difference between results of studies with larger (852–3,600 minutes) vs. smaller (198.8–720 mins) difference in total minutes of rehabilitation between treatment arms for motor impairment measures of the upper limb, immediately after intervention, (p = 0.06) (Appendix JJ - Analysis 4.4).

Analysis of the scatter plot for this outcome (Figure 7) is limited by the small number of data points, but suggests a positive association between difference in total amount of rehabilitation and motor impairment measures of the upper limb. There are no outlying studies of particular note for this scatter plot.

Only one study reported motor impairment of the upper limb and two studies reported SAE/Death, therefore these outcomes were not included in the subgroup analysis for objective two.

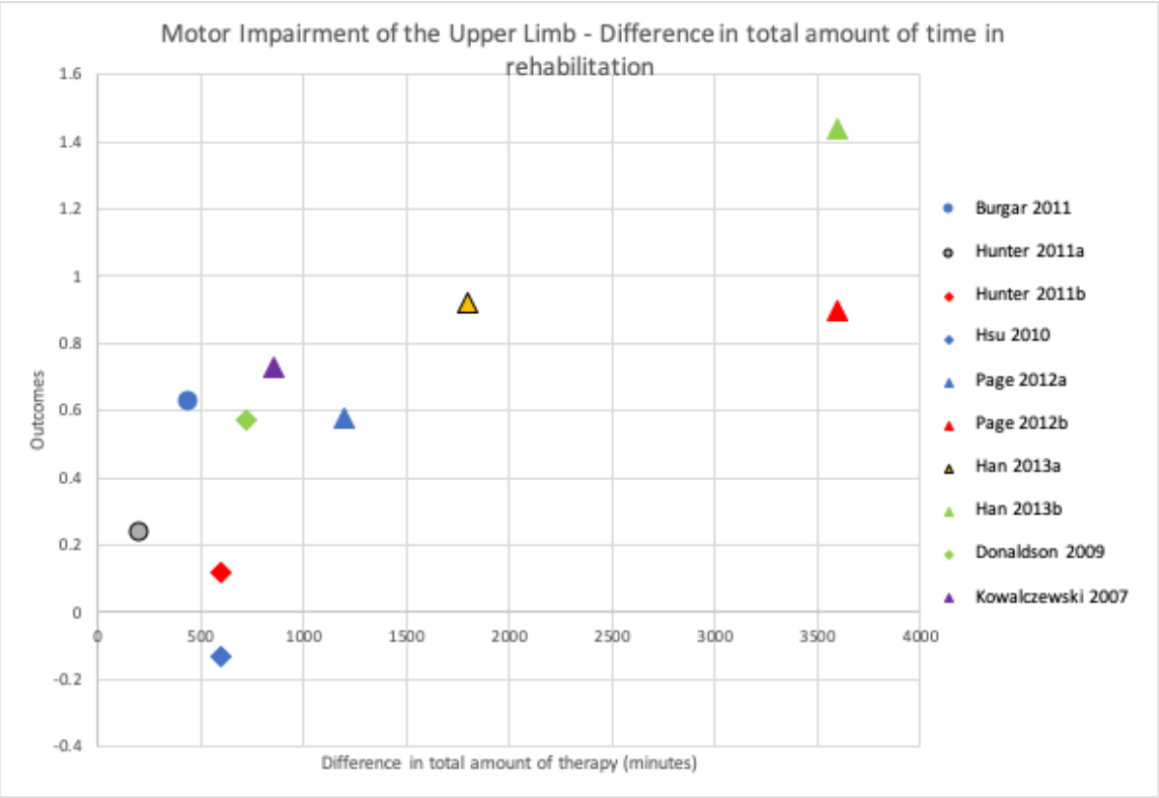

Figure 7 Scatter diagram plotting difference in total minutes of rehabilitation against outcomes (SMD) for motor impairment measures of the upper limb, immediately after intervention

4.7.2.3 Objective Three: To assess the effect of rehabilitation schedule on activity following stroke in terms of average minutes of rehabilitation provided per week, average frequency of rehabilitation and total duration of rehabilitation.

We planned to address this objective by grouping studies with similar rehabilitation schedules and undertaking meta-analyses for each group. Lack of similarity between studies precluded this approach, but we noted that we could extrapolate from most studies the minutes of rehabilitation per week. We used this to conduct subgroup analyses of the primary and secondary outcomes immediately after intervention. We used a median split based on difference in number of minutes of rehabilitation provided per week between study arms to compare studies with a larger difference in terms of number of minutes of rehabilitation provided per week to those with a smaller difference. In addition to this, we produced scatter plots of difference in number of minutes spent in rehabilitation per week (i.e. difference between study intervention groups in terms of number of minutes of therapy received per week during the study) plotted against the

estimated treatment effect (Standardised Mean Difference). Therefore, we conducted subgroup analyses of the primary and secondary outcomes immediately after intervention.

Forest plots for this objective are found in Appendix KK

4.7.2.3.1 Analysis 5.1 — ADL Outcomes

The test for subgroup differences shows that there is no significant difference between results of studies with larger (213–600 minutes) vs. smaller (46.5–150 minutes) difference in minutes of rehabilitation provided per week on ADL outcomes, immediately after intervention (p = 0.44) (Appendix KK - Analysis 5.1).

Analysis of the scatter plot for this outcome (Figure 8) is limited by the small number of data points. Tentatively, it suggests a small positive association between difference in total amount of rehabilitation per week and ADL outcomes. One study is an exception to this. Dromerick et al. (2009) found a large but non-significant benefit in favour of the control group, as explained in analysis 4.1.

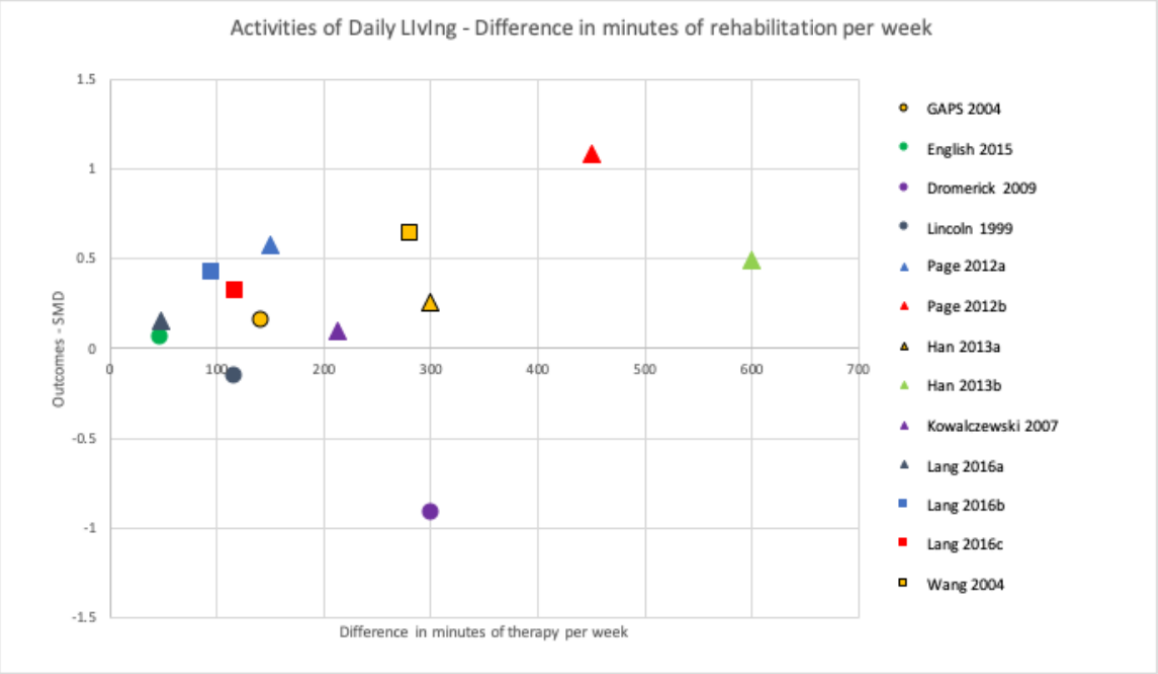

Figure 8 Scatter diagram plotting difference in minutes of rehabilitation per week against outcomes (SMD) for activities of daily living, immediately after intervention

4.7.2.3.2 Analysis 5.2 — Activity measures of the Upper Limb

The test for subgroup differences shows that there is no significant difference between results of studies with a larger (213–600 minutes) vs. smaller (48–150 minutes) difference in minutes of rehabilitation provided per week for activity measures of the upper limb, immediately after intervention (p = 0.14) (Appendix KK - Analysis 5.2).

Analysis of the scatter plot for this outcome (Figure 9) is limited by the small number of data points, but suggests a positive association between difference in amount of rehabilitation per week and improved activity measures of the upper limb. There are two notable studies. Kowalczewski et al. (2007) found a relatively large but non-significant effect in favour of additional therapy, despite a relatively smaller difference in total amount of therapy. The potential reasons for this were explained in analysis 4.2. Dromerick et al. (2009) found a large but non-significant benefit in favour of the control group, as explained in analysis 4.1.

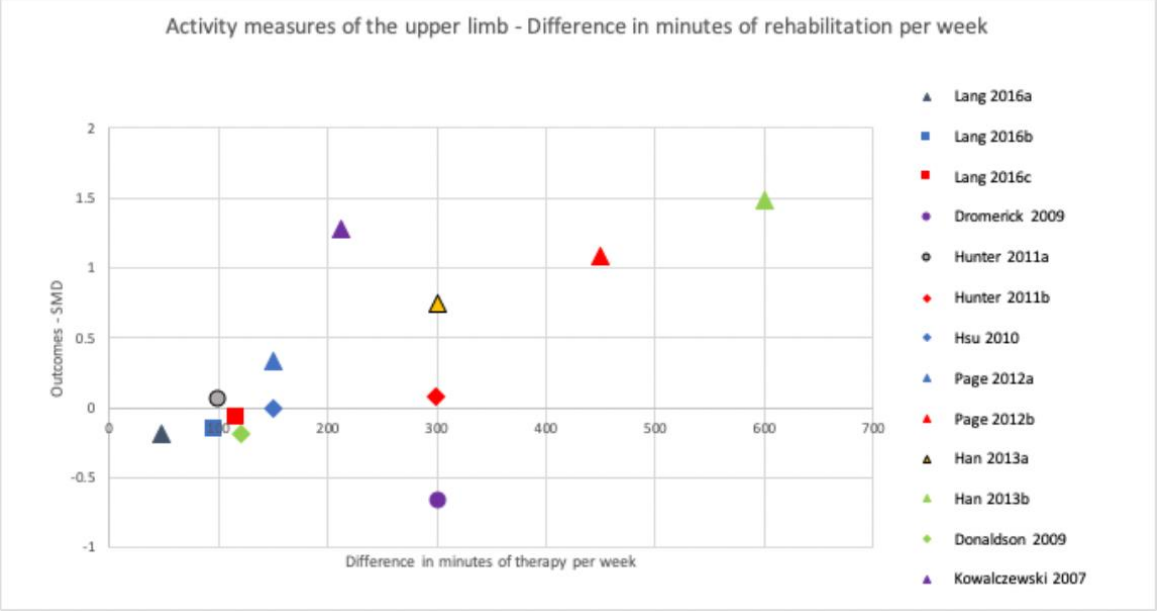

Figure 9 Scatter diagram plotting difference in minutes of rehabilitation per week against outcomes (SMD) for activity measures of the upper limb, immediately after intervention

4.7.2.3.3 Analysis 5.3 — Activity measures of the lower limb

The test for subgroup differences shows that there is no significant difference between results of studies with a larger (140–150 minutes) vs. smaller (46.5–138 minutes) difference in minutes of

rehabilitation provided per week for activity measures of the lower limb, immediately after intervention (p = 0.64) (Appendix KK - Analysis 5.3).

The scatter plot for this comparison can be seen in Figure 10. Due to the lack of data points, it is not possible to draw any meaningful conclusions from these data.

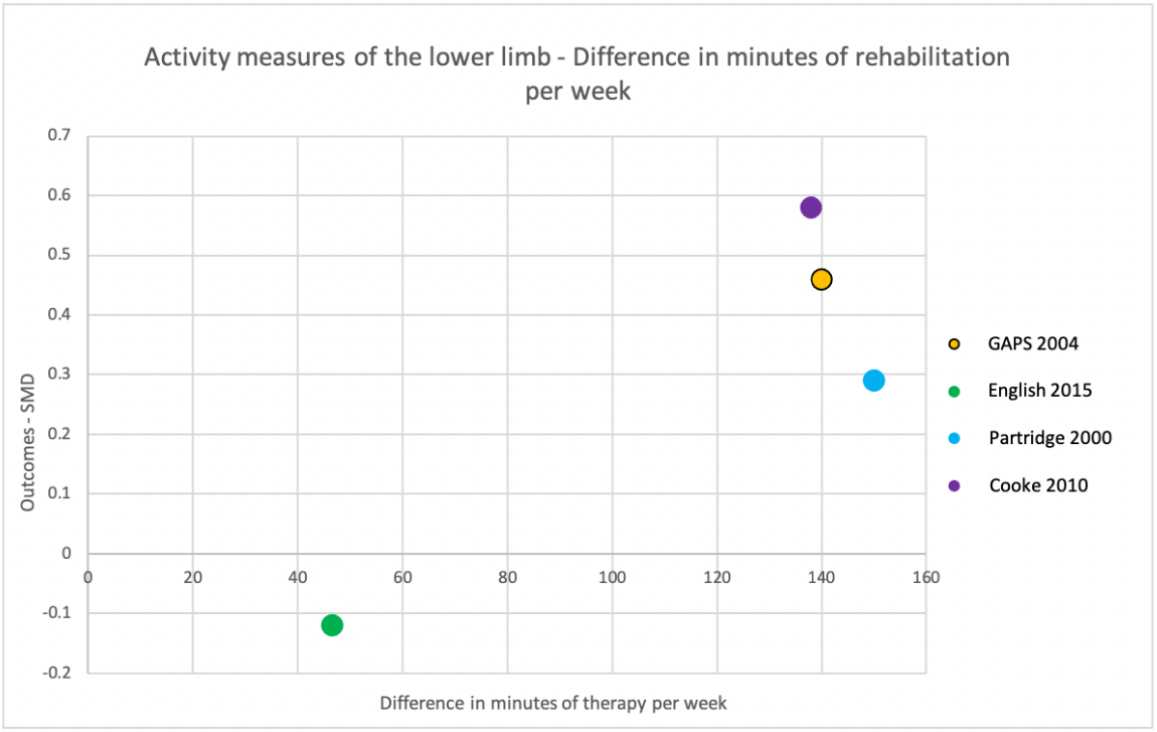

Figure 10 Scatter diagram plotting difference in minutes of rehabilitation per week against outcomes (SMD) for activity measures of the lower limb, immediately after intervention

4.7.2.3.4 Analysis 5.4 — Motor impairment measures of the Upper Limb

The test for subgroup differences shows that there is no significant difference between results of studies with larger (298.9 – 600 minutes) vs. smaller (99.4 – 213 mins) difference in minutes of rehabilitation provided per week for motor impairment measures of the upper limb, immediately after intervention (p = 0.22) (Appendix KK - Analysis 5.4)

Analysis of the scatter plot for this outcome (Figure 11) is limited by the small number of data points, but suggests a positive association between difference in amount of rehabilitation per week and motor impairment measures of the upper limb. There are no outlier studies of particular note.

Only one study reported motor impairment of the upper limb and two studies reported SAE/Death, therefore these outcomes were not included in the subgroup analysis for objective three.

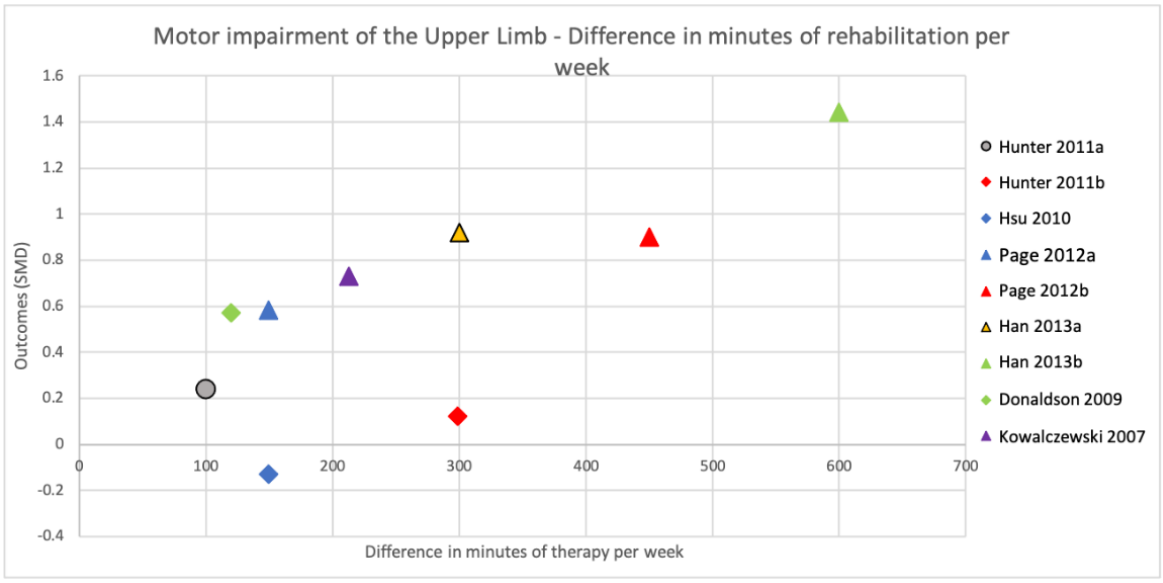

Figure 11 Scatter diagram plotting difference in minutes of rehabilitation per week against outcomes (SMD) for motor impairment measures of the upper limb, immediately after intervention

4.7.3 Subgroup Analyses and Assessment of Heterogeneity

Despite the absence of significant variability in our pooled estimates, we undertook subgroup analyses using the inverse variance method with a random effects model. We did this to determine if any of the factors identified impacted findings. Subgroup analyses were undertaken for analyses in objective one (more vs. less therapy) immediately after intervention, but exclude motor impairment measures of the lower limb and SAE/Death, due to the small numbers of studies.

4.7.3.1 Effect of time since stroke

We investigated the effect of time since stroke by conducting subgroup analyses, comparing studies of participants in the first six months since onset of stroke (subacute) with studies of participants longer than six months since stroke (chronic). We did not find any significant differences between subgroups for any analyses (see Appendix LL).

4.7.3.2 Hours of intervention provided per week

We investigated the effect of hours of therapy provided per week, comparing studies that provided less than 5 hours, 5 hours or more (but less than 10 hours), 10 hours or more (but less than 20 hours) and 20 hours or more of interventional therapy to the experimental group per week. We did not find any significant differences between subgroups for any analyses (Appendix LL).

4.7.3.3 Upper limb therapy vs. Other therapy

In order to investigate the effect of therapy focus on outcomes, we compared studies that provided upper limb therapy with studies that provided other therapy (general rehabilitation or mobilisation). We were only able to undertake this subgroup analysis for ADL outcomes, as studies that measures the other included outcomes (activity of the upper limb, activity of the lower limb and motor impairment of the upper limb) either didn't include upper limb interventions or only included upper limb interventions. For ADL outcomes we did not find a significant difference between subgroups (Appendix LL).

4.7.3.4 Electro-mechanical technology vs. No electro-mechanical technology

To investigate the effect of type of therapy on outcomes, we compared studies that use electro-mechanical technology with studies that did not use electro-mechanical technology. We did not find any significant differences between subgroups for any analyses (Appendix LL).

4.8 Discussion

4.8.1 Summary of main results

The aim of this review was to evaluate the effect of time spent in rehabilitation on measures of activity and impairment after stroke. We included 21 studies which analysed 1,412 participants. Both rehabilitation time and rehabilitation schedule varied between studies. The difference in total time between control and intervention groups ranged from 186 to 6160 minutes with a median difference of 840 minutes.

The first objective was to establish if more of the same rehabilitation therapy resulted in greater improvement in activity than less time. We have low to very low certainty of evidence of

no effect on ADL outcomes, activity measures of the upper limb and lower limb. We have low to very low certainty of an effect in favour of additional time on impairment measures of the upper limb and lower limb at the end of treatment, but not on medium term follow-up (two weeks to six months after intervention). Most of the studies included did not demonstrate a clinically important difference. We have low certainty that more time spent in rehabilitation did not increase risk of death or serious adverse events, but few studies reported these outcomes.

The second objective was to assess the effect of difference in total rehabilitation time on recovery of activity. We compared studies with a larger difference in total rehabilitation time to those with a smaller difference in total rehabilitation time. Greater difference between study arms (more time vs. less time) resulted in a significantly greater improvement in ADL outcomes and activity impairment measures of the upper limb. There was no such significantly greater improvement found for motor impairment measures of the upper and lower limb. Analysis of scatter diagrams plotting difference in total amount of rehabilitation against outcome must be treated with caution, due to the small number of data points (3-17 per scatter diagram) and outliers. They did, however, suggest that a greater difference in amount of rehabilitation led to improved outcomes for ADL measures, and impairment and activity measures of the upper limb. Collectively, these findings suggest that more total time spent in rehabilitation may be beneficial, provided the increased amount reaches a threshold. Visual inspection of the scatter diagram in Figure 3 estimates that the minimum difference in total amount of therapy to effect a change in ADL measures is 1000 minutes (16 hours and 40 minutes). The data suggests this would achieve a SMD of 0.2, which is considered a small effect (Cohen 1988), unlikely to represent a clinically meaningful change to a stroke survivor. This finding is tentative, due to the small number of data points and the dearth of studies with large contrast in amount of rehabilitation between control and intervention groups.

The third objective was to assess the effect of rehabilitation schedule in terms of average minutes of rehabilitation provided per week, average frequency of rehabilitation provided per week and total duration of rehabilitation. Wide variation in rehabilitation schedules limited potential to pool data, but seventeen studies compared more vs less minutes of rehabilitation per week, therefore, we analysed this aspect of rehabilitation schedule. Greater difference in between study arms (more time vs. less time) in terms of amount of rehabilitation provided per week resulted in no significantly greater improvement for ADL outcomes, activity measures of the upper or lower limbs and motor impairment measures of the upper limb. Analysis of the scatter diagrams for this objective must also be treated with caution due to the small number of data points and outliers. Overall, they suggest that a greater difference in amount of rehabilitation per week leads to improved outcomes.

Scatter diagrams may infer elements of rehabilitation schedule that influence outcome. Winstein et al. (2019) found a non-significant effect in favour of the control group, despite a relatively large difference in amount of time spent in rehabilitation. In this study, rehabilitation was provided in three, week-long bouts each separated by 1 month. This unique schedule may have limited the benefit of rehabilitation. Kowalczewski et al. (2007) found a relatively large effect in favour of additional rehabilitation, despite a relatively smaller difference in total amount. This study provided different amounts of FES exercise therapy to two groups; one received intervention daily and one received intervention weekly. Potentially, daily rehabilitation may be beneficial in addition to increased total amount of time. The studies of both Han et al. (2013) and Page et al. (2012b) seem to have elicited positive findings. These studies have been examined in detail to determine common threads that may have influenced their positive results, the most obvious being that they both provided large amounts of rehabilitation (up to 2 hours and three hours per week day, over an 8 and 6-week period respectively). Finally, Wang et al. (2004) provided the greatest contrast in total amount rehabilitation of all included studies, however, their outcomes were not better than some studies that provided an overall smaller contrast in amount of rehabilitation. Notably, intervention in Wang et al. (2004) was provided over a 6- month period, meaning there was less intervention per-week than in other studies. Potentially concentration of rehabilitation is an important factor.

4.8.2 Overall completeness and applicability of evidence

The following issues should be considered when judging the overall completeness and applicability of these findings.

4.8.2.1 The intervention

The between-group difference in amount of the intervention was, in most studies, small. Fifteen studies (20 comparisons) reported the amount provided per week. In 60% of these comparisons, the difference was 150 minutes or less (30 minutes per-day, 5-days per week). In only 25% of comparisons was the difference 300 minutes or more (60 minutes per day, 5- days per week). These small differences may have contributed to the lack of effect seen. Subgroup analyses that grouped studies by the amount of interventional rehabilitation given found no significant between-group differences, but each subgroup only included a small amount of studies.

We were interested in understanding the effect of time spent in rehabilitation, however, for most included studies, amount of time participants spent in rehabilitation was not reported.
Except for the five studies of participants in the chronic stage, the intervention was in addition to

time spent in 'standard rehabilitation', which was neither consistently nor comprehensively reported. Our analysis was therefore of the effect of the intervention time only, which underestimates the total amount received. In their trial, Rodgers et al. (2003) accurately recorded the time spent in all rehabilitation (intervention and control) and noted that the difference was less than planned. They attributed this to “competitive therapy bias” (Rodgers et al. 2003 p.587); those delivering intervention were not blinded to group allocation and, therefore, may have prioritised the control group for 'standard rehabilitation'. As is the case with many rehabilitation trials, providers of rehabilitation in the majority of our included studies were not blinded to group allocation. Therefore, trials may have been subject to 'competitive therapy bias', resulting in a smaller than intended between-group difference in amount of intervention provided. This may have contributed to the lack of effect seen.

Five of the included studies reported time planned for rehabilitation, without reporting time delivered. The inability to determine the amount of time participants spent in rehabilitation (not just the intervention) means the findings of this review only consider the difference between study arms, not the effect of difference in total amount of rehabilitation or whether the total amount of rehabilitation was delivered.

The definition of rehabilitation in this review was intentionally broad, taking an 'intervention agnostic' approach. A wide variety of interventions were therefore included and a subgroup analysis of the effect of specific interventions was only undertaken where we considered there was a sufficient number of studies. We therefore only conducted subgroup analyses of studies that used Electro-mechanical technology vs. all other studies and studies that focussed on upper limb rehabilitation vs. all other studies. Neither analysis showed any significant differences between groups.

For the majority of studies in this review, intervention was provided in an inpatient setting. It is possible that setting has an impact on ability to deliver more rehabilitation. Indeed, the five studies that reported issues with adherence were all inpatient settings. Burgar et al. (2011) attributed adherence issues to factors related to the inpatient setting including early discharges, scheduling conflicts and participant tolerance. The Glasgow Augmented Physiotherapy Study Group (2004) reported that adherence to the planned therapy schedule related to therapists' ability to deliver the augmented amount of therapy time. Five of the seven studies that were low risk of bias for adherence to the intervention were studies of participants in the chronic stage. Although not stated, it is likely that in these studies, intervention was provided in the outpatient/community. Potentially there are fewer barriers to rehabilitation delivery in the outpatient/community setting.

This review only examined the effect of time spent in rehabilitation. Time spent is one component that may contribute to 'rehabilitation intensity'. Other potential components of 'rehabilitation intensity' include number of repetitions performed (Scrivener et al. 2012), rate of repetitions (Klassen et al. 2020) and physiological effort exerted (Outermans et al. 2010). We speculate that other components of ‘rehabilitation intensity' may be important in determining the effect of time spent in rehabilitation; potentially, more time spent is equated with more repetitions and accounts for improved outcomes. However, whilst not examined per se, within a single type of intervention different amounts were unlikely to be different in terms of physiological effort exerted and rate of repetitions as type of intervention was controlled. Research suggests that other components of 'rehabilitation intensity' may affect outcomes. Klassen et al. (2020) found a significant improvement in walking outcomes for participants that had undertaken more repetitions and expended greater physiological effort (measured by heart rate) compared to participants whose intervention was less 'intensive', despite both groups spending the same amount of time in rehabilitation. Similarly, French et al. (2016) found a beneficial effect for lower limb and gait outcomes for repetitive task training compared to control. Potentially, repetitive task training provides a greater number of repetitions compared to standard care.

4.8.2.2 Participants

We considered the extent to which participants were representative of the stroke population and identified areas for attention.

Mean age of participants ranged from 44 to 76.5 years. According to Lui and Nguyen (2018), 50% of strokes occur in people over the age of 75 and these individuals are at higher risk of poor functional outcomes. It is possible that older people are not well-represented in the included studies and, therefore, applicability of the findings to this group is uncertain. Likewise, many of the studies excluded participants with impaired cognition and/or communication.

Studies provided limited information regarding participants' stroke severity and/or baseline impairment. As such, we don’t know if the review findings are applicable irrespective of stroke severity. Initial stroke severity is an important predictor of outcomes (Rost et al. 2016; Bhaskar et al. 2017) and therefore, possibly a factor that influences response to rehabilitation.

Many studies excluded participants with cognitive impairment and/or communication impairment, which both commonly occur after stroke (Engelter et al. 2006; Douiri et al. 2013). Therefore, the included participants may not be representative of the general stroke population, limiting the generalisability of this review's findings.

Sixteen studies were with participants in the sub-acute stage following stroke, the remaining five were with participants in the chronic stage. Subgroup analyses suggest there was no effect for additional time in rehabilitation for most outcomes, between participants in the sub- acute stage and participants in the chronic stage. However, this was not the case for the ADL outcomes, where participants in the chronic stage showed an effect and participants in the sub- acute stage did not. When applying the findings of this review, it may be important to consider time since stroke and the fact that more time in rehabilitation seems beneficial for improving ADLs, an outcome highly correlated with quality-of-life following stroke (Kim et al. 2014) later post- stroke.

4.8.2.3 Outcomes measured

In this review, we pooled outcome measures of the same construct (i.e. activities of daily living, activity of the upper limb etc.) using the Standardised Mean Difference (SMD). Although this allowed the inclusion of a greater number of studies, there are limitations to this approach. It is highly likely that, although of the same construct, the different outcome measures would have measured slightly different things and had different sensitivities to change. In addition, having pooled outcome measures, the effect of the analyses is a standardised mean difference. This reports the effect in a standardised unit, unrelated to the units used by the included measures and is therefore difficult to interpret meaningfully in clinical practice Schünemann HJ et al. (2021). In the Summary of Finding's tables we have reported Cohen's effect sizes to aim to assist with interpretation. There were limited follow-up measures, particularly long-term, which precludes prediction of sustained benefits.

We noted that none of the included studies considered participant experience of rehabilitation. Chen et al. (2019) found that 13.6% of stroke survivors report therapy as an unmet need following stroke. Therefore, it would be valuable to establish if more rehabilitation resulted in improved participant experience. However, this was beyond the scope of this review and would likely involve analysis of qualitative and/or mixed methods studies.

4.8.3 Quality of the evidence

Certainty of our primary analysis (more vs less time spent in rehabilitation) was assessed using the GRADE approach, considering five domains:

4.8.3.1 Risk of Bias

The majority of analyses received a serious (and in some cases, very serious) GRADE rating for risk of bias. This was due to the proportion of study outcomes considered to be at some

concern or high overall risk of bias and a tendency for a greater effect for additional rehabilitation seen when studies with high risk of bias were removed. This has greatly contributed to a reduction in GRADE assessments, indicating low and very low certainty of the evidence. The most consistent source of bias across study outcomes was the inability to establish risk of bias in the selection of reported results, as few studies published protocols or registered trials with sufficient detail. There tended to be greater risk of bias for follow-up measures, due to loss of follow-up data.

4.8.3.2 Inconsistency

Of all study analyses (excluding sensitivity and subgroup analyses), only one (Analysis 2.3) had an I^2 of 50% or more. This level of consistency of findings is surprising, given the heterogeneity across studies in type of rehabilitation delivered. Possibly, selection criteria of studies were such that people with a similar type of stroke (in terms of severity and rehabilitation needs) were included in studies. Additionally, except for a few studies, a similar amount of rehabilitation tended to be delivered to intervention and control groups, which may have contributed to consistent findings. Subgroup analyses undertaken to assess heterogeneity did not find any significant differences.

4.8.3.3 Indirectness

We did not consider that the study analyses included serious indirectness. Our selection criteria was such that the studies included directly addressed our primary objective. We considered studies that reported issues with adherence to intervention may lead to indirectness of the intervention, particularly if this led to a lack of difference in the intervention received by the included groups. However, when these studies were removed in sensitivity analyses, findings were not greatly affected.

4.8.3.4 Imprecision

We considered studies to have serious imprecision if the 95% confidence interval includes an effect size of no difference. This was true for four of the five analyses. Many studies had small samples sizes, which may have contributed to imprecision.

Publication Bias

We strongly suspect publication bias for the majority of the analysis, supported by the assessment of non-reporting bias in studies (Appendix AA) and the funnel plots. We are aware of studies that

measured outcomes, but the data for these outcomes was not reported and is unavailable. Additionally, there are some studies which we considered could have measured some outcomes but not reported their findings. The aforementioned lack of study protocols contributes to this issue.

In summary, the GRADE assessment indicates that the analyses for objective one are of low to very low certainty.

4.8.4 Potential biases in the review process

Despite undertaking a thorough search, it is possible that some eligible studies were missed. Our searches resulted in an exceptionally large number of records, due to the many and varied search terms used to capture the concept of 'time spent in rehabilitation'. Title screening, undertaken by one person (BC), excluded studies that were clearly irrelevant and specifically: not related to stroke; investigations of surgical or pharmaceutical interventions and with non- human participants. It is unlikely, that this screening led to missed studies.

For eight potentially eligible studies, we were unable to determine whether they met the selection criteria and authors have not responded to our enquiries. Two studies that satisfied the selection criteria were not included because data were unavailable and authors have not responded to our enquiries.

In determining study eligibility, review authors had to decide if the rehabilitation provided between intervention and control groups was the same, except for the amount of time spend. Rehabilitation is a complex intervention, which naturally varies from individual to individual. Judgements were based on study authors' intention to provide the same type of rehabilitation, but despite this, there were instances when study eligibility were debated. Procedure for this followed the plan described in our study protocol, but also included other study authors (GK and JM) when agreement couldn't be reached between those involved in the study selection process (BC, JB and JW).

Two review authors, working independently, extracted data from the studies and assessed risk of bias for all outcomes of included studies. Any discrepancies were resolved through discussion with a third author. Review authors did not screen for inclusion, extract data or assess risk of bias for any studies in which they were involved.

Two review authors independently made judgements regarding the constructs measured by outcome tools to determine whether outcomes of interest were measured.

One study (Wang et al. 2004) was written in Chinese, with an English abstract. Two independent translators translated parts of the text to enable data extraction and assessment of risk of bias. However, other biases within this text may have existed, of which we are not aware.

We were unable to assess the third objective as planned and made a post hoc decision about meeting this objective. Although we did not consider study results when making this decision, it is possible that a post hoc data analysis change could have introduced bias.

4.8.5 Agreements and disagreements with other studies or reviews

We considered agreements and disagreements with other studies and reviews in relation to our review objectives.

4.8.5.1 Does more of the same rehabilitation therapy results in greater improvement in activity measures?

To our knowledge, this is the first systematic review with meta-analysis to only include studies that compare different amounts of the same type of rehabilitation. All other reviews have included studies in which the experimental and control interventions differed in type of intervention, as well as amount of intervention and some meta-analyses included studies that measured effect of rehabilitation vs. no rehabilitation. However, there are reviews that have examined the effect of time spent in rehabilitation. These are considered in terms of their agreements and disagreements with our review.

Eleven systematic reviews with meta analyses have studied the effect of time spent in rehabilitation following stroke (Langhorne et al. 1996; Kwakkel et al. 1997; Kwakkel et al. 2004b; Galvin et al. 2008; Cooke et al. 2010a; Veerbeek et al. 2011; Lohse et al. 2014; Pollock et al. 2014a; Sehatzadeh 2015; French et al. 2016; Schneider et al. 2016). Relevant findings of these studies and their agreements/disagreements with this review are summarised in Appendix MM.

Six reviews measured the effect of additional time spent in rehabilitation on ADL outcomes. Four (Kwakkel et al. 1997; Kwakkel et al. 2004b; Galvin et al. 2008; Pollock et al. 2014a) found significant differences in favour of additional rehabilitation, one (Sehatzadeh 2015) found no significant difference in ADLs (measured by the Barthel Index) and one (Veerbeek et al. 2011) found no significant effect for basic ADLs (Barthel Index, SMD 0.11, 95% CI -0.12 to 0.34), but a moderate effect for extended ADLs (pooled Nottingham Extended ADL checklist and Frenchay Activities Index, SMD 0.54 95% CI 0.20 to 0.88).

Four reviews measured the effect of additional time on upper limb activity. In agreement with this review, three reviews (Kwakkel et al. 2004b; Cooke et al. 2010a; French et al. 2016) found no significant difference between groups. However, the fourth review (Sehatzadeh 2015) reports significant benefit for additional time spent, measured by the ARAT.

Six reviews measured the effect of additional time spent in rehabilitation on activity measures of the lower limb. In agreement with this review, three found no effect for additional time spent (Galvin et al. 2008; Sehatzadeh 2015; French et al. 2016). However, two reviews found significant effects for activity measures of the lower limb, in favour of additional time (Kwakkel et al. 2004b; Veerbeek et al. 2011). The sixth review (Cooke et al. 2010a) did not pool outcomes for lower limb activity and found a non-significant effect for the Rivermead Mobility Index and a significant effect in favour of less time in rehabilitation for walking speed.

One review measured the effect of additional time spent in rehabilitation on upper limb motor impairment. Cooke et al. (2010a) found a significant effect in favour of less time for grip strength, but a significant effect in favour of more time for the motricity index.

One review measured the risk of death or deterioration. In disagreement with our review, Langhorne et al. (1996)found that the risk of death or deterioration was significantly lower in groups that received additional time in rehabilitation (OR 0.54 95%CI 0.3 to 0.85), albeit with a wide confidence interval across only five studies.

The lack of agreement between reviews may be influenced by the lack of certainty of evidence and variation in study dates and methodologies (e.g. objectives and selection criteria), as well as the aforementioned inclusion of studies that differed in the type of intervention provided, not just the amount.

4.8.5.2 What is the effect of total rehabilitation time on recovery of activity?

We found three systematic reviews with meta-analyses that explored the effect of total time spent in rehabilitation. Kwakkel et al. (2004b) used a cumulative meta-analysis, finding that a difference of at least 16 hours in treatment time between groups is required to obtain a significantly better outcome for ADLs. Lohse et al. (2014) used meta-regression to explore the effect of total scheduled therapy time on effect sizes. They found a reliable dose-response relationship between time scheduled for therapy and improvement in measures of function and impairment. Finally, Schneider et al. (2016) undertook a ROC (Receiver operating characteristic) curve analysis of false versus true benefit. This indicated that an extra 240% of rehabilitation is required to make certain a better outcome for activity. The findings of Kwakkel et al. (2004b) and

Schneider et al. (2016) agree with our finding, that a large difference between intervention groups is required to achieve a significantly better outcome. The finding of Lohse et al. (2014) do not suggest that a larger difference is required between groups to see a beneficial effect, which is contrary to the findings of this review and the others described. This difference could be due to differences in inclusion criteria and statistical methods.

Other studies support the finding that a very large amount of rehabilitation may achieve a significant response. McCabe et al. (2015) compared three interventions (Motor learning, robotics plus motor learning and FES plus motor learning), all provided five hours/day, five days/week for 12 weeks to a population of participants more than one year post stroke. All groups made clinical significant improvements post-intervention but with no significant between group differences. Similarly, Ward et al. (2019) describe the outcomes of 224 stroke survivors in the chronic stage, who attended an upper limb rehabilitation programme, receiving 30 hours of intervention per week for 3 weeks. At the end of intervention, there were significant improvements in all outcomes measured, maintained at 6-month follow-up. Neither of these studies were included in this review, as McCabe et al. (2015) compared different, dose-matched interventions and Ward et al. (2019) was not an RCT. We are unable to find any studies of similarly large amounts of rehabilitation (i.e. five hours per day) in participants in the subacute stage post-stroke. This may potentially be due to the challenges of delivering this amount of therapy early after stroke (Burgar et al. 2011; Hunter et al. 2011).

4.8.5.3 What is the effect of rehabilitation schedule in terms of average minutes per week, number of sessions per week and total duration of rehabilitation?

We found one systematic review with meta-analysis that explored the effect of rehabilitation schedule. Findings from Pollock et al. (2014a) suggest that 30 to 60 minutes of physical rehabilitation delivered 5 to 7 days a week provides a significant benefit for function recovery when compared to no intervention or usual care. However, this study also reports that, for ADL outcomes, more than once-daily intervention may provide even more benefit. In agreement with Pollock et al. (2014a), our findings suggest that daily intervention may be more beneficial than less-than daily intervention.

4.9 Authors' conclusions

4.9.1 Implications for practice

An increase in time spent in the same type of rehabilitation after stroke results in little to no difference in meaningful activities such as activities of daily living and activities of the upper and lower limb but a small benefit in measures of motor impairment (low to very low certainty of evidence for all findings). If the increase in time spent in rehabilitation exceeds a threshold, this may lead to improved outcomes. There is currently insufficient evidence to recommend a minimum beneficial daily amount in clinical practice.

Additional time spent in the same type of rehabilitation does not increase the risk of serious adverse events/death, but this finding is of low certainty and should be interpreted with caution, as few studies monitored these outcomes.

The findings of this review are limited by a paucity of research trials with large contrasts in amount of rehabilitation delivered between intervention and control groups.

4.9.2 Implications for research

There is currently insufficient, high-quality evidence to determine the effect of time spent in rehabilitation. However, findings from high quality trials with a large contrast in amount of therapy delivered indicates that this area warrants further research.

To provide evidence for the effect of time spent in rehabilitation, adequately powered, high quality RCTs are required. Such studies should be undertaken in a stroke population, studying groups of participants spending different amounts of time in the same type of rehabilitation. Findings of this review suggest that the total contrast in amount of time between groups should be a minimum of 1,000 minutes. Outcomes at an activity level are required to determine if more time spent in intervention results in a meaningful change.

Study quality would be improved by enhanced reporting. Publication of protocols (or detailed trial registry entries) and reporting of all measured outcomes would allow for accurate judgement of potential reporting bias. Actuate reporting of amount of rehabilitation delivered, not amount of rehabilitation planned is imperative. Additionally, when undertaking any study assessing effect of amount of time spent in a specific intervention, it is crucial that researchers accurately report the time spent in all rehabilitation, not just interventional rehabilitation. This is of particular importance when those delivering rehabilitation are aware of participant group allocation. Finally,

it is important that studies report baseline stroke severity, to examine its impact on response to rehabilitation.

An individual participant data meta-analysis might provide further information regarding the effect of time spent, specifically if certain characteristics of either the participant or the intervention effect outcomes.

In addition to 'time spent', other characteristics of rehabilitation may be important, such as, type of rehabilitation, stage of recovery, rehabilitation 'intensity' (such as number/rate of practice repetitions, physiological effort or task difficulty) and rehabilitation schedule.

These characteristics also warrant further exploration.

4.10 Contributions of authors

Beth Clark initiated and co-ordinated the review, but it was undertaken with the full support of all the review authors.

All authors contributed to the conception and design of this review.
BC, JB and JW screened titles and abstracts of publications identified by the searches.
BC, JB, JW and SE extracted trial and outcome data from the selected trials and analysed outcome data.
BC, JW and JB assessed risk of bias in the included studies.
All review authors contributed to the interpretation of results and to the final presentation of this study

4.11 Differences between protocol and review

4.11.1 Title

Title reworded, to enhance clarity.

4.11.2 Background

Changes made to update the background section (including updating references) and enhance readability.

4.11.3 Objectives

Objectives have undergone some rewording to clarify and enhance readability and to conform with the preferred Cochrane format. The nature of the objectives has not changed.

4.11.4 Methods

The following minor changes have been made to the methods between protocol and review:

Under 'criteria for considering trials for this review' we altered the wording under 'type of intervention' to enhance clarity. We added that we included studies that varied in the time spent in rehabilitation, but did not report a specific time-related measurement. This had not been anticipated when writing the protocol.

We have removed 'Participant experience' as a secondary outcome as it does not relate to the objectives of this review.

Electronic Searches:

- CIRRIE (cirrie.buffalo.edu/database/) was not included, as it has been amalgamated with REHABDATA
- Planned to include the Australian and New Zealand Clinical Trials Registry (ANZCTR), but this registry was excluded, as we were unable to export results
- Planned to include the UK Clinical Trials Gateway (UKCTG), but excluded, as this registry pulls data from ISCRTN and ClinicalTrials.gov, both of which were searched in this review.

Risk of Bias 2 tool used (had planned to use the Risk of Bias tool). Therefore, this section has been re-written in accordance with the editorial checklist for the RoB 2 tool.

RevMan Web was used (had planned to use RevMan5)

Protocol states that 2 review authors would independently screen the titles and abstracts of the studies retrieved. Owing to the very large number of records found, the first step of study

selection was that one person screened titles and excluded any studies that were clearly irrelevant, before moving on to two people screening titles and abstracts.

Detail added regarding how we would deal with studies with more than 2 intervention groups, as this was not clear in the protocol

We added that we would only undertake funnel plots when there were 10 or more studies. This is based on the advice in the Cochrane Handbook

We added an assessment of non-reporting bias, in accordance with Chapter 13 of the Cochrane Handbook

We added two subgroup analyses, to compare the effect of time spent in therapy dependent on the type of intervention provided. We reasoned that the type of intervention may affect outcomes and, therefore, more time spent in one type of therapy may have greater benefit than more time spent in another type of therapy. These analyses were determined post-hoc, as they were dependent on the types of studies found in the literature search. The two analyses undertaken (Upper limb therapy vs. other therapy and Electro-mechanical technology vs. No electro-mechanical technology) were chosen, as there were studies in each category to enable a comparison and both comparisons were considered likely to be of interest to readers.

4.11.5 Sensitivity Analyses

We did not perform a sensitivity analysis to determine the effect of any unit of analysis issues, as we believe we had mitigated for unit of analysis issues within the review.

We did not perform a sensitivity analysis to determine the effect of inclusion of cluster RCTs, as none were included

We performed sensitivity analyses to assess the effect of excluding studies of an overall high risk of bias, in accordance with the guidance for use of the RoB 2.

We added a sensitivity analysis, excluding studies that were at high risk of bias risk of bias due to deviations in adherence to interventions. This addition was made due to the change in RoB tool used.

4.11.6 Measurement of Treatment Effects

We did not undertake a Meta-regression, as planned for objective two. The advice in the Cochrane Handbook, chapter 10 (Deeks et al. 2021) is that meta-regression should not be undertaken when there is fewer than 10 studies. Meta-regression was considered for the 2 outcomes which did have more than 10 studies, but given the small number of studies we felt it was sufficient to use a consistent descriptive approach across all outcomes. Instead, we undertook subgroup analyses and created scatter plots using Microsoft Excel to provide a descriptive analysis.

We were unable to address the 3rd objective as planned. Due to limited similarities in the rehabilitation schedules between studies we were unable to group studies as planned, to undertake meta-analyses for the different groups. As an alternative, we compared studies with a larger difference between arms in terms of number of minutes of rehabilitation provided per week to those with a smaller difference between arms in terms of number of minutes of rehabilitation provided per week.

Chapter 5 Why do some people with stroke not receive the recommended 45 minutes of Occupational Therapy and Physiotherapy? Findings from focus groups to inform a Delphi study

5.1 Introduction to chapter

This chapter presents focus groups exploring why some people with stroke do not receive the recommended minimum of 45 minutes of therapy. This is the first stage undertaken to answer the second research question: Why do people with stroke not always receive the recommended minimum amount of therapy? To demonstrate comprehensive reporting of this study, the 'Consolidated criteria for reporting Qualitative research' (COREQ) checklist (Tong et al. 2007) was completed (Appendix NN).

This paper, with the Delphi study paper presented in the next chapter, will be submitted as a pair to BMJ open. The paper is presented here-in.

Title: Why do some people with stroke not receive the recommended 45 minutes of Occupational Therapy and Physiotherapy after stroke? Findings from focus groups to inform a Delphi study

Authors: Clark B, Burridge J, Whitall J, Turk R, Hughes A.M, Truman J

5.2 Introduction

In England, the National Clinical Guideline for Stroke (Intercollegiate Stroke Working Party 2016) recommends that:

> "People with stroke should accumulate at least 45 minutes of each appropriate therapy every day, at a frequency that enables them to meet their rehabilitation goals,

> and for as long as they are willing and capable of participating and showing measurable benefit from treatment". (Intercollegiate Stroke Working Party 2016 p.25)

This guideline was introduced in 2008 and since 2013, the Sentinel Stroke Audit Programme (SSNAP) has audited its achievement based on the provision of therapy five days a week. Recent audit findings suggest this guideline is achieved for 37% and 34% of those appropriate for OT and PT respectively (Bahalla et al. 2021). It is unclear why it is not achieved for all people considered appropriate.

Stroke is the second most common cause of global disability, with more than 80 million stroke survivors worldwide (Johnson et al. 2019). Such disability results in reduced quality of life for people with stroke and their carers (Lewthwaite et al. 2018; Oyewole et al. 2020) and has a significant effect on national economies (Patel et al. 2020). Occupational therapy (OT) and physiotherapy (PT) are received by 80% and 85% (respectively) of people following stroke as part of inpatient stroke unit care (Royal College of Physicians 2014). These therapies contribute to post-stroke recovery including, but not limited to, increased independence in activities of daily living, community reintegration, improved postural control and mobility (Legg et al. 2006; Langhorne et al. 2011; Shing 2011; Pollock et al. 2014a). Whilst there is evidence of the benefits of OT and PT following stroke, there is not clear evidence regarding who should receive it, when and how much.

Three recent studies report factors that influence the amount of therapy a person receives in the context of the 45 minute guideline (Clarke et al. 2018; Taylor et al. 2018; Gittins et al. 2020). Despite different study designs, each identified resource provision (number of therapists or amount of therapy time) as a reason why people with stroke may not receive the guideline recommendation. This suggests that therapists must decide not only who is appropriate for therapy, but who will receive it in the context of a limited resource. Therapists use observation and assessment to decide who will receive therapy and the amount they will receive (McGlinchey and Davenport 2015; Clarke et al. 2018). Therapists are gatekeepers of therapy. No study to date has used therapist focus groups to explore why a person may not receive the recommended 45 minutes of therapy.

This study explores why some people with stroke do not receive the RCP's recommended minimum of 45 minutes of therapy, five days a week (the standard currently audited) and the factors that influence therapy provision. The findings informed the design of a Delphi study, which gained consensus from experienced therapists.

5.3 Methodology

Focus groups are appropriate for studying the decision-making process. They are based on social constructionism theory, where individuals develop understanding through social interactions. This may be important considering that therapists' decision-making may be based on tacit knowledge, which is not easily articulated. Finally, they are suitable for addressing sensitive topics, such as guideline non-achievement (Barbour 2018).

A convenience sample of Occupational Therapists (OTs) and Physiotherapists (PTs) from two geographical areas of southern England participated[1]. The groups included therapists from teams treating people with stroke (either Early Supported Discharge (ESD) or inpatient) and aware of the 45 minute therapy guideline. Participants were invited via an email from the researcher, provided by a senior therapy contact within their organisation (Appendix QQ); hence it is not known how many originally declined to participate. However, to provide context for the number of therapists likely invited, one area had 36 stroke beds and the other had 37 stroke beds. All participants who met the criteria and agreed to participate attended a focus group. Focus groups were held in acute hospitals and both lasted approximately 90 minutes.

A topic guide comprising open-ended questions with prompts was piloted and used (Barbour 2018), (table 5). No other stimulus material was used, to avoid influencing the discussion. Beth Clark (BSc (Hons) Occupational Therapy) facilitated both groups, with pre-briefed research assistant co-facilitators (one per group). At the time of the focus groups, Beth was working as an Interprofessional Unit Lead on a stroke unit, in the same geographical area as the participating teams and consequently had worked with some of the focus group participants in the past. She

[1] Please see Appendix OO for the Participant information sheet and Appendix PP for the consent form

was also a Doctoral student, who had undertaken training in qualitative research methods and analysis.

Table 5 Topic Guide

Topic Guide

- What does this guideline mean to you and your service?
  ○ Has it changed anything in terms of service provision in order to try and achieve the 45 minutes of therapy?
  ○ What would change if the 45-minute recommendation no longer existed?
  ○ Do you think that the people accessing your service get the right amount of therapy?
  ○ How do you decide when to stop a specific therapy (i.e., OT or Physio), or when to stop therapy altogether?
- What are the Pros and Cons of having this guideline?
- What influences your decisions regarding therapy provision?
  ○ Anything to do with the patient/carers/relatives?
  ○ Anything to do with resources?
  ○ Anything else?

The focus groups were audio-recorded, transcribed, and the data analysed using reflexive thematic analysis (Braun and Clarke 2006; Vaismoradi et al. 2016; Braun and Clarke 2022), from an interpretivist approach (Mason 2018). Field notes taken by the co-facilitator during the focus groups also contributed to the data analysis. An inductive approach to coding was used (Ryan and Bernard 2003; Braun and Clarke 2006; Vaismoradi et al. 2013), supported by operational and analytical memos (Charmaz 2014; Green and Thorogood 2018). One researcher (BC) undertook the analysis. Coding and themes were discussed with and reviewed by another researcher (JT) to test assertions. Participants were not asked to review transcripts, nor comment on findings, but were all invited to participate in the Delphi study, to which the findings of the focus group contributed (Clark et al. 2021b).

The concept of data saturation was considered inconsequential in relation to this study. Not only are there issues with data saturation in the context of reflexive thematic analysis ((Braun and Clarke 2019) but the aim of this study was not to establish all possible reasons why a person may not receive 45 minutes of therapy, but to establish common reasons, to be examined further (and potentially added to) in a Delphi study.

Ethical approval was sought from the University of Southampton (ERGO II 17994) and from the Research and Development departments of the NHS trusts participating in the research (IRAS ID 189272)

This study is part of a wider programme of work, within which the opinions of people with stroke on the 45 minute guideline have been sought. As this study is specifically about therapists' implementation of the guideline, the opinions of people with stroke did not directly influence this study.

5.4 Findings

Nine therapists participated in two focus groups (table 6).

Table 6 Demographics of clinicians

	Profession	Years working in the service	Therapist seniority*	Gender (% female)
Focus group one	Physiotherapist – 2 Occupational Therapist - 1	4 – 12 years	Band 6 – 2 Band 7 - 1	100%
Focus group two	Physiotherapist – 4 Occupational Therapist - 2	11 months – 7 years	Band 6 – 4 Band 7 – 2	100%

*Band 6 – Senior therapist, Band 7 - Advanced therapist/team lead

Five themes were generated from the data, each divided into sub-themes (figure 12)[2]. Each theme related to a factor that influenced amount of therapy provided. The themes and subthemes are herein described.

[2] Please see appendix RR for the coding framework

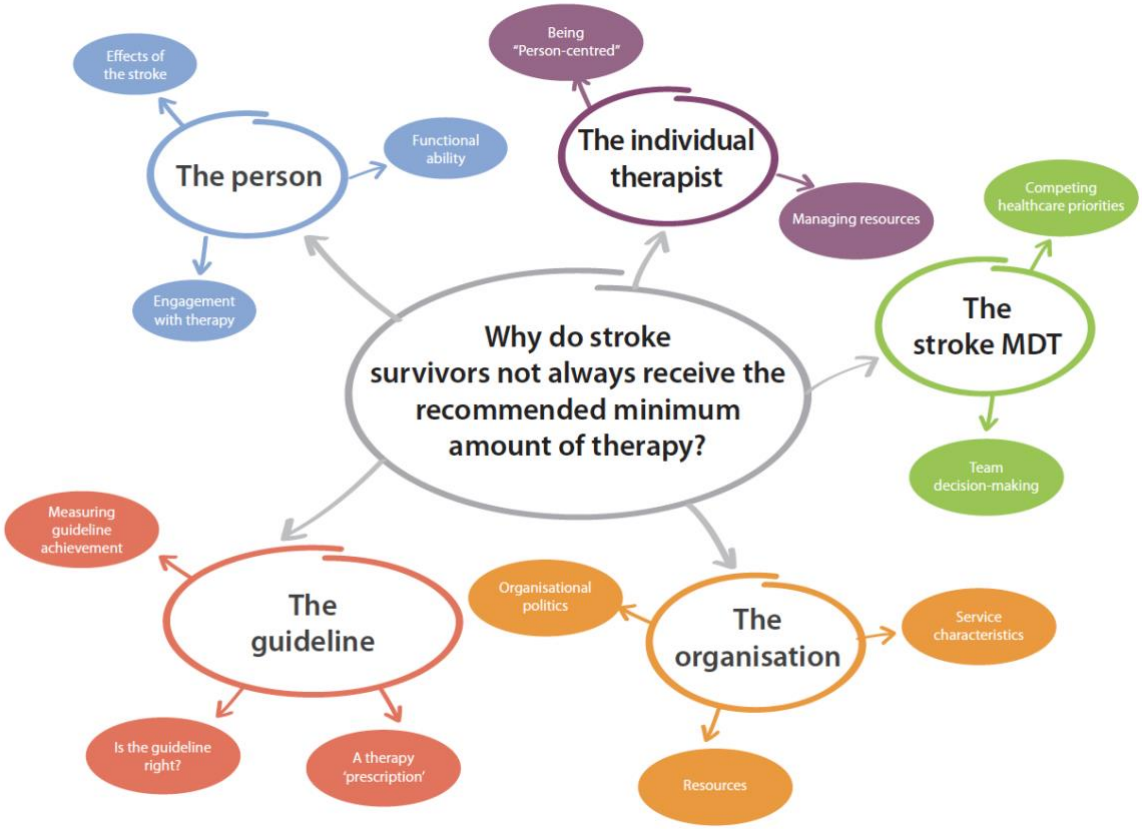

Figure 12 Graphical representation of focus groups' themes and sub-themes

5.4.1 Theme one: The person

Factors related to the person receiving therapy influences amount delivered. This includes the effects of their stroke, their functional ability and their engagement with therapy.

5.4.1.1 Effects of the stroke

The effect of stroke on a person may influence the amount of therapy they receive, with medical effects heavily cited as reasons for non-delivery of the guideline:

> *"One of the main ones is the medically unwell patients… if their blood pressure is unstable, or their heart rate, or all that kind of stuff…"* (FG1, p4, lines 10-14)

As well as blood pressure and heart rate, medical issues mentioned were fatigue, nutritional status, palliative care, co-morbidities, and being generally 'unwell'. This finding is supported by literature, which reports that medical complications, level of consciousness and fatigue can

impact therapy delivery post-stroke (Hakkennes et al. 2011; Otterman et al. 2012; Taylor et al. 2015; Clarke et al. 2018). Impaired attention, a common sequela of stroke (Loetscher et al. 2013), was also cited as a reason why a person might not receive the guideline:

> *"They might not have the attention to process everything that's going on or what you're asking them to do."* (FG2, p4, lines 36-37)

Additionally, groups identified that both low mood and lack of motivation may lead to less therapy; these issues were discussed separately, but could be linked as this quote suggests:

> *"We've had some people with low mood who just don't want to engage, and, as long as we feel, like, there's not a mental capacity issue, then, you kind of have to respect that."* (FG1, p28, lines 21-24)

Other research literature supports the perception that low mood and lack of motivation may reduce the amount of therapy a person received after stroke (Skidmore et al. 2010; Otterman et al. 2012; McGlinchey and Davenport 2015), and that low mood is common after stroke (Wade et al. 1987; Hackett et al. 2008).

5.4.1.2 Functional ability

The person's current and pre-stroke level of function may influence the amount of therapy they receive. In discussion of function, therapists identified issues related to both current dependence and ability to self-manage. Whilst current dependence was easy to define, relating to the level of care need a person had, self-management was a harder concept to clarify, but would appear to be related to their ability to take an active role in their therapy:

> *"…They could participate in five sessions of 45 minutes but they wouldn't get the benefit from it, they don't necessarily need it, they could self-manage in between those times so they have a lighter input than 45 minutes, five times a week."* (FG2, p6 lines 10-13)

These discussions were multifaceted as they were influenced by a person's pre-stroke level of function which appeared to influence the expectation that the therapist had, for example:

> *"Anyone who was maybe fully dependent before, we would maybe think about whether it's worth our resource to get so involved. If someone came from a nursing home where*

they were well supported – they weren't particularly independent, then we would change our expectations for that person." (FG1, p4, lines 29-32)

This suggests that dependence prior to stroke may be an indicator that the guideline is not appropriate for an individual. However, therapists also discussed that the guideline was not appropriate for an individual if they have returned to their pre-stroke level of functioning:

"Some of our patients we deem not to require the 45 minutes, who are perhaps up and mobile already but they have had a stroke and actually giving them some cardiovascular fitness might benefit them, but our threshold is above that… we tend to think they're at their baseline and ability to cope to go home so we draw a line there and give them less than the 45 minutes." (FG2, p6 line 41 – p7 line 2)

In this case, it was considered that the person may benefit from therapy for their general fitness, but as they are functioning at their pre-stroke level, they are excluded from receiving the guideline. In both cases, knowledge of someone's pre-stroke functioning influenced therapy delivery. Other research reports finding that a person's pre-stroke functional level (Hakkennes et al. 2011; Gittins et al. 2020) and current ability (McGlinchey and Davenport 2015) influence therapy delivery.

5.4.1.3 Engagement with therapy

A person's engagement with therapy influences the amount they receive. Engagement is a complex concept, which includes the person's response to, participation with and tolerance of therapy, as well as their consent to therapy.

Therapists within this study identified that those making progress and engaging with therapy were more likely to receive the 45 minute guideline, with one of the groups highlighting that participation must be consistent:

"There's probably another group of patients that we'd maybe withdraw from, as well, that's the ones that aren't consistently… I think, for us, it's a lot about consistency, if they

do it one day but not the other and so on, it doesn't actually go anywhere." (FG2, p17 line 45 – p18 line 3)

There was no further explanation regarding why consistency was important, or why someone might not consistently participate. Potentially, it links to therapists' need to manage their time effectively by prioritising those who consistently participate.

A person's ability to tolerate 45 minutes of therapy also effects engagement. Other studies identify that reduced tolerance of therapy may result in less therapy delivered (Foley et al. 2012a; Clarke et al. 2018), a finding also identified in the focus groups:

"I guess, the drawback is that… maybe some of the lower-level patients just not being able to tolerate the full 45 minutes and then the difficulties and logistics of getting back to do smaller chunks more regularly with them in terms of our timetabling." (FG1, p20 line 45 – p21 line 2)

Before someone can respond to, participate in and tolerate therapy, they must give their consent. Participants report that those who don't consent to therapy do not receive therapy.

"If they've got capacity and they can make their own decisions and they don't want therapy… then that's their decision… they might not have therapy if that's not what they want." (FG2, p18, lines 8-12)

People may not consent to therapy, as they have other priorities. In the inpatient setting, receiving visitors was considered a competing priority, meaning people may not want therapy then. In the ESD setting, people may prioritise the desire to "get on with life" over therapy:

"…Especially if it's someone who doesn't get a lot of visitors and they've got one precious person, they've sat there all day on their own and the one time their visitors come, you want them… So it's getting, balancing what's the priority for the patient today…" (FG1, p25, lines 38-43)

> *"You get quite a variety as well, don't you, in terms of those who want the therapy and that's prioritised, and those who want to get on with life and that's prioritised…"* (FG2 p5, lines 27-30)

There were other non-specific priorities mentioned such as a person having an appointment or desire to use their time differently. No examples of the person's priorities impacting therapy delivery have been found in previous research.

5.4.2 Theme two: The individual therapist

Individual therapists' decision-making influences the amount of therapy delivered. Focus group findings suggest that therapists feel a significant personal responsibility for resource allocation. This manifests in therapists wanting to be person-centred but also managing their time as a finite resource.

5.4.2.1 Being person-centred

Being person-centred considers therapists' belief that people should receive the therapy that is best for them, regardless of guideline recommendations.

> *"It's not like we have a stop-clock it's purely like, well, I've done what I need to do, oh, it's only been 20 minutes, that's what they've needed, or that's only what they've managed to tolerate, or we've come out the gym and you're like, oh my gosh, we've been in there for 75 minutes, how did that happen, we got a bit carried away…"* (FG2, p11, lines 41-45)

This relates to both the amount of therapy people receive and also how they receive it. The groups discussed that a joint OT and PT session could be reported as two separate sessions in SSNAP. This group of therapists felt that such joint session should only be undertaken if it was in the person's interest and not to increase guideline achievement:

> *"We do that with patients… that will benefit from joint sessions as opposed to those who would tolerate 45 minutes of both separately, we don't do it as an alternative we do it because that's the best thing for the patient."* (FG2, p7 line 45 – p8 line 1)

Research suggests that therapists are person-centred when making decisions regarding the amount of therapy to provide, with Taylor et al. (2015) identifying that a person's individual characteristics effect amount of therapy delivered and McGlinchey and Davenport (2015) reporting the importance of including people in decisions about their therapy.

In addition to being person-centred, therapists identified the need to manage the expectations of people with stroke and their relatives/carers. Expectations of therapy may be based on people's awareness of the guideline and/or the therapy the person has already received:

> *"…They're expecting that they have had this daily therapy so far and they are continuing to expect this daily therapy and then you're taking that away and how they deal with that can be really tricky sometimes as well."* (FG1, p5, lines 17-19)

The need for therapists to justify discontinuation of therapy demonstrates that they feel responsible for decisions made regarding the amount of therapy provided.

5.4.2.2 Managing resources

Therapists believe they are "holding the purse strings"; that they are responsible for appropriate management of therapy time and this can impact decisions about therapy delivery:

> *"you wouldn't want to give them more therapy for the sake of giving them more therapy and actually prioritise them above someone else who will actually gain more from that input and intensity."* (FG2, p6 lines 26-28)

This quote speaks of the prioritisation of people for therapy, which links with the findings of McGlinchey and Davenport, that physiotherapists assign people as 'high' or 'low' priority for intervention, depending on factors that are tacitly understood (McGlinchey and Davenport 2015).

Participants discussed how other stroke-related targets, such as new assessment targets, create conflicting priorities for therapists. In one of the groups, a participant reported that rehabilitation was the third priority, after new assessments and discharges:

> *"We'd probably, well, we'd prioritise the new patient assessments first, over anything else or the discharges and then the rehab sessions after that."* (FG2, p28, lines 29-30)

The impact of managing new assessments and discharges on rehabilitation is identified in other research (McGlinchey and Davenport 2015; Taylor et al. 2015; Clarke et al. 2018; Taylor et al. 2018). These competing priorities are resource-based and potentially reflect a lack of flexibility within services.

5.4.3 Theme three: The stroke Multidisciplinary Team (MDT)

Reasons why someone might not receive 45 minutes of therapy related to the MDT. Findings from the focus groups suggest that competing healthcare priorities and therapist team decision-making effects the amount of rehabilitation a person receives.

5.4.3.1 Competing healthcare priorities

Competing healthcare priorities are other priorities within the MDT, which interfere with a person's therapy and were only discussed in relation to inpatients. In both groups, it was cited that the requirement to go for investigations could negatively impact a person's therapy input:

> *"And then there's always going to be other things that go on …you know, somebody might get called for chest x-ray"* (FG2, p4, lines 17-18)

Healthcare interventions provided by other members of the MDT were also identified as a reason why someone may not receive the guideline:

> *"Sessions may not start on time as well, you go to the patient, you've given them prior warning, when you get there, they need their medications, which haven't been given yet, their NGs still attached…"* (FG2, p14, lines 43-45)

This results in people being unavailable or unready for rehabilitation input. Research literature supports these findings. Foley et al. (2012a) suggest that people being off the ward affects therapy delivery. Other studies report that people's lack of readiness (including not yet dressed, not finished eating) impacts therapy delivery (McGlinchey and Davenport 2015; Taylor et al. 2015; Clarke et al. 2018).

5.4.3.2 Team decision-making

Other therapists (not directly treating the person) may influence the amount of therapy a person receives. Both focus groups reported therapist meetings, in which the caseload is discussed:

> *"…In our regular meetings, that's where those decisions are made at the MDT meetings, to decide actually they need this many sessions of Occupational Therapy …"* (FG2, p18 line 46 – p19 line2)

The purpose of these discussions is to aid appropriate allocation of resources; to ensure all people who required a minimum of 45 minutes of therapy received it, before addressing other priorities. However, within this discussion, there may be an element of team decision-making about the amount of therapy delivered and case discussion may influence individual therapists' decision-making. Similarly, Taylor et al. (2015) identifies that teamwork facilitates joined-up working across the MDT and therapists used daily MDT meetings to review the amount of therapy people receive.

5.4.4 Theme four: The organisation

Defined as the NHS organisation in which the person with a stroke is treated. This theme is concerned with service characteristics, resources and organisational politics. It identifies how some aspects of the organisation effects the amount of therapy a person receives.

5.4.4.1 Service characteristics

Service characteristics influence the delivery of the therapy guideline. People receiving Early Supported Discharge (ESD) input are less likely to receive the guideline, as they receive less therapy than inpatients. ESD is a model of stroke care, in which rehabilitation traditionally delivered in hospital is provided to those suitable in their own environment (Langhorne et al. 2017a). The RCP guidelines for stroke state that ESD input should imitate inpatient stroke unit care (Intercollegiate Stroke Working Party 2016). Thus, the therapy guideline remains applicable and is measured via SSNAP. The October-December 2018 SSNAP data reports people in ESD services received an average of 14.3 minutes and 16.1 minutes daily OT and PT respectively. For inpatients, these figures were 41.1 minutes and 35 minutes (Sentinel Stroke National Audit Programme 2018).

This study supports this, with both focus groups reporting that most people receiving ESD don't receive more than one session per day, even if they have more than one therapy involved:

> *"If they are patients who could really tolerate that higher intensity then they might have two 45 minute sessions or two therapies a day, but that's actually quite unusual and I think from a capacity point-of-view that's quite unusual and that's probably where the staff and the other factors start influencing…"* (FG2, p8, lines 27-30)

Whilst one of the focus groups discussed people receiving ESD only wanting one visit per day the other reported resource issues (such as staffing) impact people receiving more than one visit per day.

Theme one identified that someone receiving ESD may not prioritise therapy in favour of people wanting to "get on with life." Potentially, it is easier to provide therapy to people in hospital, as they are a captive audience, viewing therapy as a way of filling time, or facilitating their discharge. Additionally, people who receive ESD tend to have had a mild to moderate stroke (Intercollegiate Stroke Working Party 2016) and potentially have developed increased responsibility for themselves, as opposed to being reliant on healthcare professionals (Langhorne et al. 2017a).

The focus groups identified that a characteristic of ESD services that limits therapy delivery is the time-limited nature of services:

> *"You kind of start off with 'you're going to have 6 weeks of therapy' and when the 6 weeks is up it feels a bit more comfortable to say, 'we can't see you anymore'."* (FG2, p18, lines 14-16)

This suggests that people are discharged from ESD because they have received the service for a pre-determined amount of time, not because they are no longer benefiting from therapy, a requirement of the guideline. This is not identified as an issue for inpatients; however, inpatient therapists report the fast-pace and fluctuating caseloads, typical of the setting, makes therapy provision difficult:

"We have no control over the number of patients on our caseload." (FG2, p23, line 25)

To our knowledge, the effect of service characteristics on delivery of the 45 minute guideline has not been identified before in literature.

5.4.4.2 Resources

Resource availability influences therapy provision. Therapists believe that there are issues with both the number and availability of staff, which impacts guideline provision:

"Yeah, we do have days where there's maybe sickness or people taking TOIL days for weekends and it all accumulates on one bad day" (FG1, p23, lines 37-38)

Other research supports the finding that more staff results in improved achievement of the guideline (Clarke et al. 2018; Gittins et al. 2020) and sometimes, therapists make decisions about someone's suitability for therapy, based on resource availability (Taylor et al. 2018). Resource availability also impacts therapists' provision of more than once-daily therapy intervention, potentially limiting the provision of flexible, person-centred care. Therapists reported that when people find a single 45-minute session unmanageable, they attempt to provide multiple shorter sessions. However, this is challenging:

"So doing 3 lots of… fifteen minutes for every patient on your caseload… or the ones (who would benefit)… would be really tricky…" (FG1, p16, lines 7-14)

Therapists in focus group two reported that they were able to provide therapy in this manner, because they are adequately resourced to do so:

"Quite often we break our sessions up, so they may have 20 minutes in the morning and 25 minutes in the afternoon… we're lucky that we've got the staffing to be able to do that." (FG2, p4, lines 9-12)

The latest edition of the RCP guidelines for stroke recommend that people should "accumulate at least 45 minutes of each appropriate therapy every day" (Intercollegiate Stroke Working Party 2016 p.25) and that early after stroke, short, regular interventions are preferable. This is an update on the fourth edition of the RCP guideline, which did not include the word 'accumulate' and does not advise short, regular therapy sessions. Focus Groups' findings suggest that some settings find it challenging to provide multiple sessions, therefore, the inability to tolerate 45 minutes of therapy in a single session could be a reason why someone doesn't receive the recommended amount of therapy. Clarke et al. (2018) found that, when therapists were unable to deliver 45 minutes in one session, rarely did they return later.

5.4.4.3 Organisational politics

Focus group findings suggest political aspects within the organisation influence the delivery of the 45 minute guideline. Managers' interest in the 45 minute guideline may also affect its provision. Therapists believe that managers 'judge' their performance against the achievement of such guidelines:

> *"…Because it's more recognised by managers as something that we should be achieving or working towards and they're judging what we're doing…"* **(**FG1, p3, lines 2-3)

However, this has the benefit of protecting therapy staffing levels and highlighting staffing issues that have limited therapy delivery.

> *"We've been able to justify the amount of staff that we had… we have been able to say "Look – have you seen what our targets are? Do you know we have to see every patient for 45 minutes?" The only way you can do that is with a certain amount of staff."* (FG1, p3, lines 29-33)

The nature in which SSNAP measures achievement of the guideline, corresponding to a published indicator of quality for an organisation lends a political aspect to guideline achievement and may influence the perception of the guideline. Although there is no specific penalty for guideline non-achievement, Trusts that do not achieve it could be viewed as 'underperforming'. Taylor et al. (2018) reports concern amongst therapists regarding the effect that guideline performance may have on future commissioning decisions, specifically contract renewal, which could result in commissioner-centred care as opposed to patient-centred care.

5.4.5 Theme five: The guideline

The presence of the 45 minute guideline and its measurement effects the amount of therapy a person receives. It considers the guideline as a therapy prescription, whether the guideline represents good practice and the measurement of its achievement.

5.4.5.1 A therapy prescription

Therapists initially consider the guideline a "prescription" for the amount of therapy everyone should receive:

> *"When they first come in they're obviously having that daily input because everyone is for 45 minutes until you can, kind of, justify otherwise…"* (FG1, p21 line 46 – p22 line 1)

This suggests that therapists must provide justification if a person is not receiving the recommended minimum amount. Indeed, Clarke and colleagues found that the guideline (specifically its measurement via SSNAP) shapes therapy delivery, with some therapists feeling a conflict between their clinical judgement that the person can't tolerate a longer session and the implications this would have for their SSNAP score (Clarke et al. 2018). This conflict was demonstrated in the focus groups, with one therapist reporting that the requirement to provide everyone with 45 minutes of therapy may mean that those who require more than 45 minutes of therapy don't receive it:

> *"If you're not needing to see the slow stream ones every day, you can maybe then provide a higher intensity to the higher level patients and go back and see them again, because…..not that you can't do that now, you just don't have the time because of every other patient that you're trying to see for 45minutes…you don't have the opportunity to go back and see those patients that would really benefit from further input"* (FG1, p27 lines 15-21)

This indicates there may be conflict between a therapist achieving the guideline for someone whose therapy benefit is questionable and providing enhanced therapy to someone who will benefit.

The presence of the guideline prompts further decision-making when under-resourcing limits therapy delivery. Therapists described two options in these circumstances; to see all people for less time, or to see fewer people for more time:

> *"If you are low on staff, is it better that less patients are seen, but for 45 minutes and they might only get seen every other day or is it better that they get seen every day, but maybe only for a 20-minute session? I don't know…"* (FG2, p22, lines 23-26)

Potentially, practice differs between therapists in such situations, due to a lack of clarity regarding which approach provides the greater benefit. Finally, during the focus groups, the 45 minute guideline was regularly referred to as a target:

> *"It's sort of given you a little motivating target, as a therapist, that, have all of my patient's had 45 minutes today?"* (FG1, p15, lines 34-36)

It is not clear from the focus groups if therapy usually stops when 45 minutes is reached, or if it continues, provided this is appropriate for the person.

5.4.5.2 Is the guideline right?

Despite using the guideline to direct decisions about the amount of therapy provided, therapists acknowledge that 45 minutes isn't right for everyone. For some people, 45 minutes of therapy isn't enough:

> *"And some patients …they almost need a lot more than 45 minutes to justify them staying in for therapy."* (FG1, p26 line 38 – p27 line 2)

In both focus groups, therapists report that their sessions are not limited to 45 minutes, if people required more than this:

"…if we were going to do something in the community for their goals and it's going to take longer, we factor that in, because that's their goal, that's what they want to do, whether it's getting back in the swimming pool, whatever… so we don't just go "I can't do that in 45 minutes, we can't do that activity." (FG2, p24, lines 5-10)

For other people, it's acknowledged that therapy schedule, not just amount, may be important:

"sometimes you feel like, actually, patients would benefit from a bit more little and often, rather than a 45 minute block." (FG1, p16, lines 7-9)

However, participants concurred that, for most people, the recommended minimum of 45 minutes was appropriate:

"Most people would, sort of, tolerate 45minutes, whereas, like, an hour for everybody, you know, it's not going to be realistic, but then half an hour you wouldn't get much done either, so it's kind of a nice balance." (FG1, p.20, 35-37)

5.4.5.3 Measuring guideline achievement

Throughout the focus groups reference was made to the measurement of the guideline achievement via the SSNAP audit. At times, it appeared that the two entities (the 45 minute guideline and the SSNAP audit) were interchangeable, meaning the same thing to therapists. They felt that, although time-consuming, auditing the guideline was beneficial, as it has raised its profile:

"I think it's helped highlight it… the need to do the 45minutes… there was such a push for, you have to get all of these patients in… and getting a good score." (FG1, p15, lines 5-14)

There was also discussion in the focus groups that SSNAP data collection for therapy stops when people no longer have active therapy goals:

> *"Once they've achieved their, or they've not achieved their goals then they're discharged and that's their SSNAP data done."* (FG2, p7, lines 19-20)

The practice of no longer recording SSNAP data when a person is no longer receiving therapy is identified by Taylor et al. (2018). Similarly, Clarke et al. (2018) reports inconsistency between stroke units regarding the recording of maintenance therapy. The practice of ceasing SSNAP recording is at odds with SSNAP guidance, which states that, prior to discharge, SSNAP recording for therapy should cease when a person no longer has a deficit (Intercollegiate Stroke Working Party 2021). It is therefore possible that some people may not receive the guideline, as they have been discharged from SSNAP recording.

5.5 Discussion

5.5.1 Summary of findings

This study undertook focus groups with therapists, asking why a person with stroke might not receive the recommended minimum of 45 minutes of Occupational Therapy and Physiotherapy, 5 days-per-week. Findings of this study suggest that reasons why a person do not receive the therapy recommendation in inpatient and ESD services relate to either suitability of the guideline for the person with stroke or the ability of the service to deliver the guideline.

Suitability of the guideline for the person with stroke depends on factors such as their medical status, their cognition, how well they are engaging with therapy and therapists' belief that they will benefit from therapy. SSNAP data indicates that Occupational Therapy and Physiotherapy are suitable for 80% and 85% of people respectively. However, some of the factors related to guideline suitability found in the focus groups indicate that there are people who are suitable for therapy, but are not consistently suitable for the 45 minute recommendation. It is not known if therapists use the same criteria to judge suitability for the guideline, or if there are inconsistencies between therapists' judgements, which could result in unwarranted variation in therapy delivery. The ability of the service to deliver the 45 minute guideline is due to lack of resources, therapists' competing priorities and issues related to the organisation of stroke care,

findings that align with other research (Clarke et al. 2018; Gittins et al. 2020). Our findings suggest that the suitability of the guideline and organisations' ability to deliver the guideline are linked, as therapists are required to choose between achieving the 45 minute guideline for someone whose therapy benefit is questionable and exceeding the 45 minute guideline for someone whose therapy benefit is clear. They makes these, and other decisions about therapy allocation against a background of under-resourcing. Lack of therapy resources results in therapists having to make hard choices, for which they feel significant personal responsibility.

In addition, there are factors that influence the delivery of therapy, such as organisational politics and the guideline itself, including whether therapists believe it to be appropriate. These factors potentially vary between therapists and/or organisations which could lead to further inconsistency in therapy delivery.

Figure 13 Pictorial Representations of Themes

The findings are organised into five themes (figure 13). Although the themes above are described in a linear fashion, they are interwoven. Figure 13 and its description demonstrate that reasons why a person might not receive the guideline recommendation are complex. It suggests that the person is at the centre delivery of the guideline recommendation and, with their relatives/carers, interact with the therapist in a collaborative relationship. The therapist works within a stroke MDT. The therapist reports a person's progress to the team and may gain advice or additional information from them. The MDT is situated within an organisation. The organisation dictates the structure of the MDT and the MDT, 'provides' the organisation with a stroke service. There are also other potential connections and relationships between these groups. For example, a

person with stroke's previous experience of an organisation may shape their expectations of the individual therapist; an organisation's culture may influence an individual therapist. Surrounding these interconnected groups is the guideline for 45 minutes of therapy, which has influence and importance at each level. One of the potential benefits of the 45 minute guideline is its simplicity; it is relatively simple to understand and to measure. This simplicity contrasts with the obvious complexity related to its non-delivery found in this study.

5.5.2 Strengths and weaknesses of this study

To our knowledge, no other studies have explored delivery of the guideline beyond the inpatient setting; by including therapists with experience in early supported discharge, this study was able to consider the applicability of this guideline in the community. The groups were pre-existing teams, which, while reducing breadth, aids group familiarity which has been shown to increase truthfulness (Barbour 2018). Nevertheless, group members may have felt unable to disclose certain beliefs, due to concerns regarding judgment and a possible lack of confidentiality (Barbour 2018). Taylor and colleagues found that "rivalry and mistrust" (Taylor et al. 2018 p.7) between services was apparent when discussing the SSNAP audit, so the presence of a clinician from another trust (BC) may have influenced the data collected. Recruiting participants from further afield may have reduced this issue. A further limitation was that there were no focus group members below band 6, meaning the practice of less experienced therapists was not explored. Due to the small number of participants, it is not possible to generalise the findings of this study to the wider stroke therapist population. However, the aim of this study was to explore reasons why the guideline was not achieved to inform the design of the subsequent Delphi Study (Clark et al. 2021b).

5.5.3 Findings of this study in the context of prior research

Despite the identified areas of agreement there are also differences between the findings of this study and those of similar studies. Other studies have found additional factors that affect the amount of therapy delivered. Gittins et al. (2020) found that people with severe strokes received less therapy than those with milder symptoms. The focus groups did not identify that severity of stroke influences therapy provision, although they did discuss the influence of medical issues on guideline delivery. Therapists may not believe that it is the severity of stroke per se that influences the guideline delivery, but rather the resultant medical complications. Alternatively, it may be that therapists are uncomfortable with the idea that people with severe strokes receive less therapy without evidence to support such a decision. Research has identified other factors related to the person with stroke that were not identified by focus group participants, possibly

because they did not consider them relevant, such as level of social support (Hakkennes et al. 2011; Otterman et al. 2012), gender (Gittins et al. 2020) and ethnicity (Taylor et al. 2015; Gittins et al. 2020). Prior research has identified that the time therapists spend in non-clinical tasks (e.g. information exchange, paperwork and training), influences the amount of therapy delivered (McGlinchey and Davenport 2015; Clarke et al. 2018). Therapists in the focus groups did not identify this, potentially because they don't recognise that these tasks limit therapy delivery.

Consistent with other studies (McGlinchey and Davenport 2015; Clarke et al. 2018), focus group participants did not refer to evidence when discussing guideline delivery. Potentially, therapists believe that the guideline is based on sound research evidence and therefore, they do not need to consider further evidence. Alternatively, it may be that many therapists rely on their clinical experience, rather than research, to inform decision-making (Salbach et al. 2010).

A unique finding of this study is the application of the guideline in ESD services. Focus group findings suggest there are issues with the implementation of this guideline in ESD, suggesting that people with stroke don't always want this intensity of input once home and some ESD services are not resourced to provide the guideline level of intervention. Although the guideline states the person should receive therapy "…for as long as they are willing and capable of participating and showing measurable benefit from treatment" (Intercollegiate Stroke Working Party 2016 p.25) it was acknowledged that their ESD services were time-bound, meaning that potentially, therapy has to stop even though a person may continue to benefit from receiving it.

Post data-analysis, it was noted that the findings of this study show some similarities to the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al. 2009). This is a meta-theoretic framework, derived from a synthesis of implementation models, to provide a framework to either evaluate the implementation of research into clinical practice, or to design an implementation study. The CFIR presents five domains that influence implementation; these are the individuals involved, the inner setting, the outer setting, the intervention characteristics, and the implementation process. The CFIR domains show some overlap with the five themes identified in this present study. The person and the individual therapists are the individuals involved, features of the MDT and the Organisation parallel with features of the inner setting and the outer setting respectively, and the guideline parallels with the intervention characteristics. These parallels likely exist as the 45 min has been (and continues to be) implemented into clinical

practice. The present study does not present any findings about the implementation process, possibly because this was not the objective of the study. Potentially, further analysis of the implementation of the 45 minute guideline utilising the CFIR may highlight ways to improve the implementation of the guideline in clinical practice.

5.5.4 Findings of this study in the context of clinical practice

The guideline for 45 minutes of Occupational therapy and Physiotherapy is based on consensus as opposed to research evidence (Intercollegiate Stroke Working Party 2016) and is not achieved for all people suitable for therapy after stroke. This study has identified reasons why some people don't receive this level of intervention and the factors that influence therapy delivery in the context of the guideline. To our knowledge, it is the first study to use focus groups to explore this question and the findings support the findings of other studies that have examined similar questions using ethnography (Taylor et al. 2018) and mixed-methods case studies (Clarke et al. 2018). Whilst the guideline is very clear in terms of the expectation for therapy delivery, services would benefit from clear guidance regarding the staffing numbers required to deliver the recommendation across the stroke pathway (including ESD) to support service managers in the development of business cases. Whilst the RCP has provided comprehensive guidance for SSNAP reporting, therapists may benefit from clear, concise, evidence-based guidance for implementation of the guideline in clinical practice, particularly regarding how to reduce administrative burden on therapists to optimise face-to-face therapy time and prioritisation criteria when resources limit delivery.

5.6 Conclusions

This study has provided evidence for the reasons why 63% of people receiving OT and 66% of people receiving PT in England, Wales and Northern Ireland (Bahalla et al. 2021) don't receive a minimum of 45 minutes of therapy, five days per week. Reasons relate to 1) the consistent suitability of the guideline for people with stroke and 2) services' ability to delivery this amount of intervention. These two factors are related; therapists decide who should receive therapy and how much in the context of a) resource availability and b) people's need and the benefit they will experience. The requirement to deliver on the 45 minute guideline, may be at odds with clinical judgement. One consequence of these findings is that the 45 minute guideline may not be fit for purpose; it may not improve quality of therapy provision and may not reduce unwarranted variation between services and should be reviewed.

Focus group findings contributed to the development of statements for the first round of a Delphi study that gained consensus from wider group of Physiotherapists and Occupational Therapists regarding the reasons why a person may not receive 45 minutes of therapy after stroke.

Chapter 6 Why do some people with stroke not receive the recommended 45 minutes of Occupational therapy and Physiotherapy? Consensus from a Delphi study

6.1 Introduction to chapter

This chapter presents a Delphi study undertaken to gain consensus for reasons why some people with stroke do not receive the recommended minimum of 45 minutes of therapy. Building on the findings of the focus, this study was undertaken to answer the second research question: Why do people with stroke not always receive the recommended minimum amount of therapy? This paper, with the focus group paper presented in the previous chapter, will be submitted as a pair to BMJ open. The paper is presented here-in.

Title: Why do some people with stroke not receive the recommended 45 minutes of Occupational Therapy and Physiotherapy? Consensus from a Delphi Study

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6.2 Introduction

Following a stroke, people participate in occupational therapy and physiotherapy as part of in-patient (Langhorne et al. 2020) and Early Supported Discharge (ESD) services (Langhorne et al. 2017a). These therapies are appropriate for 80% and 85% (respectively) of people as part of inpatient stroke unit care (Royal College of Physicians 2014) and aim to support recovery from stroke. The Royal College of Physicians (RCP) provides guidelines for the management of stroke care in England, Wales and Northern Ireland. This includes a specific recommendation regarding amount of rehabilitation to be delivered:

> "People with stroke should accumulate at least 45 minutes of each appropriate therapy every day, at a frequency that enables them to meet their rehabilitation goals, and for as

> long as they are willing and capable of participating and showing measurable benefit from treatment". (Intercollegiate Stroke Working Party 2016 p.25)

According to the Sentinel Stroke National Audit Program (SSNAP), therapy should be goal directed, provided to either an individual or a group. It includes home visits (where the person Is present) and training of people with stroke and their carers. It does not include non-person contact activities, such as documentation and case reviews (Intercollegiate Stroke Working Party 2021). The Sentinel Stroke National Audit Program (SSNAP) reports that 34% of people considered appropriate for Physiotherapy and 37% for Occupational Therapy received this guideline amount (Bahalla et al. 2021), based on delivery of therapy five days-a-week. It is unclear why not all people considered appropriate achieve this amount of rehabilitation.

Other research has considered factors that influence therapy provision post stroke using mixed-method case-studies (Clarke et al. 2018), ethnography (McGlinchey and Davenport 2015; Taylor et al. 2018) and secondary analysis of SSNAP data (Gittins et al. 2020). Collectively, these studies found that availability of resources (in terms of therapists' time) and clinical presentation of people with stroke influence therapy provision (McGlinchey and Davenport 2015; Clarke et al. 2018; Taylor et al. 2018; Gittins et al. 2020). Although some of these studies have included therapist interviews (McGlinchey and Davenport 2015; Clarke et al. 2018; Taylor et al. 2018), to our knowledge, no study has aimed to gain consensus from therapists on reasons why the 45 minute guideline is not always achieved. Neither have previous studies considered deliver of the 45 minute guideline beyond the inpatient setting.

In previous work, we have undertaken therapist focus groups, which provide additional insights into why people might not receive the recommended minimum amount of therapy from the perspective of those delivering intervention (Clark et al. 2021a). We have used the finding of these focus groups to inform this study, which aims to gain consensus from Occupational Therapists and Physiotherapists regarding the reasons why some people with stroke do not receive the recommended minimum of 45 minutes of therapy, five days-a-week, and the factors that influence therapy provision, in inpatient and community settings.

6.3 Methodology

Ethical approval for this study was obtained from the University of Southampton (ERGO II 17994). All participants provided electronic consent for the Delphi process at recruitment.

6.3.1 Study Design

A Delphi methodology was used to gain consensus (Murphy et al. 1998; James and Warren-Forward 2015). Three iterations of electronically administered questionnaires presented a series of statements. Participants rated their level of agreement with the statements, using Likert scales. After each round, responses were summarised and reported back to the participants. Statements which achieved consensus were removed and those which did not achieve consensus were revised and included in the next Delphi round. This process continued, until further consensus was considered unachievable.

Delphi statements were developed using our focus group data, (Clark et al. 2021a) and relevant research literature (Ilett et al. 2010; Skidmore et al. 2010; Hakkennes et al. 2011; Foley et al. 2012a; Otterman et al. 2012; McGlinchey and Davenport 2015; Taylor et al. 2015; Clarke et al. 2018; Taylor et al. 2018). BC collated fifty-one, first round statements into a 6-part questionnaire (with headings: about you, reasons related to the stroke survivor, reasons related to the individual therapist, reasons related to the stroke MDT, organisational reasons, and the guideline and its measurement). A Physiotherapist, who met the selection criteria below, piloted the statements to test acceptability and ensure there were no ambiguities. Statements were revised accordingly. For each Delphi statement, participants rated their agreement using a 6-point Likert scale. Responses ranged from strongly disagree to strongly agree. Statements that were experience-dependent also included the option “unable to answer based on my experience.” For all statements, participants had the opportunity to comment and, in round one, to suggest further criteria for consideration.

Prior to data collection, consensus was defined as 75% agreement. There is no universally recognised definition of consensus for a Delphi study (Fink et al. 1984; Vernon 2009), but values of around 70% are common (Vernon 2009), and the agreement of 3 out of 4 clinicians was considered reasonable consensus.

6.3.2 Recruitment

Target recruitment for the Delphi was 30 – 50 participants (Murphy et al. 1998; Black 2006), who met the following criteria:

- Occupational Therapist or Physiotherapist
- Experience in delivering therapy after Stroke (in inpatient, ESD or community)
- Aware of the 45 minute guideline

Participants were recruited via specialist interest groups (Royal College of Occupational Therapists; Specialist Section for Neurological Practice and Association of Chartered Physiotherapists in Neurology), with the request that group members forward the invitation to anyone else who may be interested in participating. Those that met the criteria (self-reported) and consented were included in the study[3]. Nominal demographic data were collected to characterise the study sample.

6.3.3 Data Collection

Data were collected electronically, using the University of Southampton iSurvey software (www.isurvey.soton.ac.uk). After providing written informed consent, participants were given a link to the first round of the Delphi questionnaire. Participants had a minimum of 4 weeks to complete round one. Round one was analysed (details below) prior to round two's development and distribution to participants. The same process was undertaken for round three. Only participants who had completed the previous round were eligible to participate in the next round.

6.3.4 Data Analysis

The 6-point Likert scales were divided into thirds, to indicate agreements (strongly agree/agree) disagreement (strongly disagree/disagree) or an ambiguous outcome (slightly agree/slightly disagree) (Black 2006). In addition to this descriptive analysis, median of scores and interquartile range are presented, to demonstrate the distribution of opinion. Median and IQR were generated by giving each Likert scale response a numerical score, from 1 (strongly disagree) to 6 (strongly agree) and calculated using Microsoft Excel. Analysis of the Delphi statements adhered to the following iterative process for each of the three rounds:

[3] [3] Please see Appendix SS for the Participant information sheet and Appendix TT for the consent form

Step one - Statements that achieved consensus (75% or more respondent agreement in either agreement, disagreement or an ambiguous outcome) were removed from the Delphi questionnaire.

Step two – statements for which consensus was not achieved were reviewed by three authors (BC, JT and JB) and either reworded for inclusion in the following round or excluded if participants' responses suggested that consensus was unlikely. These decisions were made in the context of the spread of responses and content analysis of participants' comments. A table was developed to manage the statement review process (Table 7, which gives examples of statements reviewed). Full analysis of all the Delphi statements can be found in Appendix UU.

Following completion of round one, additional topics for consideration identified by participants were reviewed and statements added to round two. In rounds two and three, any statement that was reworded from the previous round included a link to the results of the previous statement, so participants could consider their response in relation to the group response in the previous round.

Table 7 Example of table used to review Delphi statements

Concept	Original Statement	Agreement – Thirds	Agreement – Binary*	Relevant Comments	New Statement
Effect of impaired attention on therapy delivery	Round 1 - A therapy session may end if the stroke survivor is not able to maintain appropriate attention to the therapy input	Disagree - 2.9% Ambiguous - 31.4% Agree - 65.7%	Disagree – 8.6% Agree – 91.4%	"Dependent on the reasons for this impaired attention - if other approaches or methods are not successful." (strongly agree) "Part of the OT session will be to improve their attention- starting with shorter sessions as tolerated" (slightly disagree) (Many comments allude to the use of strategies)	A therapy session may end if the stroke survivor is not able to maintain attention to the therapy input, despite strategies to assist with maintenance of attention
	Round 2 - A therapy session may end if the stroke survivor is not able to maintain attention to the therapy input, despite strategies to assist with maintenance of attention	Disagree – 6.9% Ambiguous – 24.1% Agree – 69%	Disagree – 6.9% Agree – 93.1%	**"**Therapy may be to increase attention" (disagree) "Need to find other strategies" (slightly agree) "In our unit we would probably take a little and often approach to patients like this or jointly treat with psychology or OT" (slightly agree) "I may first adjust the task to engage the patient" (Slightly agree)	A therapy session may end if the stroke survivor is not able to maintain attention to the therapy input, despite strategies to increase and/or motivate attention

Concept	Original Statement	Agreement – Thirds	Agreement – Binary*	Relevant Comments	New Statement
				"May continue with passive ROM and positioning" (slightly agree)	
If another HCP is seeing the person at the time of the therapy session	Round 1 - A stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session	Disagree – 17.1% Ambiguous – 42.9% Agree – 40%	Disagree – 34.3% Agree – 65.7%	"Timetabling as a team can avoid this" (slightly disagree) "We would endeavour as an MDT not to double book." (disagree) "within ESD this is timetabled to ensure this does not happen - the ward should work similarly and all professionals talking to each other" (slightly disagree) (ESD/Community avoid this issue by timetabling sessions)	In the acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session
	Round 2 - In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the	Disagree – 10% Ambiguous – 40% Agree – 50%	Disagree – 20% Agree – 80%	"we attempt to timetable patients who are needing all three AHPS to ensure this doesn't happen." (slightly agree) "timetabling/planning close communication can overcome this issue" (slightly disagree) "We can be flexible and either join their session or come back later" (slightly disagree)	In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session and I

Concept	Original Statement	Agreement – Thirds	Agreement – Binary*	Relevant Comments	New Statement
	time of their therapy session			"Depends on professional - sometimes can join session" (slightly agree)	am unable to reschedule
	Round 3 - In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session and I am unable to reschedule	Disagree – 0% Ambiguous – 26.32% Agree – 73.68%	Disagree – 0% Agree – 100%	"will try and organise another team member" (slightly agree) "This does happen in practice and is indicative of poor organisation of services for which the patient suffers through no fault of their own." (strongly agree) "We attempt to avoid this by timetabling." (agree) "typically it would be possible to reschedule and efforts are made to do this." (slightly agree)	Very close to consensus agreement – and binary agreement = 100%

*Binary agreement was not used to analyse consensus, but to indicate to researchers if the responses were tending towards agreement or disagreement, or if there was an equal split.

This helped to guide decisions regarding statement re-wording and decisions about removal of statements in consensus was considered unlikely.

Three rounds were undertaken, between October 2019 and May 2020. A fourth round was considered, but not executed, as the number of respondents had dropped and there was potential for increased pressure on participants, due to the Covid-19 pandemic.

6.3.5 Patient and Public involvement

This study is part of a wider programme of work, within which the opinions of people with stroke on the 45 minute guideline have been sought. However, as this study is specifically about therapists' implementation of the guideline, the opinions of people with stroke did not directly influence this study.

6.4 Results

Forty-five participants consented to study participation and 35 (78%) completed round one. Of the 35 that completed round one, 29 (83%) completed round two and 26 (90%) completed round three. Please see table 8 for participant details.

Table 8 Participant information

		Round One	Round Two	Round Three
Total Number	(Physiotherapist/ Occupational Therapist)	35 (20/15)	29 (16/13)	26 (12/14)
Years experience working with people with stroke	Less than 1 year	2	0	0
	1 year	0	0	0
	2 years	1	1	0
	3 years	1	3	2
	4 years	2	1	3
	5 years	2	2	2
	6 years	4	3	1
	7 years	3	2	4
	8 years	2	1	0
	9 years	2	1	2
	10-15 years	8	9	6
	16+ years	8	6	6
Therapists' seniority*	Band 5	1	1	1
	Band 6	16	13	13
	Band 7	14	11	9
	Band 8a	4	4	3
Area(s) of stroke care participants consider themselves experienced in	Hyper-acute inpatient	16	14	14
	Inpatient	29	22	20
	ESD	15	12	11
	Community-based rehabilitation	13	10	11

*Band 5 – Entry level for newly qualified therapists, Band 6 – Senior therapist, Band 7 - Advanced therapist/team lead, Band 8a – Clinical specialist/service lead

Across the three Delphi rounds, a total of 121 statements were presented to participants. Of these, 32 statements reached consensus (see tables 9 and 10). These tables give the round of the Delphi in which the statement gained consensus, the statement, the number of participants that contributed to consensus, the results of the consensus (percentage and median (IQR)) and whether the statement relates to a reason for guideline non-achievement or a factor that influences therapy delivery. A further 37 statements were removed from the process (see table 11). This table presents the concept addressed in various statements, the Delphi round in which the statement was presented, the statement, the result (percentage agreement, disagreement or an ambiguous outcome), the reason the statement was removed from the Delphi study and whether the statement relates to a reason for guideline non-achievement or a factor that influences therapy delivery. Please see figure 14 for a flow-chart of the movement of statements through the Delphi rounds.

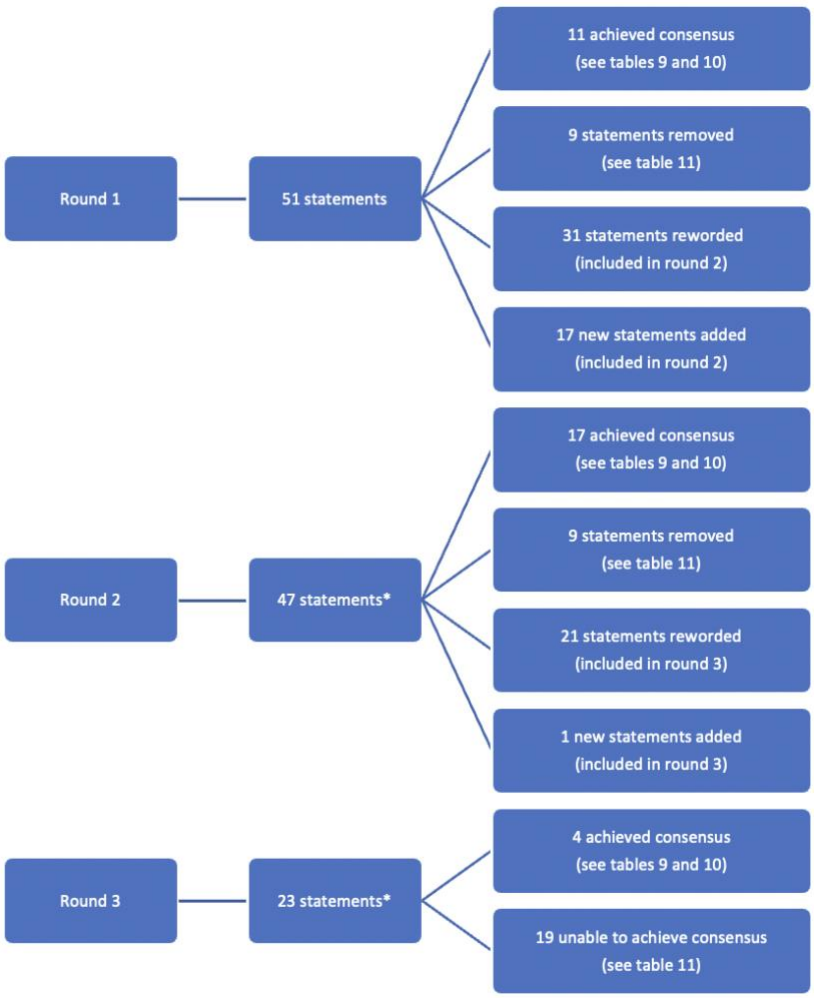

Figure 14 Flow-chart of the movement of statements through the Delphi rounds

In each round, statements that achieved consensus were removed and added to table 5 or 6, statements that were unsuitable to remain in the study were removed and added to table 7, the remaining statements

were reworded and included in the next round of the Delphi and new statements were added to the next round of the Delphi as identified.

*One statement inadvertently missed from round 2 and added to round 3

Of the 32 statements which reached consensus, 25 statements were agreed (see table 8) and seven were disagreed (see table 9). There were no statements with an ambiguous outcome (i.e. slightly agree/slightly disagree). Of the statements that were agreed, 10 related to the suitability of the person for the guideline, 11 relate to the ability of the organisation to provide the guideline and four were contextual factors that influence therapy delivery. Of the statements that were disagreed, five related to the suitability of the person for the guideline and two were contextual factors (i.e., there was consensus that these were NOT reasons/factors why someone would be considered inappropriate for the guideline).

Of the 37 statements removed, 32 were removed as consensus was considered unachievable and the remaining statements were removed as they were contained in other statements. Some of the 37 statements removed had been reworded from previous Delphi rounds (see table 10).

Table 9 Statements for which there was consensus agreement

Delphi Round	Statement	No. of participants	Results		Reason or factor
			Percentage	Median (IQR)*	
1	A Stroke survivor may not receive 45 minutes of therapy for medical reasons (such as unstable blood pressure, chest infection, nutritional status etc.)	35	Agreement (77%)	5 (5-6)	Reason
1	A therapy session may end if the stroke survivor is not tolerating the therapy input	35	Agreement (86%)	5 (5-6)	Reason
1	A Stroke survivor may not receive the recommended amount of therapy if they do not consent to therapy	34	Agreement (85%)	5 (5-6)	Reason
1	If a stroke survivor has returned to their pre-stroke level of functioning, they are less likely to continue to receive 45 minutes of therapy daily	34	Agreement (94%)	5.5 (5-6)	Reason
1	My knowledge and understanding of stroke recovery effects the decisions I make regarding amount of therapy I provide to stroke survivors	34	Agreement (76%)	5 (4.75-6)	Factor
1	It is important that I can justify the decisions I have made about the amount of therapy a stroke survivor receives	35	Agreement (94%)	5 (5-6)	Factor
1	The therapy a stroke survivor receives should be based on what they need, not on a pre-specified amount	35	Agreement (88%)	6 (5-6)	Factor
1	Stroke survivors may not receive 45 minutes of therapy in the acute setting, due the caseload being very large at times**	32	Agreement (87%)	5 (5-6)	Reason
1	Lack of therapy staff, can be a reason why a stroke survivor does not receive 45 minutes of therapy	35	Agreement (88%)	6 (5-6)	Reason
2	If there is agreement that a stroke survivor is persistently failing to make progress in therapy, they are unlikely to continue to receive 45 minutes of therapy daily	29	Agreement (83%)	5 (5-6)	Reason
2	In the community, a Stroke survivor may not receive 45 minutes of therapy if they feel it more important to get on with their life	21	Agreement (81%)	5 (5-5)	Reason

Delphi Round	Statement	No. of participants	Results		Reason or factor
			Percentage	Median (IQR)*	
2	Fatigue is a reason why a stroke survivor may not tolerate 45 minutes of therapy (particularly if they are receiving multiple therapies)	29	Agreement (83%)	5 (5-6)	Reason
2	In the Hyperacute Stroke Unit, A stroke survivor may not receive 45 minutes of therapy due to new patient assessments being seen as a priority	18	Agreement (89%)	5 (5-6)	Reason
2	In the Hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy due to patient discharges being seen as a priority	20	Agreement (80%)	5.5 (5-6)	Reason
2	In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy because of the size of the therapists' caseload**	20	Agreement (80%)	5 (5-6)	Reason
2	Within teams I have worked in non-patient contact activities (such as handover, MDT meetings, planning therapy sessions, ordering equipment and paper work) can limit therapists' ability to deliver 45 minutes of therapy to stroke survivors	27	Agreement (89%)	5 (5-6)	Reason
2	The decisions I make about the amount of therapy I provide to a stroke survivor are not influenced by the stroke survivor, relative/carers' knowledge of the 45 minute guideline	28	Agreement (75%)	5 (4.25-6)	Factor
2	In the in-patient setting, a stroke survivor may not receive 45 minutes of therapy if they need to go off the ward for a medical investigation and I am unable to reschedule their therapy that day	26	Agreement (88%)	5 (5-6)	Reason
2	The fast-paced nature of the hyperacute/acute setting can make delivery of 45 minutes of therapy more challenging	18	Agreement (89%)	5 (5-6)	Reason
2	Due to the time-limited nature of many ESD services, some stroke survivors are discharged from ESD when they would still benefit from 45 minutes of therapy, 5 days per week	16	Agreement (88%)	5.5 (5-6)	Reason
2	In ESD, it is difficult to return to a stroke survivor for a second time in a day, if they are unable to tolerate 45 minutes of therapy in one session	14	Agreement (86%)	5.5 (5-6)	Reason

Delphi Round	Statement	No. of participants	Results		Reason or factor
			Percentage	Median (IQR)*	
2	If therapists are off sick in my organisation, then some stroke survivors may not receive 45 minutes of therapy	28	Agreement (93%)	5 (5-6)	Reason
3	A therapy session may end if the stroke survivor is not able to maintain attention to the therapy input, despite strategies to increase and/or motivate attention	26	Agreement (80.8%)	5 (5-5)	Reason
3	In some circumstances a stroke survivor who remains unmotivated despite efforts to increase or manage motivation may not receive 45 minutes of daily therapy	26	Agreement (84.6%)	5 (5-5)	Reason
3	If a stroke survivor consistently does not participate in therapy, despite efforts to encourage and enable participation, then they may not be prioritised for daily therapy	26	Agreement (80.8%)	5 (5-5)	Reason

*Median and IQR calculated by transforming descriptive result to a numerical. 1 = strongly disagree, 2 = disagree, 3 = slightly disagree, 4 slightly agree, 5 = agree, 6 = strongly agree

**Statements noted to be similar. This is due to the convergence of two different statements, in response to comments made by participants

Table 10 Statements for which there was consensus disagreement

Delphi Round	Statement	No. of participants	Result	Median (IQR)*	Reason or a factor
1	How I am feeling (including my mood and physical comfort) influences the decisions I make regarding amount of therapy I provide to stroke survivors.	35	Disagreement (80%)	2 (1-2)	Factor
1	If a stroke survivor is not appropriate for 45 minutes of therapy-per-day, then they are not appropriate for any therapy	35	Disagreement (97%)	1 (1-1)	Factor
2	If a stroke survivor remains very dependent on care, they won't continue to receive 45 minutes of therapy daily	29	Disagreement (76%)	2 (2-2.5)	Reason
2	A stroke survivor will not receive 45 minutes of therapy if they lack comprehension of spoken language	29	Disagreement (93%)	1 (1-2)	Reason
2	In an inpatient setting, a Stroke survivor may not receive 45 minutes of therapy due to social issues (such as lack of social support, addiction or social complexity)	27	Disagreement (93%)	1 (1-2)	Reason
2	If a stroke survivor if of a low educational level, then they may not receive 45 minutes of therapy	29	Disagreement (97%)	1 (1-1)	Reason
3	If a stroke survivor is able to undertake ANY independent exercise, then they won't receive 45 minutes of therapy	26	Disagreement (76.9%)	1 (1-2.25)	Reason

*Median and IQR calculated by transforming descriptive result to a numerical. 1 = strongly disagree, 2 = disagree, 3 = slightly disagree, 4 slightly agree, 5 = agree, 6 = strongly agree

Table 11 Statements where consensus wasn't reached

Concept	Delphi round	Statement	Result	Reason removed	Reason or factor
1. The effect of social Issues in the community	1	A Stroke survivor may not receive 45 minutes of therapy due to social issues (such as lack of social support, addiction or social complexity)	Disagree – 70.6% Ambiguous – 14.7% Agree – 14.7%	Unable to gain consensus	Reason
	2	In a community setting, a Stroke survivor may not receive 45 minutes of therapy due to social issues (such as lack of social support, addiction or social complexity)	Disagree – 50% Ambiguous – 25% Agree – 25%		
2.Dependence on care prior to stroke	1	If a stroke survivor was dependent on care before they had a stroke, they are less likely to continue to receive 45 minutes of therapy daily	Disagree – 55.9% Ambiguous – 32.4% Agree – 11.8%	Unable to gain consensus	Reason
	2	If a stroke survivor was *fully* dependent on care before they had a stroke, they are less likely to continue to receive 45 minutes of therapy daily	Disagree – 37.9% Ambiguous – 27.6% Agree – 34.5%		
3.Engagement in therapy	2	If a stroke survivor is not engaging with therapy (possibly because they lack insight into their impairments and/or are not accepting of their need for therapy) then they may not receive 45 minutes of therapy.	Disagree – 37.9% Ambiguous – 41.4% Agree – 20.7%	Considered too like statement about participation	Reason
4. Effect of low mood	1	A Stroke survivor may not receive the recommended amount of therapy if they are low in mood.	Disagree – 23.5% Ambiguous – 47.1% Agree – 29.4%	Unable to gain consensus	Reason
	2	If a stroke survivor's low mood is limiting their therapy engagement, despite efforts and intervention to address it, then they may not receive 45 minutes of daily therapy	Disagree – 10.3% Ambiguous – 31% Agree – 58.6%		

Concept	Delphi round	Statement	Result	Reason removed	Reason or factor
	3	A stroke survivor may not receive a full 45 minutes of daily therapy if their low mood limits their engagement, despite amendments to their therapy	Disagree – 3.9% Ambiguous – 26.9% Agree – 69.2%		
5. Presence of visitors	1	A Stroke survivor may not receive the recommended amount of therapy if they have visitors	Disagree – 41.2% Ambiguous – 44.1% Agree – 14.7%	Unable to gain consensus	Reason
	2	A stroke survivor who declines therapy in preference to spending time with their visitors may not receive 45 minutes of daily therapy	Disagree – 13.8% Ambiguous – 31% Agree – 55.2%		
	3	A stroke survivor who declines therapy in preference to spending time with their visitors (despite the importance being explained to them) may not receive 45 minutes of daily therapy	Disagree – 3.85% Ambiguous – 23.08% Agree – 73.08%		
6. Person with stroke having other priorities	1	A Stroke survivor may not receive 45 minutes of therapy if they have other priorities (such as an appointment or a wish to do something else at the time they are offered therapy).	Disagree – 8.8% Ambiguous – 26.4% Agree – 61.8%	Unable to gain consensus	Reason
	2	A Stroke survivor may not receive 45 minutes of therapy if they express a lack of interest in therapy in preference to other activities (such as a non-medical appointment or a wish to do something else)	Disagree – 20.7% Ambiguous – 31% Agree – 48.3%		
	3	A Stroke survivor may not receive 45 minutes of therapy if they prioritise other activities, such as non-medical appointments or simply wish to do something else (despite the importance of therapy being explained to them)	Disagree – 7.7% Ambiguous – 23.1% Agree – 69.2%		
7. The person with stroke's anxiety	2	Their own anxiety is a reason why a stroke survivor may not tolerate 45 minutes of therapy	Disagree – 10.3% Ambiguous – 44.8% Agree – 44.8%	Unable to gain consensus	Reason
	3	If a stroke survivor is anxious and strategies to manage their anxiety are not effective, then they may not receive 45 minutes of therapy	Disagree – 3.9% Ambiguous – 61.5%		

Concept	Delphi round	Statement	Result	Reason removed	Reason or factor
			Agree – 34.6%		
8. Behavioural issues	2	If a stroke survivor has behavioural issues that impact engagement then they may not receive 45 minutes of therapy	Disagree – 10.3% Ambiguous – 31% Agree – 58.6%	Unable to gain consensus	Reason
	3	If a stroke survivor has behavioural issues that impact engagement, which cannot effectively be managed, then they may not receive 45 minutes of therapy	Disagree - 0% Ambiguous – 38.5% Agree – 61.5%		
9. Cognitive impairment	2	If a stroke survivor has cognitive impairment (either new or pre-stroke) that that impacts engagement then they may not receive 45 minutes of therapy	Disagree – 24.1% Ambiguous – 41.4% Agree – 34.5%	Unable to gain consensus	Reason
	3	If a stroke survivor has *severe* cognitive impairment (either new or pre-stroke) which impacts their engagement then they may not receive the full 45 minutes of therapy	Disagree - 11.5% Ambiguous – 38.5% Agree – 50%		
10. The person identifying goals	2	If the stroke survivor cannot identify achievable, meaningful goals, then they will not receive 45 minutes of therapy	Disagree – 65.6% Ambiguous – 10.3% Agree – 24.1%	Unable to gain consensus	Reason
	3	If the stroke survivor does not independently identify any goals they will not receive 45 minutes of therapy	Disagree - 73.08% Ambiguous – 15.38% Agree – 11.54%		
11. Therapist due to leave work	1	A stroke survivor may not receive 45 minutes of therapy because I am due to leave work and there isn't time	Disagree – 40% Ambiguous – 25.7% Agree – 34.3%	Too similar to caseload issue	Reason
12. Therapists is unwell	1	A stroke survivor may not receive 45 minutes of therapy because I don't feel well, either mentally or physically	Disagree – 71.4% Ambiguous – 24.5% Agree – 2.9%	Considered to be an organisational issue	Reason

Concept	Delphi round	Statement	Result	Reason removed	Reason or factor
13. Therapist's non-clinical commitments	2	Non-clinical commitments (such as managerial responsibility or the education/supervision of others) impact the ability of therapists to deliver 45 minutes of therapy to their caseload.	Disagree – 7.1% Ambiguous – 35.7% Agree – 57.1%	Unable to gain consensus	Factor
	3	Non-clinical commitments (such as managerial responsibility or the education/supervision of others) sometimes impact the ability of therapists to deliver 45 minutes of therapy to their caseload	Disagree - 0% Ambiguous – 30.8% Agree – 69.2%		
14. Therapist identifying goals	2	If I, as the therapist, cannot identify achievable, meaningful goals, then the stroke survivor will not receive 45 minutes of therapy	Disagree – 42.9% Ambiguous – 39.3% Agree – 17.9%	Unable to gain consensus	Reason
	3	If I am unable to identify any goals for the stroke survivor, they may not receive 45 minutes of therapy	Disagree - 23.1% Ambiguous – 26.9% Agree – 50%		
15. Meaningful/ achievable Goals	3	If neither I, as the therapist, nor the stroke survivor can identify any meaningful, achievable goals, then they will not receive 45 minutes of therapy	Disagree - 7.7% Ambiguous – 23.1% Agree – 69.2%	Unable to gain consensus	Reason
16. The person receiving other healthcare input	1	A stroke survivor may not receive 45 minutes of therapy if they are receiving other healthcare input, such as medication or artificial feeding	Disagree – 51.4% Ambiguous – 34.3% Agree – 14.3%	Unable to gain consensus	Reason
	2	A stroke survivor may not receive 45 minutes of therapy if they are not ready for therapy (e.g. not dressed, eating a meal, in the toilet, receiving medication, receiving artificial feeding)	Disagree – 17.9% Ambiguous – 57.1% Agree – 25%		
17. Decision-making with other therapists (1)	1	Other members of the MDT (including other therapists of a different profession to me) influence the decisions I make regarding amount of therapy I provide to stroke survivors	Disagree – 31.4% Ambiguous – 45.7% Agree – 22.9%	Combined with statement below, as considered similar	Factor

Concept	Delphi round	Statement	Result	Reason removed	Reason or factor
18. Decision-making with other therapists (2)	1	Therapists of the same profession to me influence the decisions I make regarding amount of therapy I provide to stroke survivors	Disagree – 11.4% Ambiguous – 48.6% Agree – 40%	Unable to gain consensus	Factor
	2	Decisions about the amount of therapy that a stroke survivor receives are discussed amongst the therapy team and are sometimes made jointly	Disagree – 10.7% Ambiguous – 17.9% Agree – 71.4%		
19. If another HCP is seeing the person at the time of the therapy session	1	A stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session	Disagree – 17.1% Ambiguous – 42.9% Agree – 40%	Unable to gain consensus	Reason
	2	In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session	Disagree – 10% Ambiguous – 40% Agree – 50%		
	3	In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session and I am unable to reschedule	Disagree – 0% Ambiguous – 26.32% Agree – 73.68%		
20. Inexperienced/ newly qualified staff	2	Inexperienced or newly qualified staff find it more challenging to deliver the recommended minimum of 45 minutes, 5 days-a-week	Disagree – 18.5% Ambiguous – 37% Agree – 44.5%	Unable to gain consensus	Factor
	3	A stroke survivor may not receive 45 minutes of daily therapy if their therapist is newly qualified and/or inexperienced	Disagree - 46.2% Ambiguous – 30.8% Agree – 23.1%		
21. MDT communication in the community	2	In the community (including ESD), lack of effective communication amongst the wider MDT can make delivery of 45 minutes of therapy a challenge	Disagree – 18.8% Ambiguous – 43.8% Agree – 37.5%	Unable to gain consensus	Reason

Concept	Delphi round	Statement	Result	Reason removed	Reason or factor
	3	In ESD/Community Services lack of effective co-ordination between community services (e.g. carers, GP, District Nurse, any other services involved) may mean stroke survivors do not receive 45 minutes of therapy	Disagree - 28.6% Ambiguous – 21.4% Agree – 50%		
22. Pressure to achieve the guideline	1	I feel pressure to achieve a minimum of 45 minutes of therapy for all stroke survivors on my caseload	Disagree – 20% Ambiguous – 45.7% Agree – 34.3%	Unable to gain consensus	Factor
23. Not wanting more than one ESD visit per-day	1	Stroke survivors receiving ESD input don't want more than one session of therapy-a-day when they are at home	Disagree – 39.1% Ambiguous – 34.8% Agree – 26.1%	Unable to gain consensus	Reason
24. Likelihood of receiving more than one session per-day in ESD	1	Stroke survivors receiving Early Supported Discharge (ESD) input are unlikely to receive more than one session of therapy-a-day when they are at home	Disagree – 29.2% Ambiguous – 12.5% Agree – 58.3%	Unable to gain consensus	Factor
	2	Stroke survivors receiving ESD support are unlikely to receive more than one therapy session per day at home (i.e. only one visit per-day from the ESD service)	Disagree – 37.5% Ambiguous – 18.8% Agree – 43.8%		
25. Appropriateness of the guideline for ESD	1	The guideline for 45 minutes of therapy is not appropriate for stroke survivors receiving ESD (please consider justifying your answer in the comments below)	Disagree – 58.3% Ambiguous – 25% Agree – 16.7%	Unable to gain consensus	Factor
	2	The guideline for 45 minutes of therapy is appropriate for most stroke survivors receiving ESD	Disagree – 16.7% Ambiguous – 11.1% Agree – 72.2%		
26. Difficult to return to people in the inpatient setting (if they	1	Logistically, it is difficult to return to a stroke survivor for a second time in a day, if they are unable to tolerate 45 minutes of therapy in one session	Disagree – 14.3% Ambiguous – 48.6% Agree – 37.1%	Unable to gain consensus	Reason
	2	In an inpatient setting, it is difficult to return to a stroke survivor for a second time in a day, if they are unable to tolerate 45 minutes of therapy in one session	Disagree – 36% Ambiguous – 12%		

Concept	Delphi round	Statement	Result	Reason removed	Reason or factor
don't receive 45 mins in a 'block'			Agree – 52%		
27. Effect of therapy space/ equipment	2	My ability to provide 45 minutes of therapy can be limited by inadequate therapy space and/or equipment	Disagree – 35.7% Ambiguous – 28.6% Agree – 35.7%	Unable to gain consensus	Reason
28. The influence of the guidance on therapy delivery (organisational level)	1	The achievement of a good SSNAP score for my organisation influences how therapy is provided to stroke survivors	Disagree – 15.6% Ambiguous – 25% Agree – 59.4%	Unable to gain consensus	Factor
	2	The delivery of therapy within my organisation has changed in order to increase the achievement of the 45 minute guideline	Disagree – 28.6% Ambiguous – 21.4% Agree – 50%		
	3	Since the publication of the guideline, my organisation has changed to improve achievement of 45 minutes therapy	Disagree - 19.2% Ambiguous – 15.4% Agree – 65.4%		
29. Sufficient funding to provide the recommended amount	2	The service I work in is not appropriately funded to provide therapy for at least 45 minutes per day, five days per week	Disagree – 35.7% Ambiguous – 14.3% Agree – 50%	Unable to gain consensus	Factor
	3	The service I work in is not sufficiently well-funded to provide therapy for at least 45 minutes per day, seven days per week	Disagree - 23.1% Ambiguous – 15.4% Agree – 61.5%		
30. Effect of being discharged on SSNAP	1	If a stroke survivor is discharged from therapy on SSNAP, then they won't receive 45 minutes of daily therapy	Disagree – 28.1% Ambiguous – 28.1% Agree – 43.8%	Unable to gain consensus	Factor
31. Alternative if unable to provide 45 minutes (1)	1	When I am unable to provide a minimum of 45 minutes of daily therapy, the best alternative is to provide daily therapy at a lesser number of minutes	Disagree – 14.3% Ambiguous – 34.3% Agree – 51.4%	Unable to gain consensus	Factor

Concept	Delphi round	Statement	Result	Reason removed	Reason or factor
32. Alternative if unable to provide 45 minutes (2)	1	When I am unable to provide a minimum of 45 minutes of daily therapy, the best alternative is to provide 45 minutes of therapy on fewer days	Disagree – 20.6% Ambiguous – 44.1% Agree – 35.3%	Unable to gain consensus	Factor
33. The influence of the guidance on therapy delivery (therapist level)	1	The presence of the 45 minute guideline influences the amount of therapy I provide to stroke survivors	Disagree – 17.1% Ambiguous – 25.7% Agree – 57.1%	Unable to gain consensus	Factor
	2	I provide 45 minutes of therapy because the guideline says I should	Disagree – 28.6% Ambiguous – 42.9% Agree – 28.6%		
	3	The existence of the 45 minute guideline increases the amount of therapy I provide to stroke survivors	Disagree - 15.4% Ambiguous – 34.6% Agree – 50%		
34. Providing 45 minutes of therapy 7 days-a-week	1	Providing 45 minutes of therapy seven days a week is not appropriate for the majority of stroke survivors	Disagree – 40% Ambiguous – 48.6% Agree – 11.4%	Unable to gain consensus	Factor
	2	Most stroke survivors would not want, tolerate or need 45 minutes of therapy, 7 days a week	Disagree – 46.4% Ambiguous – 21.4% Agree – 32.1%		
	3	Most stroke survivors do not want, tolerate or need 45 minutes of therapy, 7 days a week	Disagree - 53.9% Ambiguous – 26.9% Agree – 19.2%		
35. Delivering 45 minutes of therapy post-ESD	2	It is unrealistic to deliver 45 minutes of therapy, 5 days a week in a community service (post-ESD)	Disagree – 27.8% Ambiguous – 16.7% Agree – 55.6%	Unable to gain consensus	Factor
	3	It is unrealistic to deliver 45 minutes of therapy, 7 days a week in a community service (post-ESD)	Disagree - 31.3% Ambiguous – 18.8%		

Concept	Delphi round	Statement	Result	Reason removed	Reason or factor
			Agree – 50%		
36. People who would benefit from 45 minutes receive it.	1	Stroke survivors who would benefit from more than 45 minutes of therapy-per-day, generally receive it	Disagree – 48.6% Ambiguous – 14.3% Agree – 37.1%	Unable to gain consensus	Factor
	3	Stroke survivors who would benefit from more than 45 minutes of therapy-per-day, will receive it	Disagree - 26.9% Ambiguous – 46.2% Agree – 26.9%		
37. Pressure to achieve the guideline, if not clinically indicated	1	I feel pressure to provide all stroke survivors with a minimum of 45 minutes of therapy, even if it is not clinically indicated.	Disagree – 67.6% Ambiguous – 32.4% Agree – 0%	Similar to statement about influence of the guideline on therapy delivery	Factor

6.5 Discussion

This Delphi study gained consensus between therapists on 32 statements related to the 45 minute guideline, and was unable to gain consensus on a further 32 statements. As therapists' decision-making determines therapy delivery, therapists' views on this topic are important. The three main findings of this study are discussed; 1. Reasons why a person might not receive the guideline amount of therapy (the person's suitability vs. the organisation's ability), 2. Challenges regarding the guideline in ESD and 3. Statements on which consensus could not be achieved

6.5.1 Reasons why a person might not receive the recommended 45 minutes

All the consensus reasons why a person may not receive the guideline amount of therapy fall almost equally into one of two categories. Ten out of 21 are reasons why a person may not receive the guideline amount of therapy, relative to their medical status, tolerance of and progress in therapy. The remaining 11 statements relate to the organisation's ability to provide the guideline, for reasons such as size of therapists' caseload and other priorities competing with rehabilitation delivery. As all reasons fell into one of these two categories, the suggestion is that, if people don't receive the 45 minute guideline, it is due to either the suitability of the guideline for them, or the organisation's ability to provide the required therapy.

Support for the guideline suitability/organisation's ability is found in a study by Gittins et al. (2020), who applied multi-level mixed effects regression models to SSNAP data to investigate factors associated with amount of therapy delivered. They found that patient-related characteristics, such as pre-morbid disability and stroke severity had the strongest influence on therapy delivery, but that there were organisational factors, such as day and time of admission and type of stroke team, that were also influential. Clarke et al. (2018) also found that there were issues with organisation's ability to deliver the 45 minute guideline in terms of resource usage and availability.

The guideline acknowledges that not all people are suitable for 45 minutes of therapy, 5 days-per-week, stating those "willing and capable of participating and showing measurable benefit from treatment" (Intercollegiate Stroke Working Party 2016 p.25) should receive it. SSNAP accounts for this in the calculation of guideline achievement, by excluding any people with stroke who were not appropriate for therapy at any point during their admission. However, six of the 10

consensus reasons related to suitability indicate that some people who are suitable for therapy, may not be suitable for the full 45 minutes or may be able to engage with therapy some days, but not others. For example:

A therapy session may end if the stroke survivor is not able to maintain attention to the therapy input, despite strategies to increase and/or motivate attention

This is supported by the almost unanimous disagreement in the Delphi study that people with stroke who are not appropriate for 45 minutes of therapy per-day are not appropriate for any therapy.

It is unclear if the issues of a person's suitability and the organisations' ability are mutually exclusive or if they are ends of a spectrum along which therapists make decisions about those most suitable for the 45 minute guideline in the context of resource availability. This possibility is supported by consensus on contextual factors, which therapists agree influence the delivery of the guideline (such as the therapists' knowledge and experience) and the finding from other research, that therapists allow their knowledge of resource availability to influence their judgement of who is suitable for therapy (Taylor et al. 2018).

Findings related to the reasons why a person might not receive the recommended 45 minutes, have the following implications for future guidelines and clinical practice. Suitability of 45 minutes of therapy for all people suitable for therapy requires further consideration, as findings of this study suggest that suitability for therapy does not equate to suitability for a minimum of 45 minutes. A recent Cochrane review found that additional time spent in rehabilitation following stroke had no effect on measures of Activities of Daily Living (Clark et al. 2021c). Potentially, this finding relates to the importance of selecting the right people for intensive rehabilitation (Kwakkel 2006; Stinear et al. 2017). Therapists would benefit from clear guidance regarding how to make such selections. There is currently some evidence regarding how therapists make these decisions (McGlinchey and Davenport 2015; Clarke et al. 2018; Taylor et al. 2018), however our study and that of Taylor et al. (2018) identify that there are inconsistencies in therapy delivery. Additionally, therapists would benefit from clear guidance regarding how to optimise time available to therapists, avoiding unnecessary wastage. De Wit et al. (2005), in their comparison of

four European rehabilitation centres, found that people with stroke in the UK centre received the least amount of therapy, despite having more therapy time available than the other centres. Similarly, Clarke et al. (2018) found that the way therapists organised their time positively influenced achievement of the 45 minute guideline. In addition to clear guidance regarding how therapists can optimise time available for therapy, organisations must ensure that therapy departments are appropriately funded to deliver the guideline, following the guidance provided regarding the recommended staffing levels for stroke units (Intercollegiate Stroke Working Party 2016).

6.5.2 Challenges regarding delivering the guideline in ESD.

Therapists mentioned specific challenges regarding delivery of the guideline in ESD services. To our knowledge, no other study mentions the delivery of the guideline in ESD. Twelve of 14 therapists with experience in ESD responded strongly agree/agree when asked if returning to someone more than once-per-day is difficult (which is required if they are unable to tolerate 45 minutes of therapy in one session). Additionally, some people who would benefit from ongoing therapy do not receive it, due to ESD services being time-limited (e.g., 6 weeks maximum input). The guideline states that people should continue to receive 45 minutes if they are showing measurable benefit, therefore time limited ESD services may interfere with achievement of this. However, therapists in ESD services teach people to manage their own rehabilitation and, therefore, ongoing daily therapy input may not be appropriate. This possibility may explain lack of consensus on the appropriateness of the guideline in ESD services. Despite 13 of 18 therapists agreeing that "the guideline for 45 minutes of therapy is appropriate for most stroke survivors receiving ESD", there were therapists that disagreed with this statement commenting that it was dependent on the person's goals and that ESD needs to be less prescriptive and adapt to the needs of the individual. Additionally, there was a lack of consensus on whether people receiving ESD had more than one session per day (in total, not per-discipline involved). Some participants commented that interprofessional working is key and some people don't want more than one visit per-day, as they find it intrusive. These issues may contribute to the reduced amount of therapy delivered in ESD compared to inpatient care (Bahalla et al. 2021). Taken together, these findings suggests that the 45 minute guideline may not be suitable for people receiving ESD input and, potentially, a different recommendation should be provided for ESD.

6.5.3 Statements on which consensus could not be achieved

Potential reasons for lack of agreement were based on a qualitative analysis of participants' comments. Lack of consensus appears to be due to either a) structural and/or institutional

differences between services or b) differences between therapists' approach to a given situation. An example of differences between services was the lack of consensus regarding the effect of therapy space and/or equipment. As such resources can vary between services, this may be a consideration for some sites, but not for others. An example of differences between therapists' approach was the lack of consensus on the effect of a person's cognitive impairment on guideline delivery. Content analysis of the related comments suggests that some therapists would use strategies, some felt they would be unable to undertake their planned session and some felt it would depend on the impact of the cognitive impairment. These differing views reflect the similar lack of agreement regarding the impact of cognitive impairment on rehabilitation participation found in literature (Diamond et al. 1996; Cumming et al. 2013). Consensus was also not reached on statements that explored the impact of goals on guideline delivery. Goals are considered to be a key component of stroke rehabilitation (Langhorne et al. 2011), however, consensus was not reached for the effect that the absence of meaningful, achievable goals has on delivery of the guideline. This suggests inconsistency amongst therapists regarding the role of goals in therapy.

A final area, related to the guideline, on which consensus could not be reached was the concept that people who require more than 45 minutes of therapy-per-day are able to receive it. Only seven of 26 participants agreed that this happened, with staffing levels heavily cited as the reason. Statements related to this concept were only included in rounds one and three of the Delphi study, see study limitations, below. The guideline states that 45 minutes is the minimum requirement and is the standard audited via SSNAP. Guideline achievement contributes to an overall 'SSNAP Level' for an organisation, rated from A – E, with A being the most desirable score (Royal College of Physicians 2013). For Physiotherapy and Occupational Therapy, an 'A' rating is achieved if 45 minutes is delivered to a pre-determined percentage of people. The ability to achieve the top rating by only providing the minimum recommended may not incentivise organisations to provide beyond the minimum. This means some people are not receiving the therapy that would allow them the greatest chance of recovery.

Some of the statements which did not achieve consensus are reported in other studies as reasons why someone might not receive therapy. For example, Taylor et al. (2015) reports that lack of social support may effect rehabilitation input. However, in our study, therapists did not reach consensus regarding the effect that lack of social support had on achievement of the 45 minute guideline in the community. Similarly, Skidmore et al. (2010) report that depressive symptoms

effect participation in rehabilitation, yet in our study, consensus was not reached for the effect of low mood on therapy input, despite being included in all three rounds.

Overall, the lack of consensus amongst therapists suggests that there are differences between services and between individual therapists regarding therapy delivery. Therefore, a person's experience of stroke care will be dependent on the service they access and potentially, their therapist too. Variation in therapy delivery is acknowledged by the Seventh Annual SSNAP data report (Bahalla et al. 2021). Potentially, variation could be reduced by providing therapists with summarised, evidence-based information regarding how to optimise therapy delivery and national stroke competencies for therapists.

6.5.4 Strengths and limitations of the study

To our knowledge, this study is the first to examine consensus amongst therapists for the reasons why a person may not receive the 45 minute guideline after stroke. However, findings of this study must be considered in light of its limitations. The Delphi techniques seeks to gather consensus (Vernon 2009) and, thus, findings should not be considered fact. However, therapists' opinions regarding why someone may not receive the guideline are relevant considering the role that therapist's decision-making plays in therapy delivery. A criticism of the Delphi technique is that results only represent simplified concepts (Powell 2003). In the context of this study, there may be additional reasons why a person does not receive the guideline amount of therapy, which this study has not captured, as the results only represent the reasons that reached consensus. There were many concepts where consensus could not be achieved. Based on content analysis of the comments in the Delphi rounds, reasons for the lack of consensus have been presented. However, due to the nature of the method, those reasons have not been confirmed by participants. The diversity of participants may have influenced lack of consensus. Greater levels of consensus may have been gained from a more homogenous group, focusing on a single aspect of the stroke pathway (e.g. acute inpatient or ESD). Potentially, participant diversity in terms of profession and amount of experience may have also affected findings. Another limitation is that the second and third rounds of the Delphi were completed by fewer than the lower target of 30 participants, potentially resulting in findings that are not generalisable to a wider therapist population. This may be particularly the case for statements which were experience-dependent. Consensus on one such statement is attributed to the responses of only 14 participants. It is possible that some of the statements that did not achieve consensus would have done so with a larger sample. On the other hand, those who did participate were predominantly very

experienced stroke therapists. Based on those who participated in round one, therapists had a median nine years' experience in stroke and were a median band seven. The views of less experienced therapists (who may form a large proportion of the therapy workforce) are not well-represented and may be different to therapists with more experience. Finally, unfortunately one statement re-worded from round one was inadvertently missed from round two of the Delphi. It was included in round three, to mitigate, but means this statement only had the opportunity to be reviewed twice in the Delphi study, and it did not reach consensus. Based on the comments made by participants, study authors did not feel this statement would reach consensus with a third Delphi round.

6.5.5 Unanswered questions and future research

This study adds to the emerging evidence for the implementation of the 45 minute guideline; but there remain unanswered questions. It is not known which consensus reasons are most commonly occurring in clinical practice and if either the suitability of the guideline or the organisations' ability to deliver the guideline have a greater influence in guideline non-delivery. This could be investigated by undertaking an observational, cross-sectional, prospective survey across England, Wales and Northern Ireland. Additional benefits of undertaking such a study would be validation of the findings of this study and further investigation of potential variations in therapy delivery. This would lead to enhanced understanding of the ongoing suitability for the guideline in clinical practice and the intervention required to increase guideline achievement.

This study has also raised further questions in relation to the 45 minute guideline. There is a question regarding the guidelines' suitability for people receiving ESD and if its unsuitability might help explain the low guideline achievement in this setting. Additionally, further understanding regarding delivery of the therapy beyond the minimum recommended 45 minutes would help to understand if people are receiving the amount of rehabilitation that therapists believe they need.

6.5.6 The impact of COVID-19 on these findings

Data collection for this study occurred just prior to and during the early stages of the COVID-19 pandemic; there is evidence that the pandemic has affected therapy delivery. Early in the pandemic, there was a reduction in stroke admissions (Bahalla et al. 2021) and guidance from the RCP was that people should be discharged from hospital as soon as they could safely be cared for at home. This would affect the delivery of inpatient therapy, due to shorter length of stay. Telerehabilitation was encouraged as a means of supporting peoples' rehabilitation at home (Ford

et al. 2020; Royal College of Physicians 2020). Telerehabilitation is the use of information and communication technologies (for example, videoconferencing) to enable communication between a therapist and a person with stroke remotely (Laver et al. 2020). Ford et al. (2020) reports that telecommunication can occur synchronously (i.e. face-to-face with a therapist in 'real time') or asynchronously (i.e. using computer-based interventions that remotely monitor and adapt exercises). According to the definition of therapy given by SSNAP (Intercollegiate Stroke Working Party 2021), therapy delivered via telerehabilitation (either synchronously or asynchronously) could contribute to the 45 minute guideline. The use of telerehabilitation, therefore would affect the delivery of community-based therapy.

The long-term effects of the pandemic on Stroke Services are not known, but arguably the use of telerehabilitation in the community will continue, as a way of delivering more therapy where appropriate. There is low-quality evidence that telerehabilitation is as effective as face-to-face therapy in stroke (Laver et al. 2020); and there is acknowledgment that new models of rehabilitation delivery must be evaluated to ensure outcomes and standards are maintained (Ford et al. 2020).

The findings of this study likely remain relevant to inpatient stroke rehabilitation, as there does not appear to have been a significant change to inpatient therapy delivery and, according to SSNAP data, remains consistently underachieved (Royal College of Physicians 2021). However, potentially more rehabilitation is now occurring in the community, particularly if the use of telerehabilitation has been embraced by stroke therapy teams and service users. This may have implications for the findings of this study, related to the delivery of rehabilitation in the community.

6.6 Conclusion

Confirming the findings of our focus group study (Clark et al. 2021a), the three findings of this study contribute to two conclusions:

First, findings suggest there are issues with the suitability of the guideline; that there are some people suitable for therapy that are not suitable for a minimum of 45 minutes in a day, or may tolerate 45 minutes of therapy some days, but not others. Additionally, it may not be suitable for

some people receiving ESD, as they may believe it stops them 'getting on with life'. Findings from this study and others (Clark et al. 2021a) suggest that therapist decision-making in terms of the 45 minute guideline is complex, which contrasts with the simplicity of the current guideline.

Second, there are issues with the delivery of the guideline. Services have limited ability to deliver the guideline, there are inconsistencies between therapists and services in guideline delivery and people who require more than 45 minutes of therapy do not consistently receive it.

Future research should focus on why the guideline is not achieved, especially in ESD, and why people who require more than 45 minutes may not receive it. This could contribute to practical guidance for therapists to optimise therapy delivery for people after stroke.

Chapter 7 Discussion

7.1 Introduction

Motivated by personal experience in clinical practice, this research sought to examine the recommendation for 45 minutes of therapy daily following stroke. A narrative review of the literature identified critical gaps in understanding of the research evidence for and implementation of the 45 minute guideline, from which the following research questions were developed:

1. Does the evidence for the effect of time spent in rehabilitation support guideline recommendations for therapy following stroke?

2. What factors determine whether someone receives the recommended minimum amount of therapy?

3. Is the 45 minute guideline fit for purpose?

In this chapter, the findings of the study are synthesised. The unique contributions this research has made to understanding the suitability of this guideline presented, and recommendations for the future of this guideline provided.

7.2 Summary of findings

The Cochrane review found that when comparing studies of more versus less therapy of the same type, there was no effect for an increased amount of rehabilitation on measures of activities of daily living (ADL) or upper and lower limb activity. A small effect (Cohen 1988) favouring additional time spent in rehabilitation was found in upper and lower limb impairment measures. When comparing studies with a greater versus smaller difference in the amount of total rehabilitation provided between intervention arms, greater difference resulted in significantly greater improvement in ADL outcomes, activity and motor impairment measures of the upper limb. These findings suggest that a large amount of additional rehabilitation may improve

outcomes after stroke, but little evidence to guide a minimum beneficial daily amount. Visual inspection of scatter diagrams indicates that, in future research, a minimum difference of 1000 minutes of rehabilitation between intervention arms is required to significantly affect ADL measures. The certainty of the evidence on which these findings are based was low to very low due to the inclusion of studies with a high risk of bias, high likelihood of publication bias and findings of low precision. Potentially, the lack of effect may be due to studies with insufficient between-group contrast in the amount of therapy delivered. Indeed, for many studies, it was impossible to calculate the total time spent in rehabilitation as none of the studies undertaken in the subacute phase (16 of 21) reported 'routine rehabilitation' in sufficient detail to a) determine if it was comparable between studies' arms and b) calculate the total amount of time participants spent in rehabilitation. The latter is the primary reason why evidence for a minimum recommended amount of therapy cannot be calculated.

The focus groups and Delphi study sought to discover why some people with stroke do not receive the recommended minimum amount of therapy. The focus group results found that reasons why a person does not receive the recommended 45 minute minimum fall into two categories; the person's suitability for the guideline amount of therapy and the organisation's ability to provide this amount of therapy. In addition to the reasons for non-delivery of the guideline, the focus groups found that there are factors that influence therapy delivery in relation to the guideline. The focus group findings were organised into five themes, each representing a factor influencing the amount of therapy a person received. These factors were the person themselves, the therapist treating them, the stroke MDT, the NHS organisations and the guideline itself.

Findings from the focus groups were used to develop statements for a Delphi study to gain consensus from therapists in clinical practice regarding reasons why a person may not receive the guideline and factors that influenced guideline achievement. Consensus was gained for 32 statements and could not be gained for a further 32 statements. Of the 32 statements for which consensus was gained, 21 were reasons why a person might not receive the guideline. Reflecting the findings of the focus groups, consensus reasons why a person may not receive the guideline amount of therapy fall almost equally into one of two categories. Ten reasons related to the person's suitability of the guideline and 11 related to the organisation's ability to provide the recommended amount.

Regarding the person's suitability for rehabilitation, the guideline acknowledges that not all people are suitable for 45 minutes of therapy, five days a week, stating that those "willing and capable of participating and showing measurable benefit from treatment" (Intercollegiate Stroke Working Party 2016 p.25) should receive it. To account for this, SSNAP excludes those who are not suitable for therapy at any point whilst under the care of the stroke team. Findings from both the focus groups and the Delphi study suggest that some people suitable for therapy are not suitable for a minimum of 45 minutes. Additionally, there are some people who are suitable for therapy on some days but not others. This fluctuating suitability is not reflected in the SSNAP data collection. In such circumstances, the audit would record that the guideline had not been achieved for the person, despite the person being unsuitable for the guideline on that day.

The 32 statements for which consensus could not be achieved indicate differences between therapists and services in therapy delivery. Of particular note is the lack of consensus regarding whether people who need more than 45 minutes of daily therapy receive this.

Both the focus group and Delphi study identify issues with delivery of the guideline in ESD services, including issues with the suitability of the guideline in ESD and issues with delivering 45 minutes of daily therapy in ESD.

7.3 Discussion of findings

The findings of this programme of research are discussed in relation to four themes:

- Evidence for the 45 minute guideline
- Some people with stroke are unsuitable for 45 minutes of daily therapy
- Some services are unable to deliver 45 minutes of daily therapy
- Is the 45 minute guideline fit for purpose?

7.3.1 Evidence for the 45 minute guideline

Findings from the Cochrane review question the evidence base for the guideline.

The RCP guidelines acknowledge that the 45 minute guideline is based on expert consensus. However, they state that this consensus is based on the evidence that more therapy improves outcomes after stroke, quoting studies by Kwakkel et al. (2004b) and Lohse et al. (2014) (Intercollegiate Stroke Working Party 2016). The Cochrane review found no evidence of an effect for more therapy on measures that are likely to be meaningful to a person with stroke, such as ADLs and activity measures of the upper and lower limb. The difference between the Cochrane review and these other systematic reviews with meta-analyses is that the Cochrane review only included studies that compared different amounts of the same type of therapy. Both Kwakkel et al. (2004b) and Lohse et al. (2014) included studies where groups that received more therapy also received a different type of therapy and studies that compare intervention to no intervention. Lohse et al. (2014) included 34 studies in their meta-analysis, 10 of which compared Constraint-induced movement therapy (CIMT) to a control intervention that did not include CIMT. CIMT (and modified versions of CIMT) are considered the most effective treatment for upper limb weakness after a stroke, involving up to 6 hours of task-specific practice per day and constraint of the affected upper limb for 90% of waking hours (Kwakkel et al. 2015). The difference between CIMT and conventional rehabilitation goes beyond the time spent in rehabilitation.

The Cochrane review found an effect favouring additional time spent in rehabilitation for ADLs and activity measures of the upper limb when a threshold for amount of therapy is crossed. This indicates that there *is* a minimum amount of therapy that a person requires after a stroke to effect positive change in their functional ability. Owing to limitations in the information provided by studies, this minimum amount could not be established in the Cochrane review. Systematic reviews with statistical analysis undertaken by Kwakkel et al. (2004b) and Schneider et al. (2016) support the Cochrane's finding that a threshold needs to be crossed for an increased amount of therapy to be beneficial. Neither study provided specific evidence to define this threshold amount, as their findings were relative between experimental and control groups. A further study by Lohse et al. (2014) used meta-regression to explore the effect of scheduled therapy time on outcomes. This study found a positive dose-response relationship between time scheduled for therapy and improvements in function measures without a minimum threshold requirement, contrary to the Cochrane review findings, Kwakkel et al. (2004b) and Schneider et al. (2016). The

difference in findings may be due to the statistical methods employed and the study inclusion criteria, which did not control the type of therapy. These findings suggest there is a minimum amount of therapy required to effect a positive change, but this amount has not yet been established.

A Cochrane review undertaken by Pollock et al. (2014a) examined physical rehabilitation approaches to recover function and mobility following stroke. Their study included sensitivity analyses, which grouped studies that provided a similar amount of therapy (the number of minutes per day and days per week on which therapy was provided). They found that an amount of 30-60 minutes per day, five to seven days per week of physical rehabilitation, resulted in significant improvements in functional recovery when compared to no intervention, but that more therapy may occasion greater improvements. This finding seemingly supports the recommendation for a minimum of 45 minutes of daily therapy. However, the authors stressed that there was substantial heterogeneity between studies and conclusions about the amount of rehabilitation were not robust.

There are alternatives to a time-based recommendation for increasing 'therapy intensity' post-stroke. Task difficulty is an element of therapy 'dose' (Hayward et al. 2021). Ensuring that tasks are at an optimal level of challenge (neither too easy nor too difficult) supports recovery after stroke, but identifying the right level of challenge for an individual may be complicated (Pollock et al. 2014c; Woodbury et al. 2016). Studies have shown that an increased number of practice repetitions have a beneficial effect on outcomes (Hsieh et al. 2012; French et al. 2016; Abdullahi 2018), although the required number of repetitions is unknown (French et al. 2016). Other studies have used heart rate reserve (HRR) as a measure of the cardiovascular intensity in stroke rehabilitation, demonstrating that increased cardiovascular intensity results in better outcomes (Outermans et al. 2010; Hornby et al. 2016). In a recent study, Klassen et al. (2020) compared a usual care group with a 'higher intensity' group that spent similar amounts of time in rehabilitation, but the higher intensity group achieved almost 4 times the amount of practice repetitions and spent more than twice as much time in the "aerobic training zone" (≥40% HRR). The findings of Klassen et al. (2020) indicate that time spent in rehabilitation is not the most influential variable and, therefore, is not a good proxy for rehabilitation intensity.

7.3.2 Some people with stroke are unsuitable for 45 minutes of daily therapy

Participants in the focus groups and the Delphi study identify that the 45 minute guideline is unsuitable for some people following stroke. Some people's suitability for the guideline fluctuates; they may be suitable for a minimum of 45 minutes of therapy on some days, but not five days per week (the current audited standard). They may tolerate some therapy, but not 45 minutes, even when split into shorter sessions. According to the Delphi study, the latter may be particularly relevant if they have multiple therapies involved. Reasons for peoples' unsuitability include being medically unwell, the effects of their stroke (e.g. impaired attention, fatigue, high level of care needs) and an inability to tolerate 45 minutes of daily therapy. Additionally, the focus groups and Delphi study provide evidence that the 45 minute guideline may not be suitable for people receiving ESD services. Some people do not want therapy at home, as they feel it interferes with them 'getting on with their life', despite it being clinically appropriate.

The Delphi study explored additional reasons why a person may be unsuitable for the 45 minutes guideline, but these additional reasons did not reach the pre-defined 75% level of consensus. Therefore, these areas remain ambiguous, with some therapists believing they may affect a person's suitability for the 45 minute guideline, and others believing they don't. This includes the effect of the person being fully dependent on care prior to their stroke, how the absence of identified goals affects delivery of the 45 minute guideline and the effect of low mood, anxiety, behavioural issues and cognitive impairment on delivery of the 45 minute guideline. Potential explanations for the lack of consensus in the Delphi study related to the suitability of the guideline can be inferred from participants' related comments. Lack of consensus may be due to availability of resources (e.g., behavioural issues may impact therapy less if there is access to a psychologist to provide support with a behavioural management plan). However, comments indicate that the lack of consensus is predominantly caused by different therapists adopting a different course of action. Additionally, the focus groups identified contextual factors, such as organisational politics, that may affect guideline delivery that could differ between services. This suggests a lack of consistency between therapists and services regarding the criteria used to judge whether someone is appropriate for the 45 minute guideline.

As discussed in the focus group and Delphi study papers, other research identifies person-related factors that may limit delivery of rehabilitation following stroke. These include medical issues

(Otterman et al. 2012; Taylor et al. 2015; Clarke et al. 2018), fatigue (Taylor et al. 2015; Clarke et al. 2018), cognitive impairment (Skidmore et al. 2010; Hakkennes et al. 2011; Taylor et al. 2015), tolerance of therapy (Foley et al. 2012a; Clarke et al. 2018), consent to therapy (Foley et al. 2012a; McGlinchey and Davenport 2015), pre-stroke function (Hakkennes et al. 2011; Gittins et al. 2020), post-stroke function (Skidmore et al. 2010; Hakkennes et al. 2011), mood (Skidmore et al. 2010) and motivation (McGlinchey and Davenport 2015; Taylor et al. 2015). Notably, studies don't distinguish between people being unsuitable for any therapy and variable suitability for therapy, where the person may be able to engage with therapy one day by not the next. A person's suitability for the guideline is not the only reason why it may not be delivered. However, Gittins et al. (2020) examined SSNAP data using multilevel mixed-effects regression models and found that factors related to the person had the most significant influence on the amount of therapy received.

The wording of the guideline identifies that 45 minutes of daily therapy is not suitable for everyone. It states that the guideline applies to those who "are willing and capable of participating and showing measurable benefit from treatment" (Intercollegiate Stroke Working Party 2016 p.25). Therefore, therapists who don't deliver a minimum of 45 minutes of therapy to those who are unsuitable are working within the guideline. However, despite the guideline stating it should only be provided to people who are willing, capable and will benefit, the SSNAP audit collects data about the amount of therapy delivered for all people who receive any therapy after stroke (beyond assessment only). In other words, the SSNAP audit assumes that those who are suitable for any therapy are suitable for 45 minutes of therapy, five days per week. The focus groups and Delphi study found that this is not the case.

The SSNAP audit is the only measurement of this guideline's achievement. It lacks the sensitivity required to measure achievement of the guideline for those whose suitability for therapy fluctuates or is below 45 minutes of daily rehabilitation. Therefore, it does not accurately capture the achievement of the 45 minute guideline.

7.3.3 Some services are unable to deliver 45 minutes of daily therapy

SSNAP data reports that, in inpatient services, the 45 minute guideline is achieved for 34% and 37% of people for Physiotherapy and Occupational Therapy, respectively (Bahalla et al. 2021). These figures exclude those people who were not suitable for therapy at any point during their admission. Therefore, some lack of achievement is attributed to people whose suitability for therapy is fluctuation (i.e., they are suitable for some therapy but not consistently suitable for 45 minutes of therapy every day). However, findings from the focus groups and Delphi study identify issues with stroke services' ability to deliver the guideline. Some of these issues relate to resource availability (in terms of therapists' time), and some relate to the organisation of care.

Achievement of the 45 minute guideline is limited by inadequate staffing. In hyperacute and acute settings, large caseloads compound this issue. According to the focus groups, caseloads fluctuate outside of therapists' control. In the Delphi study, there was 88% agreement that "lack of therapy staff, can be a reason why a stroke survivor does not receive 45 minutes of therapy". Focus groups found that staff sickness and time taken in lieu of weekend working negatively impacted therapy delivery. These findings are echoed in other studies of delivery of the 45 minute guideline; the number of staff affects the amount of therapy delivered (Clarke et al. 2018; Gittins et al. 2020).

The data available does not provide information about whether teams are adequately staffed to deliver the 45 minute guideline. The RCP guidelines for stroke provide recommendations for the number of Physiotherapy and Occupational Therapy staff required for hyperacute and acute stroke beds (see table 12), and the SSNAP acute organisational audit provided data for the median number of whole-time equivalent (WTE) Physiotherapy and Occupational Therapy staff in stroke units across England, Wales and Northern Ireland (see table 13).

Table 12 Royal College of Physicians recommended staffing levels (WTE per 10 beds)

	Physiotherapy	Occupational Therapy
Hyperacute	1.46	1.36
Acute	1.68	1.62

Figures based on 5-day service delivery (Intercollegiate Stroke Working Party 2016)

Table 13 Reported Median (IQR) staffing levels (WTE per 10 beds)

	Physiotherapy	Occupational Therapy
Qualified	1.4 (1.1 – 1.7)	1.3 (1.0 – 1.6)
Support worker	0.5 (0.3 – 0.6)	0.4 (0.3 – 0.6)

Based on reported service delivery with services providing therapy either 5, 6 or 7 days per week (Intercollegiate Stroke Working Party 2019).

Due to the differences between the presentation of the recommendations (split into Hyperacute and acute beds, based on 5-day service provision) and the presentation of staffing levels (reported by services as part of the SSNAP acute organisational audit and split into qualified and support staff), it is not possible to draw clear conclusions regarding the adequacy of therapy staffing for guideline delivery. Additionally, it is not certain if recommended staffing levels are modelled to deliver 45 minutes of daily therapy as a target or a recommended minimum.

In addition to resource availability, delivery of the 45 minute guideline is limited by issues related to the organisation of care. In the Delphi study, there was consensus agreement that, in the acute setting, new patient assessments and patient discharges may take priority over the delivery of the 45 minute guideline. There was also consensus that people being taken off the ward for medical investigations can limit therapy delivery and that non-patient contact activities (such as paperwork) may impact guideline achievement. Comparing four European rehabilitation centres, De Wit et al. (2005) found that the UK centre had the most time available from therapists yet delivered the least amount of therapy to people post-stroke. They noted that therapists in the UK spent more time in legally required administrative tasks, which resulted in less time available for face to face therapy. In their study, Clarke et al. (2018) identified that therapists spent significant time in non-patient contact activities. They found that stroke units that reduced the number of staff members that attended handover delivered more therapy. They also observed that shared patient timetables resulted in an increased likelihood that people were ready for therapy, reduced therapist competition for peoples' time and more therapy sessions undertaken. These findings suggest there are actions that therapy teams can take to optimise time available for therapy delivery.

The focus groups and Delphi study identified specific issues with the delivery of the guideline in ESD services. Focus groups identified that people in ESD often only receive one visit per day, even if they have more than one therapy involved, and in the Delphi study, there was consensus that it is challenging to return to people a second time in a day if they are unable to tolerate 45 minutes of therapy in one session. There was also consensus that some people with stroke are discharged from ESD when they would still benefit from the 45 minute guideline due to the time-limited nature of ESD services. ESD services should be capable of delivering rehabilitation at the equivalent intensity to inpatient stroke services; however, people receiving ESD services receive less therapy than people receiving inpatient services (Bahalla et al. 2021).

7.3.4 Is the 45 minute guideline fit for purpose?

This section addresses the third research question considering, not only the guideline itself, but also the measurement of its achievement, via the SSNAP audit. Chapter two of this thesis included an evidence-based summary of the role of clinical guidelines in healthcare. Here, consideration is given to how the findings of this current programme of research and those of other research studies provide evidence for how well the 45 minute guideline fulfils the role of a clinical guideline and the effect of the audit of this guideline via SSNAP.

The literature identifies a benefit of clinical guidelines is enhanced quality of care (Feder et al. 1999; Woolf et al. 1999; Scalzitti 2001; Twaddle 2005; National Institute for Health and Care Excellence 2014). SSNAP data demonstrates that achievement of the guideline had improved from when ongoing measurement commenced (in 2013) until now, see figure 15 (Royal College of Physicians 2021)

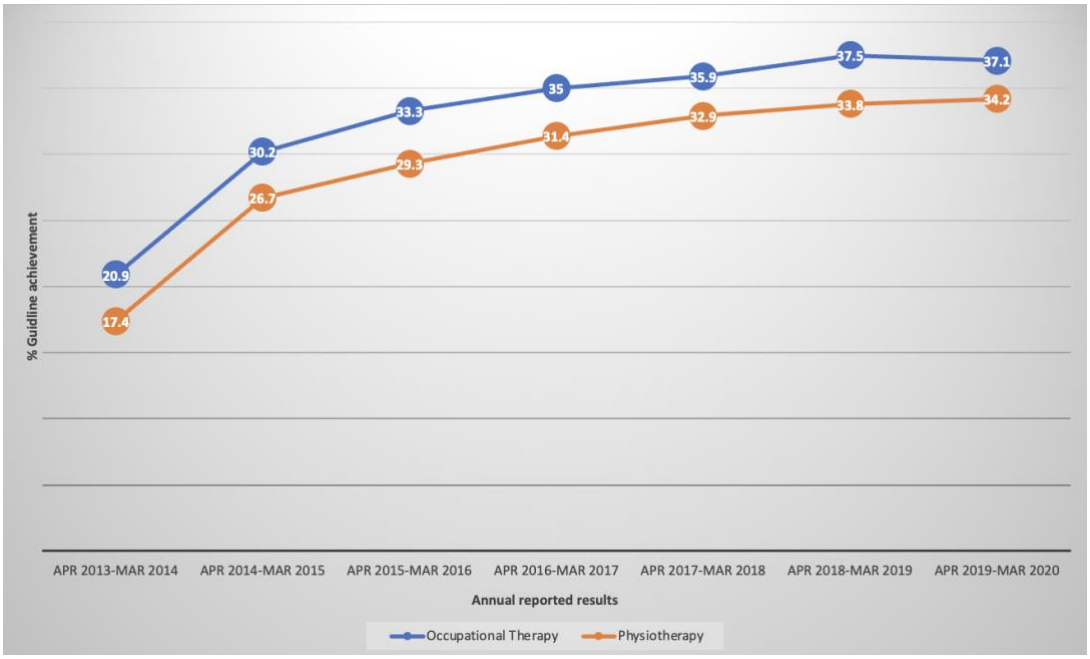

Figure 15 If applicable, patients receiving the equivalent of at least 45 minutes, five days a week (at this team) of physiotherapy and Occupational Therapy

This graph shows the achievement of the guideline for both Occupational Therapy and Physiotherapy from 2013 to 2020. It demonstrates that guideline achievement has almost doubled in that time, but also that the greatest improvements were between 2013/14 and 2014/15, with further progress slowing over time. Potentially, there is limited scope for further improvement in guideline achievement within the current guideline and resources. Despite this increased achievement of the guideline, there is no evidence regarding the effect this has had on outcomes for people with stroke, as there is no parallel measure of quality of therapy, nor measures of functional outcomes, such as the Barthel Index. Findings from the Cochrane review show that a large amount of additional rehabilitation is required to improve outcomes, therefore, whilst increased achievement of the 45 minute guideline indicates a change in process, it cannot be assumed that this has resulted in an improvement in the outcomes that are important to people with stroke.

Despite the proliferation of clinical guidelines in healthcare, there is a knowledge gap regarding the effect of guidelines on clinical practice (Kredo et al. 2016), with some authors arguing that clinical guidelines don't necessarily lead to improved quality (Kredo et al. 2016; Baldassari 2017). It is acknowledged that part of the reason for this, is that guidelines tend to focus on quantitative measures (such as time spent it therapy), which may not align with the outcomes that are most

valuable to people (Baldassari 2017). Other authors give examples of clinical guidelines that have demonstrated improved outcomes, but acknowledge that improvement depends on the quality of the recommendations and successful implementation (Barth et al. 2016; Murad 2017). This suggests that the ability of clinical guidelines to improve outcomes depends on a variety of factors, including the measurement of meaningful outcomes, successful implementation and recommendations based on high quality clinical evidence.

Clinical guidelines reduce unacceptable variability in practice, both locally and nationally (Cabana et al. 1999; Woolf et al. 1999; Broughton and Rathbone 2001). The Delphi study found that 32 statements could not achieve consensus. This considerable lack of consensus indicates that significant variability remains in clinical practice, despite this guideline being in place for 13 years (Intercollegiate Stroke Working Party 2008). The most recently published Annual Stroke report acknowledges ongoing variation in rehabilitation delivery in inpatient and community settings, identifying this as a priority for improvement (Bahalla et al. 2021). It is unclear why inconsistency remains, but the findings from the Delphi study suggest that it could be related to variations in therapists' judgement of guideline suitability for a person after stroke and structural/organisational differences between services. It is possible that inconsistency is present in the delivery of stroke rehabilitation in areas that achieved consensus. For example, there was a consensus agreement (86%) that "A therapy session may end if the stroke survivor is not tolerating the therapy input". However, it was beyond the scope of the Delphi study to examine whether all therapists judge therapy tolerance in the same way.

Guidelines should be based on the best available evidence, supplemented with expert opinion and formal consensus as required (Scalzitti 2001; Twaddle 2005; National Institute for Health and Care Excellence 2014). They should provide a rating of the quality of evidence (for example Grading of Recommendations, Assessment, Development and Evaluation (GRADE) (Grade Working Group 2004)), so clinicians are aware of the strength of the recommendations. The RCP guidelines (Intercollegiate Stroke Working Party 2016) acknowledges that the specific recommendation for 45 minutes of daily therapy is derived from working party consensus, based on evidence that more therapy improves recovery after stroke (referencing Lohse et al. (2014) and Kwakkel et al. (2004b)). This was not the finding of the Cochrane review undertaken as part of this programme of research, which found that 'more is better' is an oversimplification of the effect of time spent in rehabilitation on outcomes. The difference between the findings of the Cochrane review and the systematic reviews with meta-analyses referenced in the RCP guidelines

is that the Cochrane review only included studies that control for the type of therapy when comparing more with less. This suggests that the consensus of the Intercollegiate Stroke Working Party is not based on strong evidence; a fact that is not acknowledged via a quality rating.

It is important to ensure that the recommendations given in clinical guidelines are correct, as incorrect guidelines can lead to ineffective practice (Woolf et al. 1999). It is possible that, considering the absence of clear evidence, a recommended *minimum* of 45 minutes of daily therapy is a reasonable guideline. However, findings from the focus groups suggest that there are instances where the guideline is identified as a 'target', not a minimum, with insufficient flexibility within services to provide more. Additionally, the Delphi statement "Stroke survivors who would benefit from more than 45 minutes of therapy-per-day, will receive it" did not reach consensus, with only 27% of participants agreeing. As a result, people requiring more than 45 minutes per day of therapy may be receiving ineffective treatment. This relates to another potential disadvantage that guidelines can limit clinicians' ability to exercise or develop their clinical reasoning skills (Hurwitz 1999; Broughton and Rathbone 2001). One focus group participant indicated that there are occasions when they provide 45 minutes of therapy to a person, as the guideline states they should; however, it is their belief that another person would achieve more benefit from that therapy time in addition to the time they have already received.

Guidelines adherence (or lack thereof) can expose healthcare professionals to the appraisal of managers (Woolf et al. 1999). Indeed, in focus groups, therapists identified that managers 'judge' their performance in relation to the 45 minute guideline. This may be problematic if organisational issues outside therapists' control limit guideline achievement. For example, lack of staff is a reason for non-delivery of the guideline that reached consensus in the Delphi study; this is not under therapists' control.

The SSNAP audit measures and reports the achievement of the 45 minute guideline. Audit, the process of reviewing clinical performance against recognised standards (Foy et al. 2020)), is one of the seven pillars of clinical governance (Limb et al. 2017) and is seen as necessary to stimulate quality improvement (Fung et al. 2008; Stewart et al. 2016; Foy et al. 2020). Indeed, therapists in the focus groups felt SSNAP was beneficial, as it raises the profile of the 45 minute guideline. However, Pflueger (2015) identified that measurement can result in "gaming activities" (p. 2), where practice is adapted to achieve a target, with questionable

benefits to service users. For example, Clarke et al. (2018) identified routine joint working between therapists of different disciplines so that both disciplines could record therapy minutes for the audit. This did not increase the amount of time a person with a stroke was active during the day. In the Delphi study, 65% of participants agreed that their organisation had changed since the publication of the guideline to improve the achievement of 45 minutes of therapy, however, due to limitations of the method, the nature of the change was not established. In the focus groups, therapists identified that people were "discharged from SSNAP" (i.e., their therapy time was no longer entered into the audit) if they weren't meeting their therapy goals, a practice that is at odds with the SSNAP guidelines (ref SSNAP guidelines) and an example of a 'gaming activity'. There are other issues identified with audit for quality improvement. Indeed, although Fung et al. (2008) identified that audit stimulates change in practice, it is not clear if it makes care more effective. Pflueger (2015), in their discussion paper examining the effects of accounting for quality identified that measuring for quality may not be as simple as assumed. Based on a review of literature, they identified that the style of measurement effects outcomes and, potentially audit creates the phenomenon it pertains to measure. Indeed, in relation to the SSNAP audit of the 45 minute guideline, Taylor et al. (2018) found that measurement varied between different stroke units, and that few therapists associated the data collection with improving quality of care, but with pleasing commissioners. Literature identifies that audit requires robust, evidence-based guidelines (Stewart et al. 2016; Foy et al. 2020), but that such measures of quality can be difficult to define (Pflueger 2015). This is an issue for the 45 minute guideline which, as stated previously, is based on consensus, as opposed to robust evidence. This may account for some therapists' belief that SSNAP results do not truly reflect the quality of therapy delivery, either locally or nationally (Taylor et al. 2018).

As identified in chapter 2, guidelines should not be used to mandate practice (Hurwitz 1999); potentially, the SSNAP audit of the guideline causes it to appear a mandate, contributing to the finding in the focus group that 45 minutes of therapy is a 'target', not a recommended minimum. This is particularly problematic, as, identified earlier in this chapter, the SSNAP audit does not accurately capture the achievement of the 45 minute guideline, as it does not account for those whose suitability for the guideline fluctuates. Therefore, the SSNAP audit may cause therapists to aim to achieve the guideline when it is inappropriate. In the focus groups, one therapist reported that they aim to achieve the guideline for people whose therapy benefit is questionable, at the expense of delivering additional therapy to a person whose therapy benefit is clear.

The 45 minute guideline is simple to understand and measure. Indeed, the reasons for choosing a time-based measure of therapy intensity may be its ease of measurement and applicability to physical, cognitive and functional rehabilitation. Additionally, due to its parallels with the notions of 'dose', it aligns with the medical model, which dominate stroke services in the UK. However, Occupational Therapy and Physiotherapy following stroke have been described as a "Black Box" (Ballinger et al. 1999), with contents that are variable and difficult to characterise (DeJong et al. 2005). They are complex interventions, which, arguably, should not be governed by simple rules. Woolf et al. (1999) identified that some guidelines do not do justice to the complex decisions that health care professionals must make. In this programme of research, the focus group data found that multiple, interwoven factors affect the delivery of the 45 minute guideline, and the 32 statements in the Delphi study, which could not achieve consensus, are further evidence of complexity. Linked to this complexity is the issue that time spent in rehabilitation is only one aspect of 'therapy intensity', which may influence outcomes following stroke. As discussed previously, the number of repetitions, relative task difficulty and physiological expended effort required are important factors to consider when planning rehabilitation activities, yet the current guideline for 'therapy intensity' only considers the time spent. Challenges of including recommendations for the number of repetitions, appropriate task difficulty and physiological effort are the difficulty in measuring these aspects and, in the case of repetitions/physiological effort, their lack of applicability to all types of rehabilitation activity.

In summary, there is evidence that the 45 minute guideline and its measurement via the SSNAP audit are not ideally fit for purpose. The guideline has increased the amount of therapy that people receive, but this increase appears to be reaching a plateau. In addition, there is no evidence it has improved the quality of therapy for people with stroke, as the measurement of time spent in therapy relates only to the process of rehabilitation, not the outcomes. Despite 13 years since its first publication (and eight years since measurement commenced), significant variation in the amount of therapy delivered remains in clinical practice. The guideline is based on weak evidence, and people who would benefit from more than 45 minutes of daily therapy may not receive it. It only considers time spent in therapy when literature shows that other elements of 'therapy intensity' may be more important. There are issues with the measurement of the guideline via the SSNAP audit. Auditing the guideline has resulted in "gaming activities", which increase guideline achievement but may not benefit people with stroke. Measurement of guideline achievement positions the guideline as a mandate, as opposed to a recommendation,

and there is evidence that this leads to therapists feeling 'judged' by managers. Importantly, the audit does not accurately record the achievement of the guideline, as it cannot accommodate people whose suitability for therapy is variable or below the 45 minute threshold. These issues cumulatively suggest that the guideline and its measurement via the SSNAP audit may not be fit for purpose and, potentially, a different therapy-based guideline should be considered.

The above analysis is based on the purpose of clinical guidelines and audit, as defined in literature. Plausibly, the 45 minute guideline may be fulfilling purposes that are not defined in literature. Participants in the focus groups report that they find the guideline 'motivating'. Additionally, they identified that the guideline's presence helps justify the number of therapists they have. Potentially, the 45 minute guideline has helped protect stroke therapy services from the austerity measures, which the NHS has been subject to since 2010 (Appleby et al. 2014). This would have a consequential benefit for people with stroke. This calls into question the purpose of this guideline. Is it to improve the quality of therapy for people following stroke (as literature would suggest), or is it to raise the profile of therapy within medically-led stroke services and provide protection from service cuts?

7.4 The impact of the researcher on this research

Accounting for the role of the researcher is an important marker of quality in research (Ballinger 2006). In the discussion of the findings of this programme of work, I consider it important to reflect on the roles, values and beliefs that I brought to this research project.

As acknowledged in chapter one, the motivation for this research stemmed from my experience as an Occupational Therapist, working in inpatient/acute stroke care. In 2008, the year the 45 minute guideline was introduced, I commenced a role as a band 7 (advanced) Occupational Therapist. The guideline did not align with our practice at the time, which involved classifying people as being either a high, medium or low priority for rehabilitation, and providing an amount of rehabilitation accordingly. Introduction of the guideline prompted much discussion with my peers; where had 45 minutes come from? Why was it considered important? Was 45 minutes per day better than a similar total amount of therapy, provided over fewer days? Did this challenge the notion of therapists as autonomous practitioners? I was curious but sceptical. However, my clinical practice did not change, at least initially. My scepticism arose from the

belief that, surely the content of therapy must matter too. Much time spent in poor quality therapy was unlikely to be beneficial, yet the guideline only provided a time-based recommendation. The guideline also challenged the practice of classifying people's priority for therapy, by suggesting that all people appropriate for therapy should receive a minimum of 45 minutes. I wanted to understand the evidence that underpinned the guideline.

I was involved in changes to practice, in relation to achievement of the guideline, when auditing of the guideline commenced. This was initially a one-off audit, in 2010 and became an ongoing audit at the end of 2012. I felt that the notion of being 'judged' in relation to guideline achievement (which is how many of my therapy colleagues felt about audits of therapy) resulted in changes to practice, in order to increase guideline adherence. For example, groupwork commenced, in order to see more people within the same time. In addition, considerable time was taken to set-up processes for recording the amount of time therapists spent with people and ongoing administration to maintain these records. At the time I questioned if this was the right thing to be doing; if we were using our resources in a way that would benefit people, or if we were simply making these changes to achieve the guideline.

A change in my thinking about the guideline occurred at a similar time to the commencement on the ongoing SSNAP audit. In March 2012, I attended the "Intensity of therapy after stroke consensus meeting", a joint meeting between the Intercollegiate Stroke Working Party and The Stroke Research Network, hosted by the Royal College of Physicians. At this event, it was acknowledged that the 45 minute guideline was not based on robust evidence, but was considered a 'practical and reasonable' guideline, based on the evidence that more therapy is better. The aim of introducing such a guideline, was to improve the quality of rehabilitation; to encourage therapists to think differently about how they deliver therapy. I felt more comfortable with the guideline following this explanation, but was curious if most therapists understood this nuance, or if therapists regarded the guideline as 'correct'.

In 2013, I commenced a new role, as a Trainee Consultant Practitioner, with Health Education England. In this role, I was funded to commence a Doctorate. I decided to undertake a piece of research about the 45 minute guideline. I wanted to establish if it was the right thing to be doing for people with stroke, if it improved their recovery and supported the delivery of rehabilitation. These broad questions spurred me to look at more specific questions about the 45 minute

guideline. When reviewing the referred evidence for the 45 minute guideline, I began to question whether the literature available supported the idea that 'more is better' in terms of therapy. As discussed in chapter two, I noted that the systematic reviews with meta-analyses investigating the effect of time spent in rehabilitation, included studies that varied in the content of rehabilitation, as well as the amount of time spent. I believed that this called the argument 'more is better' into question, and was interested to explore further. Thanks to the 2010 National Sentinel Stroke Audit, I knew the guideline was not well-achieved. I was curious to know what that was; based on my own clinical experience, I suspected that this was in part related to the suitability of the guideline for some people after stroke and resource availability.

In 2014, whilst working on my doctorate, I commenced a role leading a Stroke ESD service. Whilst in post, I supported the team to embark on data collection for the SSNAP audit. I was interested in the discussions therapists had, regarding a person's suitability for 45 minutes of daily therapy, and the concerns that this could make people "too dependent" on therapy services, when they needed to start to manage their own rehabilitation, due to the limitations of service delivery. I was interested that, although the guideline stated therapy should continue for as long as people are benefitting from it, service provision did not enable this.

Whilst I have predominantly focused on my thoughts, values and beliefs as I commenced this research, it is also interesting to consider how these changed, over the seven years that I was undertaking this research project. In 2015, I returned to the acute stroke unit, which I had left in early 2013, into the role of unit lead (predominantly leading the ward and the nursing staff). I was interested to observe how much therapy input appeared to have changed. In addition to the ongoing groupwork, I noted that more junior therapists, particularly, referred to the 45 minute guideline, not only as an undisputable requirement, but also as a target; it appeared that efforts to deliver therapy beyond 45 minutes per-day were limited. It was around this time too, that I undertook a "People, Politics and Practice: Contextualising Healthcare Research" module, as part of my doctorate. This deepened my thinking about the guideline significantly. I moved from considering if the guideline was 'right', to considering the positives and negatives of such a guideline (and it's auditing via SSNAP), which may be beyond facilitating stroke recovery, but also protecting therapy services, and reducing variability in practice. The 45 minute guideline aligns with a medical model, in which therapy is not a good fit. Do we need the guideline to better-align therapy with a medical model, or do we need to advocate that this guideline (or potentially guidelines in general) does not fit with the complexities of rehabilitation after stroke?

7.5 Strengths and limitations

Each of the three papers presents considers strengths and limitations. Herein a summary is presented, as well as considering the strengths and limitations of the programme of research.

A strength of the Cochrane review is that it only included studies that compared different amounts of the same type of therapy. To our knowledge, no other systematic review with meta-analysis has examined the effect of time spent in rehabilitation in this way, and therefore, we are confident in the relevance of the findings. A limitation of the Cochrane review is the low level of certainty of the findings, predominantly due to the risk of bias in included studies and the high probability of publication bias. The predicted direction of both these biases would be towards the null hypothesis. A further limitation of the Cochrane review is that it was impossible to determine how much total rehabilitation participants received. Sixteen of the 21 studies included, the amount of 'usual care' provided as a co-intervention was not described. Consequently, the Cochrane review was not able to analyse the effect of the total amount of rehabilitation to investigate whether there is a minimum amount of rehabilitation required, below which there is no benefit of therapy.

A strength of the focus groups and Delphi studies is that they examine therapists' views. This is important, as it is therapists who make decisions about the amount of therapy to provide. Another strength is the staged design of this research element, with the focus groups informing the subsequent Delphi study. This provided credibility to the findings of the Delphi. Unfortunately, the Delphi study included fewer participants than planned. The final two rounds included 29 and 26 participants, respectively when target recruitment was a minimum of 30. The evolving pandemic may have impacted this outcome. The number of responses was particularly low for statements that were experience-dependent and, therefore, answered by a minority of participants. Whilst the Delphi study reports the consensus reasons for non-delivery of the 45 minute guideline in clinical practice, it is unable to determine which reasons are most common and if guideline non-delivery is predominantly due to guideline unsuitability for the person or service inability to deliver this amount of therapy. It was also unable to explore how contextual factors impacted guideline delivery.

To our knowledge, this study is the first to consider the 45 minute guideline beyond the inpatient context. The guideline is applicable to people after stroke for "as long as they are willing and capable of participating and showing measurable benefit from treatment" (Intercollegiate Stroke Working Party 2016 p.25), therefore it may be suitable for people receiving ESD. Achievement of the 45 minute guideline is measured by ESD services but reported differently to inpatient services.

7.6 Recommendations for clinical practice, future guideline development and future study

This programme of research has added to the evidence base for the 45 minute guideline and its relevance to clinical practice. Recommendations for clinical practice (at a therapist and organisation level) and future guideline development are herein presented. Unanswered questions concerning this topic remain, which informs recommendations for future research

7.6.1 Advice for Clinical Practice

The 45 minute guideline is a guideline; it should not be considered mandatory. It should not replace evidence-informed clinical reasoning. The guideline for 45 minutes is based on research evidence that suggests more therapy is better, and which our Cochrane Review has shown to be not entirely accurate. It is also based on consensus, the lowest quality form of evidence (Evans 2003; Ingham-Broomfield 2016). Therapists are encouraged to be mindful that 45 minutes is the minimum amount recommended, not a target that indicates therapy can stop once achieved. The presented Cochrane review indicates that a large amount of additional rehabilitation is required to influence change in ADL outcomes, and therapists are encouraged to consider which people would most benefit from a large amount of rehabilitation following stroke.

When planning interventions with people following stroke, therapists should consider other elements of therapy 'intensity', which may benefit outcomes. It is likely that time spent in therapy is not the most important factor (Klassen et al. 2020); thus therapists should ensure time spent in therapy is active, delivering an increased number of repetitions and undertaking tasks at an appropriate level of difficulty to the person.

Managers within organisations should not judge therapists' performance on the achievement of the guideline alone. Evidence suggests that routines and procedures may optimise therapists' clinical time and should be incorporated into clinical practice (Clarke et al. 2018). Beyond this, however, reasons for guideline non-achievement are likely due to factors beyond the therapists' control, such as suitability of the guideline for individuals and staffing limitations. Indeed, managers and those in commissioning should ensure that services are adequately resourced to deliver the recommended minimum amount of therapy.

7.6.2 Advice for future guideline development and measurement

It is believed that the Royal College of Physician Guidelines for Stroke will be reviewed in 2023. Based on the findings of this programme of research and the research that has been reviewed during its undertaking, the following advice is offered regarding the 45 minute guideline:

Whilst the research evidence for the 45 minute guideline remains questionable, there are benefits to having a guideline for a minimum amount of therapy. Therefore, in the absence of an evidence-based alternative, potentially the guideline for a minimum of 45 minutes of therapy should remain, providing this remains the consensus of the intercollegiate stroke working party. However, the guideline should emphasise that this is a minimum, and some people would benefit from much more therapy following a stroke. This should be reflected in auditing guideline achievement via SSNAP, with recognition to services that have delivered more than the 45 minutes of daily therapy to those who would benefit from it. Additionally, SSNAP should be adapted to allow therapists to identify when people's suitability for therapy has fluctuated (e.g., they have been suitable on one day, but not another). This could result in improved alignment between the guideline recommendations and the audit. A further suggested change to the audit is the inclusion of an appropriate measure of therapy outcome, such as the Barthel Index, to aim to capture outcomes that are more likely to be meaningful to the person with stroke.

The guideline should encourage therapists to consider other elements of therapy 'intensity' that are likely to have a beneficial effect, such as aiming for more practice repetitions and using tasks that are an appropriate level of difficulty for the person. It is acknowledged that both these factors are challenging to measure, but encouraging an intention may be the first step to incorporating an appropriate number of repetitions and appropriate task difficulty into clinical

practice. Ideally, future guidelines will include a summary of the evidence for all elements that contribute to rehabilitation intensity, not just time spent. Alongside this, the guideline should provide a rating of the quality of evidence, such as GRADE (Grade Working Group 2004) to provide therapists with clarity regarding the strength of the recommendations.

The suitability of the guideline in ESD should be considered and recommendations made explicit. The presented research suggests specific issues with the delivery of the guideline in ESD and, potentially, the guideline is not suitable for people receiving ESD services. The most recent SSNAP report acknowledges that people undergoing rehabilitation in the community receive it for fewer days than those in the hospital. Still, it should be comparable to inpatient services (Bahalla et al. 2021). If the achievement of the 45 minute guideline in ESD is presented in a comparative format to inpatient teams, commissioners of services may be more inclined to fund community services appropriately to provide a comparable amount of rehabilitation. Increased amounts of rehabilitation could be provided in the community via the use of telerehabilitation.

7.6.3 Recommendations for future research

7.6.3.1 Determining appropriate therapy recommendations for people with stroke

This study has found that there is little evidence to support a time-based guideline for therapy following stroke and limitations to its implementation in clinical practice. Therefore, a research priority is to examine which therapy-based recommendations would provide improved outcomes to people with stroke and how the outcomes of these are best measured. This would require an extensive and complex programme of research, which would include examination of other aspects of therapy intensity (such as number of repetition, physiological effort and appropriate task challenge), as well as different therapy interventions. This aligns with the research priorities of the The Stroke Priority Setting Partnership (2021), which identified the need to determine which interventions best improve strength and fitness and promote recovery in people with stroke. This work would need to be supported by further work to determine how to measure the outcomes that are most meaningful to people with stroke. It is possible that such work could conclude that use of clinical guidelines in delivery of therapy to people with stroke is not appropriate; that the complex nature of Occupational Therapy and Physiotherapy are incompatible with the reductionist nature of clinical guidelines.

7.6.3.2 Survey of therapists in practice

Regarding the programme of research presented in this thesis, future research is proposed to move from the theoretical findings to practice by comparing the findings of the Delphi study to clinical practice. This will fulfil two objectives: 1. It will validate the reasons why patients may not receive 45 minutes of therapy. 2. It will provide an understanding of the most common reasons why a stroke survivor does or doesn't receive the recommended 45 minutes of therapy five days a week.

An observational, cross-sectional, prospective survey is proposed (Newell and Burnard 2011). It will describe current practice within a cross-section of settings and therapists. A purposive sample of Physiotherapists and Occupational Therapists working with stroke survivors either as inpatients or outpatients who are aware of the 45 minute guideline will be recruited. It will include an even split of Occupational Therapists and Physiotherapists across bands 5, 6 and 7. Both inpatient and community settings will be represented. Therapists will be invited to participate via specialist interest groups within professional bodies (e.g. College of Occupational Therapists Specialist Section - Neurological Practice, Association of Chartered Physiotherapists in Neurology) and their employing organisations. An invitation to participate will be sent to the stroke units of all organisations participating in SSNAP for the attention of the lead Physiotherapy and Occupational Therapist. Those interested in participating will be asked to contact the researcher.

The data collection tool will be developed using the reasons why a stroke survivor may or may not receive the 45 minutes of therapy generated by the Delphi. Therapists will be asked to reflect on their caseload at the end of their shift, specifically considering those stroke survivors that did not receive the recommended minimum of 45 minutes of therapy (this may include stroke survivors that they have not seen at all that day, hence the requirement to enter data at the end of shift). They will then be asked to select the reason that best described why the individual treated did or did not receive a minimum of 45 minutes of therapy. This data will be collected using an online survey tool. There is no requirement to maintain a record of the treated stroke survivors for data analysis; however, during data collection, a minimum amount of data will be collected on the stroke survivors (for example, month of birth and part of postcode) to avoid duplication. The researcher will be in contact with the participants regularly, by prior agreement. This contact

could be via email or telephone, depending on the participant's preference. The purpose of this contact is to maintain the momentum of data collection, remind participants of the process and respond to any queries participants may have. The researcher will not be physically present during data collection. It is anticipated that data collection will take three months.

The non-treatment of stroke survivors is sensitive information; thus, the anonymity of the treating therapists and the stroke survivor will be maintained. Participants will be identified via a participant identification number only, and stroke survivors will be identified by only the minimal data described above. Ethical approval will be sought from the NHS Research Ethics Committee.

It is anticipated that the survey will generate statistical data regarding the main reasons why stroke survivors did not receive the recommended amount of therapy.

7.6.3.3 Randomised controlled trial to provide evidence for the effect of time spent in therapy

The Stroke Priority Setting Partnership (2021) identify the need to determine the optimal amount of therapy to achieve the best outcomes. To answer this question, high-quality RCTs that are adequately powered are required. Please see figure 16 for the suggested PICO for such a study. To test the efficacy of the 45 minute guideline in acute or sub-acute stages, a control group could receive the recommended 45 minute daily minimum amount of therapy, and an experimental group could receive a total of 1,000 minutes more of the same therapy (based on the findings of the Cochrane review). The additional therapy would need to be presented as a recommended minimum daily amount, which would be calculated based on the average length of stay in rehabilitation between the inpatient and community services. Some of the interventions could be delivered remotely via telerehabilitation, provided this could be tailored to the individual's needs, and the amount of time spent in rehabilitation could be accurately monitored. Outcomes would include an economic evaluation to analyse whether the additional investment in rehabilitation was cost-effective.

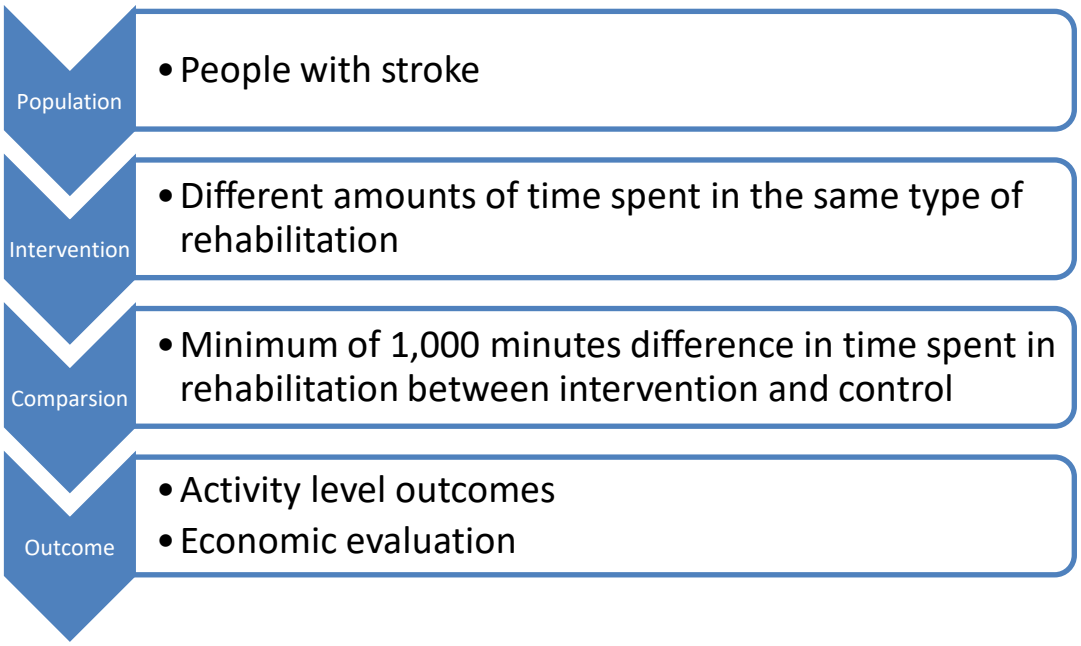

Figure 16 PICO for proposed RCT design

7.6.3.4 Secondary Analysis of Focus Group data

In addition to the data presented in this study, the focus groups gathered data regarding the impact that the 45 minute guideline has had on clinical practice. Analysis of this dataset was beyond the scope of this study but could provide further evidence for the 45 minute guideline in terms of clinical impact.

Chapter 8 Conclusions

Conclusions are presented concerning the questions this study addressed.

1. Does the evidence for the effect of time spent in rehabilitation support guideline recommendations for therapy following stroke?

This research has identified that there is insufficient evidence to recommend a specific minimum amount (in terms of time) of therapy after stroke. It has also found that 'more is better' is an oversimplification concerning time spent in therapy, but 'a lot more' therapy might lead to better outcomes. This suggests that the 45 minute guideline is based on expert consensus alone, without solid underpinning research evidence.

2. What factors determine whether someone receives the recommended minimum amount of therapy?

There are issues with the suitability of the guideline in both ESD and inpatient services. For some people who require therapy, 45 minutes is too much; others can tolerate this amount on some days but not on others. Therefore, suitability for therapy does not equate to suitability for the 45 minute guideline. For other people, 45 minutes of daily therapy is not enough; this study found that people who require more than 45 minutes of daily therapy may not receive it.

Non-delivery of the guideline is not only due to its suitability but also due to lack of resources. There is insufficient therapy time to deliver the recommended minimum amount of therapy, partly due to the organisation of stroke care but also due to inadequate therapy staffing.

3. Is the 45 minute guideline fit for purpose?

Evidence suggests that the 45 minute guideline does not meet all the requirements of a clinical guideline, as described in published literature. However, therapists, stroke services, and consequently, people with stroke may derive benefit from having a guideline for amount of rehabilitation. In the absence of an evidence-based alternative, a minimum of 45 minutes of daily rehabilitation seems reasonable. Nevertheless, a recommendation for time spent in therapy alone is too simplistic; the guideline should acknowledge the importance of other aspects of

'therapy intensity', such as the number of repetitions and appropriate level of challenge. Additionally, there are issues with the measurement of guideline achievement via SSNAP, which does not accommodate fluctuating suitability of the guideline for some people and can be a misdirected incentive. This research identifies that the 45 minute guideline and its measurement via the SSNAP audit would benefit from a review.

Further research is required to better understand the effect of time spent in therapy on outcomes after stroke to inform evidence-based guideline development and learn more about how it is implemented and audited in clinical practice.

Appendix A Characteristics of Systematic Reviews/Meta Analyses

Study ID	Main purpose of paper	Type of Paper	No. participants & time since stroke.	Quality of papers.	Outcomes
Schneider 2016	To examine the effect of extra rehabilitation of the same content on top of usual rehabilitation Included investigation into the amount of extra rehabilitation required to achieve beneficial effect.	Systematic Review with Meta-Analysis (14 studies included)	Total 954 (range 17 – 190) 4 studies had >100 participants 12 studies, participants were <6months post-stroke. 2 studies participants were >6 months post-stroke	Analysed using PEDro (scored /11) Mean score of 6.9 Range 5 – 8 Not all studies described concealed allocation and assessor blinding	Measures of activity, pooled for upper limb and lower limb
Schneider 2016 – Study Findings Only analysed results at immediate follow-up. Found that additional therapy had a beneficial effect on UL and LL activity immediately after training (SMD 0.39, 95% CI 0.07-0.71). However, there was significant heterogeneity. This was partially explained by the amount of extra practice. When sub-grouped into a small (≤100%) or large (>100%) increase, the summary diamond crosses the line of no effect for the small increase group (for pooled measures). For the					

pooled studies of a large (>100%) increase, SMD was 0.59, 95% CI 0.23 to 0.94 A ROC curve of false versus true benefit indicated that at least an extra 240% rehabilitation is needed for significant likelihood that the amount of rehabilitation will improve activity in stroke survivors					
Sehatzadeh 2015	To investigate if an increased intensity of PT after stroke results in better patient outcomes.	Systematic Review with Meta-Analysis (8 studies included)	542 total Range 30 – 109 2 studies had >100 participants All participants were within 3 months of stroke (mean range 13.4 - 71 days)	No assessment made of individual studies	Upper Limb (ARAT) Measures of Mobility ADL (Barthel Index)
Sehatzadeh 2015 – Study Findings Greater amount of therapy lead to greater improvements in UL, as measured by the ARAT (findings from two studies). The third study showed no significant difference, but the difference in treatment time between the experimental and the control group was smaller. No significant difference in measures of mobility found following an increased amount of therapy (findings from one study) No significant difference in ADL (as measured by the Barthel Index) following an increased amount of therapy (findings from 4 studies).					
Veerbeek 2011	Aim was to investigate effect of augmented (i.e. additional minutes) lower-limb exercise therapy on gait, gait-related	Systematic Review with Meta-Analysis	Total 725 (Range 17 – 114) 2 studies with >100 participants	Analysed using PEDro (scored /11)	Walking ability Comfortable walking speed

	outcomes and basic and extended ADL during the first 6 months after stroke	(14 studies included)	In 13 of the studies, participants were in the first 2 months post stroke (range <24 hours – 52 days). In one study, participants were 6.39 months post-stroke	Mean score of 6.5 Range 5 – 8 In 2 studies, assessors were not blinded to treatment allocation, only 5 undertook intention to treat analysis, 3 did not describe concealed allocation.	Maximum walking speed Basic ADL (Barthel Index) Extended ADL (?measure
Veerbeek 2011 – Study Findings Walking ability – favoured experimental (SMD 0.32, 95% CI 0.11 – 0.52) – moderate effect size Comfortable walking speed – favoured experimental (SMD 0.22 95% CI 0.01 – 0.43) – small effect size Maximum Walking Speed – borderline favoured experimental (SMD 0.34 95% CI 0.00 – 0.68) Basic ADL (Barthel Index) – non-significant SES was found (SMD 0.11 95% CI -0.12 – 0.34) Extended ADL – significant medium SES (SMD 0.54 95% CI 0.20 – 0.88)					
Galvin 2008	To examine the effects of additional time in exercise therapy. Reviews studies that use different physical therapy approaches, with outcomes at the impairment and function level.	Systematic Review with Meta-Analysis (20 studies included)	Total – 1906 Range: 25 – 282 9 Studies with ≥100 participants	Studies were assessed for potential sources of bias. 13 were considered to be High risk of bias, 7 low risk of bias. Also analyzed using the PEDro (/11)	Upper Extremity Measures Lower Extremity Measures ADLs (Barthel Index and NEADL)

			Majority of studies were of participants in the first 6 months post-stroke (19 studies).	Mean Score – 6.75 Range 5-8 Two papers had already been excluded for having a PEDro score of <5.	
Galvin 2008 – Study Findings Upper Extremity Outcome Measures: Results of the ARAT, FM-UL and the MI were pooled, all showing non-significant summary effect sizes for a greater amount of therapy. Lower Extremity Outcome Measures: Results of the FM-LL and walking speed were pooled. They showed non-significant summary effect sizes for a greater amount of therapy. Activities of daily living: When measured using the Barthel, Pooled results showed a significant result in favour of additional treatment both immediately post-treatment (SES 0.13 95% CI 0.01 – 0.25) and at 6 month follow-up (SES 0.15 95% CI 0.05 – 0.26). When measured with the NEADL, no significant outcome was found at 6 months					
Kwakkel 2004	To examine the effects of augmented treatment time by reviewing studies evaluating the effects of intensity (in terms of amount) of exercise therapy in people with stroke on ADL, gait, and dexterity.	Systematic Review with Meta-Analysis (20 studies included)	Total 2686 Range: 27 - 466 13 Studies with ≥100 participants 16 of the studies were of participants in the first 6 months post-stroke (all within the first 2 months post-stroke)	Methodological quality of included studies was assessed using a modified version of the assessment used by Kwakkel et al. 1997. Scored /14. Range of scores was 2-11 Mean 6.9	ADL Outcomes Walking Speed Dexterity

			3 of the studies were of people >6 months post stroke (1 – 5 years) One study was of unknown time since stroke	10 of the studies described the method of randomised and concealed allocation.	
Kwakkel 2004 – Study Findings ADL Outcome measures: Barthel (15 studies) FIM (1 study) and 4 other measures of ADL were used. Small, but significant SES found overall for ADL (0.13 SDU; CI, 0.03 to 0.23). In studies of people more than 6 months post stroke, only, there was a non-significant SES. (0.07 SDU; CI, -0.17 to 0.28). In studies of people in the first 6 months following stroke, there was a significant SES (0.15 SDU; CI 0.06 – 0.23) Walking Speed: Six studies investigated walking speed. Pooled finding showed a significant SES (0.19 SDU; CI 0.01 – 0.36) Upper limb Outcomes: Five studies investigated UL outcomes using the ARAT. No significant SES was found (0.03 SDU; CI -0.13 – 0.19) For the ADL outcomes, a cumulative meta-analysis was undertaken. This found that at least an additional 16 hours of exercise therapy is required to elicit a 4/5% change in outcome measure. There was a wide range in the amount of additional therapy that was provided between studies.					
Kwakkel 1997	To review studies that evaluate the efficacy of different intensities (in terms of amount of time) of stroke rehabilitation and to trace variables that may influence rehabilitation outcome.	Research Synthesis with Meta-Analysis (9 studies included, 8 RCTs and 1 retrospective cohort study)	Total 1051 Range: 27 - 428 3 Studies had ≥100 participants 7 of the studies were of participants in the first 6 months	Methodological quality of included studies was assessed using a tool developed using the Potsdam standards (score /16) Range of scores was 2-7, with a mean average of 4.33.	ADL Neuromuscular outcomes Functional outcomes

			post-stroke (all within the first 2 months post-stroke) 2 of the studies were of people >6 months post stroke (2.9 - 5 years)	Only 2 studies described their method of randomisation and in only 4 studies was there observer blinding.	
Kwakkel 1997 – Study Findings Generally speaking, experimental groups received twice as much therapy at control groups ADLs: Small, but statistically significant SES in favour of additional treatment (0.28 SDC; CI ± 0.12) Neuromuscular outcomes: Non-significant SES found (0.10 SDU; CI ± 0.21). However, following post-hoc analysis to control for organisational setting and blinding, there was a significant SES (0.35 SDU; CI ± 0.30) Functional outcomes: Statistically significant SES in favour of additional treatment (0.37 SDC; CI ± 0.24) Authors note that there were confounding variables in some of the studies included and low methodological quality of studies included – limiting the generalizability of the findings.					
Lohse 2014	To build upon the binary question of "is more therapy better?" by attempting to quantify the magnitude of functional improvement gained by increasing the amount of therapy time.	Systematic Review with Meta-analysis and meta-regression (34 - 30 studies were included in the meta-regression, due to missing data in 4 studies)	2,236 total Range 9 – 282 7 Studies had ≥100 participants 18 studies were of participants in the first 6 months post-stroke) 13 studies were of people >6 months post stroke	Methodological quality of included studies was assessed using PEDro (/11) Range of scores was 5-10, with a mean average of 8.06.	Meta analysis pooled impairment and functional outcomes Meta regression explored the relationship between time and additional therapy scheduled.

			1 study stated that participants were less than a year post-stroke 2 of the studies did not report time since stroke This study measured years post-stroke. In studies, this ranged from 0.003 – 4.631.		
Lohse 2014 – Study Findings There was an overall beneficial effect of receiving more therapy than receiving less. SES (measured by Hedges g) 0.35; 95% confidence interval, 0.26–0.45 The meta regression was performed using 4 different models, which controlled for the linear and non-linear effects of time and time since stroke They concluded that there was a significant, positive relationship between amount of time scheduled for therapy and improvement on outcome measures. This relationship was not effected by time since stroke, but there was a potentially non-linear effect of time.					
Cooke 2010	To explore the strength of the evidence for the effect of a higher dose of the same type of exercise-based therapy for motor recovery, following stroke	Systematic Review with Meta-Analysis (7 studies included)	Total 680 Range: 20 - 189 3 Studies had ≥100 participants, 4 studies had <100 participants	Assessed using the Cochrane tool for RoB. Two studies were an unclear RoB for allocation concealment. One study was high RoB for blinding. Two studies were an unclear RoB for incomplete outcome data.	Motor impairment – muscle function Motor impairment – movement control Functional Activity

	Dose was defined as time spent in therapy and/of effort expended.		6 of the studies were of participants in the first 6 months post-stroke (all within the first 2 months post-stroke) The remaining study did not provide data regarding time since stroke	One was high RoB for selective outcome reporting.	
Cooke 2010 – Study Findings Meta analysis of outcomes were limited by the heterogeneity of measures used Motor impairment – muscle function: Meta analysis was undertaken for hand grip force/strength at end of treatment. This significantly favoured the control treatment (ES -10.1; 95% CI -19.1 - -1.2). For motricity arm measured at first follow-up, there was a significant effect size in favour of experimental treatment (ES 10.7; CI 1.7 – 19.8) Motor impairment – movement control: No meta analysis could be completed Functional Activity: Meta analysis of UL function, using the ARAT was completed for all 3 time points. No statistically significant ES were found. Comfortable walking speed showed an ES significantly in favour of control treatment at first point, but a non-significant finding at second time point.. Rivermead mobility showed a non-significant ES (meta analysis only available for 1st follow-up No outcome measures were combined for meta-analysis					
Langhorne 1996	To determine whether more intensive physiotherapy leads to greater reduction in disability.	Systematic Review with Meta-Analysis	Total 597 Range: 27 – 132	Not assessed	Death Death or deterioration

	Intensity of therapy is defined as a greater number of minutes/day of therapy	(7 studies included)	2 Studies had ≥100 participants, 5 studies had <100 participants 4 of the studies were of participants in the first 6 months post-stroke. One study was of people >6 months post stroke. In one study, the participants were a wide range of time-points since stroke (8 days – 5 years) The final study did not report time since stroke.		Pooled measures of impairment Pooled measures of disability
Langhorne 1996 – Study Findings There was a non-significant reduction in the chance of death The combined outcome of death or deterioration was reduced (OR *0.54;* 95% CI *0.3-0.85; p<0.0l)* among the intensive physiotherapy group The pooled measures of impairment and disability did not show any significant results.					

Appendix B AMSTAR 2 Tool

1. Did the research questions and inclusion criteria for the review include the components of PICO?

For Yes:
- ☐ Population
- ☐ Intervention
- ☐ Comparator group
- ☐ Outcome

Optional (recommended)
- ☐ Timeframe for follow-up

☐ Yes
☐ No

2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

For Partial Yes:
The authors state that they had a written protocol or guide that included ALL the following:
- ☐ review question(s)
- ☐ a search strategy
- ☐ inclusion/exclusion criteria
- ☐ a risk of bias assessment

For Yes:
As for partial yes, plus the protocol should be registered and should also have specified:
- ☐ a meta-analysis/synthesis plan, if appropriate, *and*
- ☐ a plan for investigating causes of heterogeneity
- ☐ justification for any deviations from the protocol

☐ Yes
☐ Partial Yes
☐ No

3. Did the review authors explain their selection of the study designs for inclusion in the review?

For Yes, the review should satisfy ONE of the following:
- ☐ *Explanation for* including only RCTs
- ☐ OR *Explanation for* including only NRSI
- ☐ OR *Explanation for* including both RCTs and NRSI

☐ Yes
☐ No

4. Did the review authors use a comprehensive literature search strategy?

For Partial Yes (all the following):
- ☐ searched at least 2 databases (relevant to research question)
- ☐ provided key word and/or search strategy
- ☐ justified publication restrictions (e.g. language)

For Yes, should also have (all the following):
- ☐ searched the reference lists / bibliographies of included studies
- ☐ searched trial/study registries
- ☐ included/consulted content experts in the field
- ☐ where relevant, searched for grey literature
- ☐ conducted search within 24 months of completion of the review

☐ Yes
☐ Partial Yes
☐ No

5. Did the review authors perform study selection in duplicate?

For Yes, either ONE of the following:
- ☐ at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include
- ☐ OR two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder selected by one reviewer.

☐ Yes
☐ No

6. Did the review authors perform data extraction in duplicate?

For Yes, either ONE of the following:

- ☐ at least two reviewers achieved consensus on which data to extract from included studies
- ☐ OR two reviewers extracted data from a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder extracted by one reviewer.

☐ Yes
☐ No

7. Did the review authors provide a list of excluded studies and justify the exclusions?

For Partial Yes:

- ☐ provided a list of all potentially relevant studies that were read in full-text form but excluded from the review

For Yes, must also have:

- ☐ Justified the exclusion from the review of each potentially relevant study

☐ Yes
☐ Partial Yes
☐ No

8. Did the review authors describe the included studies in adequate detail?

For Partial Yes (ALL the following):

- ☐ described populations
- ☐ described interventions
- ☐ described comparators
- ☐ described outcomes
- ☐ described research designs

For Yes, should also have ALL the following:

- ☐ described population in detail
- ☐ described intervention in detail (including doses where relevant)
- ☐ described comparator in detail (including doses where relevant)
- ☐ described study's setting
- ☐ timeframe for follow-up

☐ Yes
☐ Partial Yes
☐ No

9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?

RCTs

For Partial Yes, must have assessed RoB from

- ☐ unconcealed allocation, *and*
- ☐ lack of blinding of patients and assessors when assessing outcomes (unnecessary for objective outcomes such as all-cause mortality)

For Yes, must also have assessed RoB from:

- ☐ allocation sequence that was not truly random, *and*
- ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

☐ Yes
☐ Partial Yes
☐ No
☐ Includes only NRSI

NRSI

For Partial Yes, must have assessed RoB:

- ☐ from confounding, *and*
- ☐ from selection bias

For Yes, must also have assessed RoB:

- ☐ methods used to ascertain exposures and outcomes, *and*
- ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

☐ Yes
☐ Partial Yes
☐ No
☐ Includes only RCTs

10. Did the review authors report on the sources of funding for the studies included in the review?

For Yes

- ☐ Must have reported on the sources of funding for individual studies included in the review. Note: Reporting that the reviewers looked for this information but it was not reported by study authors also qualifies

☐ Yes
☐ No

11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?

RCTs

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
  - ☐ AND they used an appropriate weighted technique to combine study results and adjusted for heterogeneity if present.
  - ☐ AND investigated the causes of any heterogeneity

☐ Yes
☐ No
☐ No meta-analysis conducted

For NRSI

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
  - ☐ AND they used an appropriate weighted technique to combine study results, adjusting for heterogeneity if present
  - ☐ AND they statistically combined effect estimates from NRSI that were adjusted for confounding, rather than combining raw data, or justified combining raw data when adjusted effect estimates were not available
  - ☐ AND they reported separate summary estimates for RCTs and NRSI separately when both were included in the review

☐ Yes
☐ No
☐ No meta-analysis conducted

12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?

For Yes:

- ☐ included only low risk of bias RCTs
- ☐ OR, if the pooled estimate was based on RCTs and/or NRSI at variable RoB, the authors performed analyses to investigate possible impact of RoB on summary estimates of effect.

☐ Yes
☐ No
☐ No meta-analysis conducted

13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?

For Yes:

- ☐ included only low risk of bias RCTs
- ☐ OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results

☐ Yes
☐ No

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?

For Yes:

- ☐ There was no significant heterogeneity in the results
- ☐ OR if heterogeneity was present the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review

☐ Yes
☐ No

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

For Yes:

- ☐ performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias

☐ Yes
☐ No
☐ No meta-analysis conducted

16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

For Yes:

- ☐ The authors reported no competing interests OR
- ☐ The authors described their funding sources and how they managed potential conflicts of interest

☐ Yes
☐ No

Appendix C Summary of AMSTAR 2 Scores

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Cooke 2010	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Galvin 2008	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Kwakkel 1997	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Kwakkel 2004	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Langhorne 1996	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Lohse 2014	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Schnider 2016	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Sehatzadeh 2015	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Veerbeek 2011	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆

◆ = Yes ◆ = Partial Yes ◆ - No

1. Did the research question and inclusion criteria for the review include the components of PICO?
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?
3. Did the review authors explain their selection of the study designs for inclusion in the review?
4. Did the review authors use a comprehensive literature search strategy?
5. Did the review authors perform study selection in duplicate?
6. Did the review authors perform data extraction in duplicate?
7. Did the review authors provide a list of excluded studies and justify the exclusions?
8. Did the review authors describe the included studies in adequate detail?
9. Did the review authors use satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?
10. Did the review authors report on the sources of funding for the studies included in the review?
11. If meta-analysis was performed, did the review authors use appropriate methods for the statistical combination of results?
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?
13. Did the review authors account for RoB in primary studies when interpreting/discussing the results of the review?
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

Appendix D Cochrane Protocol

Cochrane Library
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BACKGROUND

This review will explore the effect of time spent in rehabilitation after stroke. We acknowledge that 'time spent' is potentially an ambiguous term. For the purpose of this review, we consider 'time spent' to include

- the number of minutes of rehabilitation provided, per week;
- the frequency of rehabilitation provided per week (i.e. number of days per week on which rehabilitation was provided);
- the time-period over which rehabilitation was provided, or rehabilitation duration.

The outcome of rehabilitation after stroke may also be affected by how these different elements are combined. For example, the outcome of a certain number of minutes of rehabilitation provided over a shorter time-period may be different to the same number of minutes provided over a longer time-period. We acknowledge that, to some, 'time spent in rehabilitation' could be synonymous with 'rehabilitation intensity'. Whilst the term 'intensity' could be used to describe the time-related elements described above, it has also been used to describe alternative characteristics of rehabilitation, including number of repetitions performed within treatment sessions (Scrivener 2012) and physiological effort exerted (Outermans 2010). We will not explore these characteristics in this review. Other terms to describe 'time spent in rehabilitation' could be 'dose of rehabilitation' or 'amount of rehabilitation'.

Description of the condition

Stroke is a "neurological deficit attributed to an acute focal injury of the central nervous system by a vascular cause" (Sacco 2013). It is a significant, global health issue. In 2010, there were approximately 16.9 million first-ever strokes and 33 million stroke survivors worldwide (Feigin 2014). Stroke is one of the leading causes of disability (Adamson 2004). In 2010, 102 million disability adjusted life years (DALYs) were lost after stroke (Feigin 2014). In the UK alone, over 27,000 (37%) of people discharged from hospital from April 2013 to March 2014 required help with activities of daily living such as washing and dressing (Royal College of Physicians 2014). Such disability results in significant cost due to care requirements and loss of productivity (Mozaffarian 2015; Saka 2009). Better rehabilitation outcomes after stroke would reduce the impact of disability and dependence on the quality of life of people with stroke and their carers (Nichols-Larsen 2005), and national economies (Truelsen 2005).

Description of the intervention

Stroke rehabilitation is a broadly-based, multi-dimensional process encompassing interventions that aim to facilitate restitution or substitution of limitations in impairment, activity, or participation caused by stroke (Dobkin 2005; NICE 2013). According to Langhorne 2011, rehabilitation after stroke typically follows a four-stage, cyclical process of assessment of need, goal setting, intervention, and reassessment.

Previous Cochrane Reviews have explored various different rehabilitation interventions for various different outcomes after stroke. Interventions have included physical rehabilitation (Pollock 2014a), cognitive rehabilitation (Bowen 2013; Chung 2013; das Nair 2016; Loetscher 2013), telerehabilitation (Laver 2013), virtual reality (Laver 2015), acupuncture (Yang 2016), electromechanical and robot-assisted arm training (Mehrholz 2015), mirror therapy (Thieme 2012), physical fitness training (Saunders 2016), motivational interviewing (Cheng 2015), constraint-induced movement therapy (CIMT) (Corbetta 2015), repetitive transcranial magnetic stimulation (Hao 2013), and repetitive task training (French 2007). Whilst there is value in determining the efficacy of specific rehabilitation interventions, it is acknowledged that, in practice, the content of rehabilitation therapy is not clearly defined and varies between both therapists and services (Ballinger 1999; DeJong 2005). The relationship between type of therapy and response is unclear (Lohse 2014), with therapists adopting an eclectic approach (Jette 2005). Therefore, this review is adopting an 'intervention agnostic' approach, seeking to explore not if one type of rehabilitation is superior to another, but to explore the specific effect of time spent in rehabilitation.

In the Cochrane Review of 'Physical rehabilitation approaches for the recovery of function and mobility following stroke', Pollock 2014a identified that rehabilitation could be provided by a variety of professions. This included therapists, therapists with assistance from family members, physiotherapists, rehabilitation nurses, nurses, occupational therapists, doctors, sports therapists, student physiotherapists, and research physiotherapists. This review is not limited to any specific provider of rehabilitation but acknowledges that, in many countries and healthcare systems, therapists provide rehabilitation. Therefore, for the purpose of this review, we will refer to providers of rehabilitation as therapists.

This review is not limited to physical rehabilitation following stroke, but any rehabilitation intervention, where time spent in rehabilitation is greater than zero. As we are interested in exploring the effect of time spent in rehabilitation on measures of activity after stroke, we are primarily interested in rehabilitation interventions that target this level of recovery. This will be determined by studies that use activity level outcome measurements. For the purpose of this review, therefore, we define rehabilitation as any non-pharmacological, non-surgical intervention that aims to improve activity after stroke.

How the intervention might work

In this review, the intervention is any non-pharmacological, non-surgical intervention that aims to improve activity after stroke and the influence of time spent on intervention. These interventions might work through neuroplasticity: the brain's ability to modify neuronal activity and reorganise neural connections. Neuroplasticity underpins both recovery of and compensation for impaired motor function after stroke (Buma 2013; Dobkin 2005; Kleim 2008; Levin 2009; Nudo 2013). The differentiation between recovery, where survivors initially regain their pre-morbid kinematic/muscle activation patterns and compensation, where alternative kinematic/muscle activations are used to accomplish a task is thought to occur by around the first five to eight weeks after stroke (Kwakkel 2015; Van Kordelaar 2013).

Research points to many potentially important aspects of stroke rehabilitation that will influence outcomes. Kleim 2008, in their review of the evidence for experience-dependent neural plasticity, identified that repetition, the relative importance of the task undertaken, and skill acquisition (as opposed to simply use) will influence plasticity. Other authors described further important aspects in the re-learning of motor skills, such as the use of explicit versus implicit learning (Boyd 2003; Boyd 2004). The

presence of a meaningful context or goal has been shown to enhance motor learning (Ma 1999; Wu 2000). There is evidence that extrinsic feedback enhances motor-learning after stroke (Van Vliet 2006) and that stroke survivors benefit more from random practice of exercise than they do block practice (Hanlon 1996). Wulf 2010 discussed additional influences on learning, such as learning through observation, and internal versus external focus of attention and self-controlled practice. Mount 2007 discussed research related to the impact of errorless learning versus trial and error learning, whilst Levack 2006 suggested that specific, difficult goals may enhance performance. Finally, research suggests that an enriched environment enhances recovery post-stroke (Janssen 2010). The purpose of this review, however, is to explore the effect of the time spent in rehabilitation for activity level outcomes after stroke. Whilst it is acknowledged that other factors will influence outcomes, we assume that these other factors are similarly distributed in an intervention where only the time spent in rehabilitation is the variable of focus for this review.

Mechanistically, one type of learning that promotes neuroplasticity is Hebbian Learning (Hebb 1949). Hebbian (and anti-Hebbian) Learning is concerned with an increase in synaptic efficacy, due to repetitive firing of the pre-synaptic cell, causing stimulation of the post-synaptic cell, leading to increased synaptic strength (Nudo 2013). Evidence indicates that repetition is key to increasing synaptic efficacy (Kleim 2008; Nudo 2013). From a therapist's perspective, then, it could be interpreted that the time spent in rehabilitation may determine the frequency of synaptic stimulation and therefore more time spent in repetitive rehabilitation should increase synaptic strength.

As Nudo notes, behavioural experience, or the intervention itself, is one of the most important factors in the modulation of cortical function and structure (Nudo 2013). Behaviourally, there is a large body of evidence regarding motor learning (and re-learning) in non-disabled people (Wulf 2010) and also in people with stroke (Kitago 2013) where the main principles of repetition, 'just right' challenge (Guadagnoli 2004) and graded feedback (Winstein 1990) closely align with the key principles of neuroplasticity (Kleim 2008), again supporting the premise that increased time spent in rehabilitation will provide more beneficial change in the performance outcomes of a task.

Several intervention studies also suggest that the time spent in rehabilitation after stroke is more important than the type of rehabilitation. A narrative review of CIMT found that CIMT compared with dose-matched bilateral arm training did not produce significant differences in overall effect sizes (Kwakkel 2015). Phase 2 and 3 randomised controlled trials (RCTs) have found no significant differences in outcomes between CIMT and dose-matched 'traditional occupational therapy' (Dromerik 2009), robot-assisted therapy and dose-matched intensive therapy (Lo 2010), or structured task-oriented training and dose-equivalent usual care (Winstein 2016). Taken together, these and similar findings indicate that, as long as the rehabilitation provided is of equal amounts, it does not matter very much what type or content of therapy is given. This has led to many studies comparing amounts of therapy for a given population as the factor of interest (as reviewed in a later section). However, 'more is better regardless' is almost certainly an oversimplified view of how rehabilitation interventions might work.

For example, in the recent ICARE study (Winstein 2016), a usual-care low-dose group did as well as the two higher-dose-matched groups at the one-year end-point suggesting that dose of rehabilitation may not be the most important factor in recovery levels measured long after the intervention, although the three groups are confounded by having different types of intervention. Furthermore, Dromerik 2009 found that providing a greater dose of CIMT, when given early after stroke, had a detrimental effect on outcomes related to activities of daily living. This suggests that time spent in rehabilitation interacts with stage of recovery and spontaneous recovery processes. These two studies both suggest that timing of an intervention may be important. A study in the chronic population, comparing bilateral rhythmic arm training and unilateral dose-matched therapeutic exercises, determined that the two interventions did not operate through the same neuroplastic mechanisms, despite eliciting similar outcomes at the impairment and activity level (Whitall 2011). This finding indicates that type of rehabilitation and what the rehabilitation targets interacts with the underlying mechanisms in ways we do not completely understand yet.

Finally, all of the intervention studies above have the problem of how to actually dose-match different types of rehabilitation so that they are truly equivalent in effort by the patient at any given amount. This is an almost impossible task, which, given this problem as well as the evidence just presented that the type of intervention may well be important after all, leads us to question whether it is valid to compare different amounts of time spent in rehabilitation with two different interventions. We pursue this point further below.

In summary, it is thought that rehabilitation interventions 'work' by influencing the recovery from and compensation for the neurological damage caused by stroke. The time spent in rehabilitation may be a factor in determining the effectiveness of this intervention for reducing activity limitation.

Why it is important to do this review

The effect of time spent in rehabilitation post-stroke has been explored extensively in the literature, but without clear conclusions. A meta-analysis that combined outcomes showed positive results (Lohse 2014). Other meta-analyses have found in favour of increased time spent in rehabilitation (in terms of total amount or daily minutes) for walking speed (Cooke 2010; Kwakkel 2004; Veerbeek 2011). However, by contrast, Galvin 2008 found no significant beneficial effect for increased time spent in rehabilitation (in terms of total amount) of exercise therapy for walking speed.

The effect of increased time spent in rehabilitation on activities of daily living (ADLs) is also uncertain. Some meta-analyses exploring this relationship have found in favour of an increased amount of time spent in rehabilitation (in terms of total amount or daily minutes) for ADL outcomes (Galvin 2008; Kwakkel 2004; Veerbeek 2014). However, Veerbeek 2011 found a non-significant summary effect size (standard mean difference (SMD) 0.11, P = 0.36) for basic ADLs (such as personal care), but a significant, medium summary effect size (SMD 0.54, P = 0.002) for extended ADLs (such as domestic activities and community access). In addition, it is unclear if more rehabilitation is beneficial for upper limb recovery. Cooke 2010 found additional rehabilitation beneficial for upper limb muscle function, but Kwakkel 2004 found no effect for dexterity.

The suggestion that increased time spent in rehabilitation may produce favourable outcomes has led to the following recommendations.

- The National Institute of Health and Care Excellence guidance for long-term rehabilitation after stroke recommends a minimum 45 minutes of each relevant rehabilitation therapy (occupational therapy, physiotherapy, and speech and language therapy), five days per week (NICE 2013).
- The Canadian Best Practice guidelines for rehabilitation states that patients should receive a minimum of three hours of task-specific therapy, five days per week, delivered by an interprofessional stroke team (Dawson 2013).
- The Australian Stroke Foundation, Clinical Guidelines for Stroke Management states that a minimum of one hour of active practice of physical therapy (occupational therapy and physiotherapy) should be provided at least five days per week (National Stroke Foundation 2010).

These guidelines all suggest minimum daily session duration (in terms of hours/minutes of rehabilitation that should be provided) and a suggested frequency of rehabilitation (in terms of day per week) that rehabilitation should be provided. They do not all make a recommendation for treatment duration (in terms of the length of time over which rehabilitation should continue).

The published literature does not provide a clear evidence base for these guidelines (Cooke 2010; Galvin 2008; Kwakkel 1997; Kwakkel 2004; Langhorne 1996; Lohse 2014; Veerbeek 2011; Veerbeek 2014). These meta-analyses include 71 unique studies. In at least 50 of these studies, the experimental and control interventions differed in not only the amount of rehabilitation provided, but also the type of rehabilitation provided. For example, a study by Sivenius 1985, included in five of the aforementioned meta-analyses, compared stroke survivors treated in a specialist stroke rehabilitation unit to those treated in the medical wards of the local University Hospital. Whilst those in the stroke rehabilitation unit received a greater amount of rehabilitation, the difference in location may have also contributed to the difference in outcomes. Another example is Smania 2012, which compared a less intensive CIMT (and therefore described as modified CIMT - mCIMT) to "conventional therapy". As previously mentioned, it may be that type of rehabilitation influences outcomes, as well as amount of time spent in rehabilitation. Arguably, therefore, conclusions regarding the effect of amount should not be drawn from studies comparing different types of rehabilitation.

Two meta-analyses explore the "optimum amount" of rehabilitation post-stroke. Kwakkel 2004 used a cumulative meta-analysis and, although their findings did not support a precise optimal amount of time spent in rehabilitation, no ceiling effect was found. Lohse 2014 used meta-regression to explore the effect of total scheduled therapy time on effect sizes. They found a potentially non-linear relationship between total amount of therapy and outcomes. This suggests that there may be an 'optimal amount' of therapy time, beyond which the benefits of additional therapy are limited. Taken together, these meta-analyses suggest that guidelines that include a specific minimum amount of rehabilitation are pragmatically-based, as opposed to evidence-based.

Currently, there is a Cochrane Review published that explores the effect of repetitive task training on functional ability after stroke (French 2007). In addition, there is a Cochrane protocol published that plans to explore the effect of additional exercise therapy after a stroke (Galvin 2012). In their Cochrane Review 'Physical rehabilitation approaches for the recovery of function and mobility following stroke', Pollock 2014a undertook a subgroup analysis exploring the effect of dose of physical rehabilitation on functional recovery and the recovery of motor function after stroke. In addition, Pollock 2014b undertook a Cochrane Review of interventions for improving upper limb function after stroke. This review identified the need for evidence related to dose of intervention, in order to inform future research and clinical practice. Finally, a Cochrane Review by Brady 2016 included an analysis on 'intensity' of speech and language therapy (expressed in number of hours per week spent in therapy) for aphasia after stroke. As yet, there is no Cochrane Review exploring the effect of time spent in rehabilitation on activity after stroke. We consider our review important in order to determine if the increasing number of clinical guidelines that recommend a specific minimum amount of time spent in rehabilitation after stroke have an evidence base and therefore, may be important for future guideline development. Based on current guidelines and evidence there is also a strong push for technologies that enable additional practice, especially in the home and without additional therapist support. A better understanding of the importance of amount of time spent in rehabilitation will inform development of new technologies such as telerehabilitation and use of virtual reality.

OBJECTIVES

- To establish if greater time spent in rehabilitation results in greater improvement in measures of activity than less time spent in rehabilitation.
- To assess the effect of total time spent (in minutes) in rehabilitation on activity/activity limitations following stroke.
- To assess the effect of rehabilitation schedule on activity/activity limitations following stroke in terms of:
  - average minutes of rehabilitation provided per week;
  - average frequency of rehabilitation provided per week;
  - total duration of rehabilitation.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised trials that compare different amounts of time spent, greater than zero, of the same rehabilitation intervention. These may be RCTs (participants are randomised to either an experimental group or a control group) or randomised clinical trials (participants are randomised to different experimental groups). We will also include data from the first period of randomised cross-over trials. We will include cluster-randomised trials should we find any. We have restricted the types of studies to randomised trials only, as they are considered to be high-quality sources of evidence in clinical practice (Devereaux 2003) and the method by which causality can be established (Concato 2010; Horn 2005; Kersten 2010).

Types of participants

Participants will be adults (over 18 years), with a clinical diagnosis of stroke, caused by either infarct or haemorrhage (including subarachnoid haemorrhage). Participants will have received rehabilitation either in an inpatient, outpatient, or community setting. We will exclude studies that also include participants with diagnoses other than stroke as the primary diagnosis.

Types of interventions

We will include trials that compare different amounts of time, greater than zero, spent in rehabilitation. For the purpose of this review, this will be defined as any non-pharmacological, non-surgical intervention that aims to improve activity after stroke.

As discussed in the Background, there are many different types of rehabilitation intervention and many different aspects of stroke rehabilitation that may affect outcome. To establish if time spent (in terms of minutes, frequency and duration) is related to outcomes, studies included must vary only in the amount of time spent in rehabilitation between the experimental and the control conditions. If studies include more than one treatment arm, one of which meets the criteria for this review, we will include the control group and intervention arm that is compliant with the criteria for this review. If the control group of any study receives no treatment, then we will exclude the study.

Co-interventions will not preclude inclusion, provided they are administered to both experimental and control groups.

Types of outcome measures

The International Classification of Functioning, Disability and Health (ICF) aims to provide a framework for the description of health and health-related status (WHO 2001). Although published in 2001, the ICF is updated regularly. An application of the ICF is to classify the measurement of outcomes (WHO 2001). The ICF classifies the components of functioning and disability as: 1) body structures/body functions and potential impairments at this level; 2) activity and potential activity limitation; and 3) participation, the involvement in life tasks and the potential restrictions an individual may experience.

We will include published outcome measures falling into ICF categories for activity and body structures/body functions. We are primarily interested in measures of activity, as these outcomes are likely to be most meaningful to stroke survivors and to indicate a reduction in the burden of care. We are also interested in measures of body structure/body function, as they will indicate if an increased amount of time spent in rehabilitation facilitates recovery at this level. We will not include outcome measures in the participation category, as these outcomes are likely to be attributable to factors other than rehabilitation.

Primary outcomes

We will define the primary outcome measures for this analysis as ADL outcomes (an activity measure). We will include any measure of ADL, including but not limited to (and in no specific order): Barthel Index, Frenchay Activity Index, Rivermead ADL Assessment, Nottingham Extended ADL, Functional Independence Measure.

As we plan to pool these outcome measures, if studies have utilised more than one measure of ADL, we will select the measure for which they have collected the most data, in order to avoid double counting. If there are measures with equal amounts of data in a study, we will select the measure listed first in the study.

Secondary outcomes

1. Activity measures of the upper limb (e.g. Action Research Arm Test, Jebsen Taylor Hand function Test)
2. Activity measures of the lower limb (e.g. timed up-and-go, 6-minute walk test, walking speed and the Rivermead Mobility Index)
3. Motor impairment measures of the upper limb (e.g. Fugl- Meyer assessment, muscle strength, range of movement)
4. Motor impairment measures of the lower limb (e.g. muscle strength, range of movement)
5. Serious adverse events/death
6. Participant experience

As for the primary outcome measure, we plan to pool the measures used, within each secondary outcome. If studies have utilised more than one measure relevant to that secondary outcome, we will select the measure for which they have collected the most data, in order to avoid double counting. If there are measures with equal amounts of data in a study, we will select the measure listed first in the study.

We will exclude any studies that have not used any of the primary or secondary outcome measures described above.

For all outcome measures, we are primarily interested in measures taken immediately after intervention. However, we will also undertake analysis of medium-term outcomes (two weeks to six months after treatment has ended) and long-term outcomes (more than six months after treatment has ended).

Search methods for identification of studies

See the 'Specialized register' section in the Cochrane Stroke Group module. We will search for trials in all languages and arrange for the translation of relevant articles where necessary.

Electronic searches

We will search the Cochrane Stroke Group trials register and the following electronic databases from their inception.

- The Cochrane Central Register of Controlled Trials (CENTRAL) (in the Cochrane Library, latest issue);
- MEDLINE (from 1946) (EBSCO) (Appendix 1);
- Embase (from 1980) (Ovid);
- CINAHL (from 1937) (EBSCO);
- AMED (from 1985) (EBSCO);
- PsycINFO (from 1987) (EBSCO);
- Open Grey (www.opengrey.eu/);
- OTSeeker (www.otseeker.com/);
- PEDro: Physiotherapy Evidence Database (www.pedro.org.au);
- REHABDATA (National Rehabilitation Information Centre) (www.naric.com/?q=REHABDATA);
- ProQuest Dissertations & Theses (www.proquest.com/);
- CIRRIE (cirrie.buffalo.edu/database/).

We developed the MEDLINE search strategy (Appendix 1) with the help of the Cochrane Stroke Group Information Specialist and will adapt it for the other databases. We will search for all relevant RCTs regardless of language or publication status (published, unpublished, in press or in progress).

We will also search the following trials registers:

- ClinicalTrials.gov (www.clinicaltrials.gov/);
- Stroke Trials Registry (www.strokecenter.org/trials/);
- EU Clinical Trials Register (www.clinicaltrialsregister.eu);
- ISRCTN Registry (www.isrctn.com/);
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) portal (www.who.int/ictrp/en/);
- Australian New Zealand Clinical Trials Registry (www.anzctr.org.au/);
- UK Clinical Trials Gateway (www.ukctg.nihr.ac.uk).

Searching other resources

We will handsearch the reference lists of all identified studies and systematic reviews for any further potentially eligible studies and handsearch any relevant journals or conference proceedings that have not already been identified by the Cochrane Stroke Group. In addition, we will contact key authors and organisations to obtain any missing or additional trial data.

We will also undertake reference searching using Web of Science Citation Indexes for all included studies for further references to relevant trials.

Data collection and analysis

Selection of studies

We will collate the search results using bibliographic software and will remove duplicates prior to screening. Two review authors (BC and JB) will independently screen titles and abstracts of the studies retrieved via the searching process. We will exclude those studies that are obviously irrelevant. We will retrieve the full-text articles for the remaining references and two review authors (BC and JW) will independently screen the full-text articles and identify studies for inclusion, and identify and record reasons for exclusion of the ineligible studies. We will resolve any disagreements through discussion and, if required, we will consult a third author (JB). We will collate multiple reports of the same study, to ensure that no single study is duplicated in reporting. We will record the selection process and complete a PRISMA flow diagram (Moher 2009) and will complete tables of 'Characteristics of included studies' and 'Characteristics of excluded studies'.

Data extraction and management

Two review authors (of BC, JB and JW), working independently, will extract data from each study. We will use the "template for intervention description and replication" (TIDieR) checklist and guide (Hoffmann 2014) to extract data from studies identified as eligible for inclusion. In addition to the 12 points on the TIDierR checklist, we will also include information on study eligibility, the study participants, the outcomes measured (including time points) and a 'miscellaneous' section (which may include funding sources, key conclusions from the study authors, references to other relevant studies, correspondence required, and any other comments by the review author). We will include detailed information on time spent in rehabilitation in section 8 of the TIDieR checklist, entitled 'When and how much'. Prior to commencing data extraction, we will pilot the adapted TIDieR checklist to ensure the tool is extracting the data required and that review authors are using the tool comparably.

If there are any discrepancies in the data extraction, the two review authors who have extracted the data will initially try to resolve them via discussion, with involvement of the third review author where resolution cannot be achieved.

Assessment of risk of bias in included studies

Two review authors (BC and JW) will independently assess risk of bias for each study using Cochrane's tool for assessing risk of bias (Higgins 2011). We will resolve any disagreements by discussion or by involving another review author (JB). We will assess the risk of bias according to the following domains.

- Random sequence generation (selection bias)
- Allocation concealment (selection bias)
- Blinding of participants and personnel (performance bias)
- Blinding of outcome assessment (detection bias)
- Incomplete outcome data (attrition bias)
- Selective outcome reporting (reporting bias)
- Other bias

Examples of possible sources of bias are non-comparable co-interventions between intervention and control groups, baseline imbalances between groups, and deviation from study protocol. We will grade each bias, if identified, using the criteria provided in table 8.5.d of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We will grade risk of bias for each domain as high, low or unclear and we will give a justification for the grading in the 'Risk of bias' tables. If cluster-randomised trials are included, we will assess their risk of bias using the same method, but paying particular attention to the risk of bias particular to these types of studies (Higgins 2011b).

We will summarise the risk of bias for each individual study, using 'Risk of bias' summary and across studies using a 'Risk of bias' graph. The assessment of risk of bias of blinding of outcome assessment will be dependent on the potential influence that lack of blinding may have. If the outcome assessor is not blinded and we judge that the outcome measure could be influenced by the assessor, we will assign a high risk of bias. If we judge that the outcome measure could not be influenced by the assessor, we will assign a low risk of bias, regardless of whether or not the outcome assessor was blinded.

We will consider incomplete outcome data reporting in terms of outcome data missing immediately to two weeks post completion of treatment and outcome data missing to medium-/long-term follow-up.

Review authors will not assess the risk of bias for studies in which they were involved.

Measures of treatment effect

In order to address the first objective of this review, we will undertake statistical analyses using Review Manager 5 (RevMan 5) (RevMan 2014). For continuous outcomes using different scales

of measurement, we will calculate pooled standardised mean difference (SMDs) and 95% confidence intervals (CIs). We will express dichotomous outcomes as risk ratios (RR) with 95% CIs.

In order to address the second objective of this review, we propose treating the difference between arms, in terms of amount of rehabilitation, as a continuous study-level characteristic whose effect on estimated treatment effect we will also investigate using meta-regression. Based on the advice in chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011), should there be fewer than 10 studies, we will not undertake a meta-regression; we will instead conduct a subgroup analysis descriptively comparing studies with a large difference between arms (in terms of amount of rehabilitation) and those with a small difference between arms. We will use a median split based on differences in amount of time spent in rehabilitation between arms to determine the subgroups. Descriptive analysis will comprise scatter plots of differences in amount of time spent in rehabilitation (i.e. number of minutes of rehabilitation, frequency of rehabilitation) against estimated treatment effect. This will enable a simple visual inspection of whether estimated treatment effect varies with differences in amount of time spent in rehabilitation.

To address the third objective of this review, we will group together studies in which the rehabilitation schedule was similar in terms of:

- average minutes of rehabilitation provided per week;
- average frequency of rehabilitation provided per week (i.e. number of days per week on which rehabilitation was provided);
- total duration of rehabilitation.

We will undertake meta-analyses for the different groups. For continuous outcomes using different scales of measurement, we will calculate pooled SMDs and 95% CIs. We will express dichotomous outcomes as RRs with 95% CIs. We will then compare the outcomes of these analyses to determine if they identify certain traits of the rehabilitation schedule, which may lead to better outcomes.

Unit of analysis issues

We will consider unit of analysis issues in the inclusion of cluster-randomised trials. If cluster-randomised trials have been analysed taking into account the intra-class correlation, we will be able to synthesis these with other studies. The intra-class correlation is an estimation of the variability within clusters and between clusters (Higgins 2011b).

If cluster-randomised trials have not been appropriately analysed, taking into account the intra-class correlation, then we will establish if relevant information required to derive suitable estimates is provided (following the guidance in section 16.3.4 of the *Cochrane Handbook for Systematic Reviews of Interventions*, Higgins 2011b). If we are not able to derive suitable estimates, then we will exclude the study from the synthesis.

We will perform a sensitivity analysis to determine the effect of including cluster-randomised trials in the review.

Dealing with missing data

We will contact study authors to obtain any outcome data missing from the included studies. If it is not possible to obtain missing data, we will aim to at least determine the reason for missing data from study authors, in order to determine if data are 'missing at random' or 'missing not at random'.

If data are 'missing at random', we will analyse the available data and ignore missing data. If data are 'missing not at random', then we will impute the last observation carried forward. We will conduct a sensitivity analysis to determine the effect of missing data.

We will discuss the potential impact of missing data in the review.

Assessment of heterogeneity

We will visually inspect the forest plots to determine the overlap in the CIs of the studies. Poor overlap is like to indicate statistical heterogeneity (Deeks 2011). In addition, we will use the I^2 statistic to quantify heterogeneity in the study results (Higgins 2003). If the I^2 result is greater than 50%, we will consider this to represent substantial heterogeneity (Deeks 2011).

If we find substantial heterogeneity, we will explore the possible reasons for this by examining the trials in terms of their design, risk of bias, clinical settings, interventions, and participants involved. We will analyse possible sources of heterogeneity by undertaking the proposed subgroup analyses and explore the effect of potential bias by undertaking the subgroup analyses proposed.

Assessment of reporting biases

We will attempt to minimise the effect of reporting bias by using a comprehensive search strategy. We will use funnel plots of the primary and secondary outcomes to provide a visual inspection of whether treatment estimates are associated with the study size (Sterne 2011).

Data synthesis

We will not undertake data synthesis if studies are clinically diverse or demonstrate high levels of bias across all important domains. Where we consider studies to be sufficiently similar, we will conduct meta-analyses by pooling the appropriate data using RevMan 5 (RevMan 2014) following the guidance provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011). One author (BC) will enter the data into RevMan 5 and a second author (SE) will check the accuracy of this. We will resolve disagreements through discussion.

We will use a random-effects meta-analysis (DerSimonian 2015), regardless of the level of heterogeneity between studies. If the studies are heterogeneous, then this is the appropriate model to use. However, if heterogeneity is low, a random-effects model will return very similar results to a fixed-effect model.

Provided enough studies are identified, we will undertake a meta-regression by pooling the appropriate data using RevMan 5 (RevMan 2014). The *Cochrane Handbook for Systematic Reviews of Interventions* states that meta-regression should not be considered if there are fewer than 10 studies in a meta-analysis (Deeks 2011). We will use a random-effects meta-regression (Thompson 2002), utilising the 'metareg' macro for the Stata statistical package (www.stata.com). One author (BC) will enter the data into Stata and a second author (SE) will check the accuracy of this. We will resolve disagreements through discussion.

GRADE and 'Summary of findings' table

We will create 'Summary of findings' tables to present the findings of our first objective, using the seven outcomes identified: ADL, activity measures of the upper limb, activity measures of the lower limb, motor impairment measures of the upper limb, motor impairment measures of the lower limb, serious adverse events/ death, and participant experience.

We anticipate using three tables, to summarise the findings of the data synthesis as follows.

- Greater time spent in rehabilitation versus lesser time spent in rehabilitation after stroke (outcomes immediately after intervention).
- Greater time spent in rehabilitation versus lesser time spent in rehabilitation after stroke (outcomes from two weeks to six months after intervention).
- Greater time spent in rehabilitation versus lesser time spent in rehabilitation after stroke (outcomes after six months after intervention).

For each outcome, we will report the number of participants that contribute to the finding, the relative effect, direction of effect and the quality of the evidence. Please see Table 1 for the template of the 'Summary of findings' table we will use.

We will analyse the quality of the evidence using the evidence grading system developed by the GRADE collaboration (GRADE 2013), using the methods described in section 12.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011).

Subgroup analysis and investigation of heterogeneity

Where studies have provided the necessary information, we will stratify the studies to analyse possible sources of heterogeneity using the following characteristics.

- Studies in which the experimental group has received five hours or more of rehabilitation per week.
- Studies in which the experimental group has received 10 hours or more of rehabilitation per week.
- Studies in which the experimental group has received 20 hours or more of rehabilitation per week.
- Studies in which the experimental group has received 30 hours or more of rehabilitation per week.
- Studies in which the rehabilitation has been provided within the first six months after stroke.
- Studies in which the rehabilitation has been provided after six months after stroke.

We require studies to provide clear indication of the time spent in therapy per week and the time post-stroke that intervention was provided, in order to undertake this analysis.

Sensitivity analysis

We will perform a sensitivity analysis by descriptively comparing the results of two meta-analyses that either include or exclude studies that meet at least one of the following criteria:

- no description of randomisation;
- no description of concealed allocation, or no concealment used;
- no description of blinding of outcome assessors, or no blinding of outcome assessors used, where outcome measurement could have been influenced by the assessor;
- unclear or inadequate approaches of dealing with missing data (including studies in which we have been required to impute missing data);
- Inclusion of cluster-randomised trials.

We have chosen these criteria as being important markers of potential sources of bias.

ACKNOWLEDGEMENTS

We thank Hazel Fraser, Joshua Cheyne, and the Editors of the Cochrane Stroke Group for their support and assistance in the development of this protocol.

Appendix E CENTRAL Search Strategy

#1 MeSH descriptor: [Cerebrovascular Disorders] this term only

#2 MeSH descriptor: [Basal Ganglia Cerebrovascular Disease] this term only

#3 MeSH descriptor: [Brain Ischemia] explode all trees

#4 MeSH descriptor: [Carotid Artery Diseases] explode all trees

#5 MeSH descriptor: [Cerebral Small Vessel Diseases] explode all trees

#6 MeSH descriptor: [Intracranial Arterial Diseases] explode all trees

#7 MeSH descriptor: [Intracranial Embolism and Thrombosis] explode all trees

#8 MeSH descriptor: [Intracranial Hemorrhages] explode all trees

#9 MeSH descriptor: [Stroke] explode all trees

#10 MeSH descriptor: [Vasospasm, Intracranial] this term only

#11 MeSH descriptor: [Vertebral Artery Dissection] this term only

#12 (stroke* or poststroke or apoplex* or cerebral vasc* or brain vasc* or cerebrovasc*orcva* or SAH):ti,ab,kw (Word variations have been searched)

#13 ((brain* or cerebr* or cerebell* or intracran* or intracerebral) near/5 (isch?emi*or infarct*or thrombo* or emboli* or occlus*)):ti,ab,kw (Word variations have beensearched)

#14 ((brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid)near/5(haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)):ti,ab,kw (Wordvariations have been searched)

#15 MeSH descriptor: [Hemiplegia] this term only

#16 MeSH descriptor: [Paresis] explode all trees

#17 MeSH descriptor: [Gait Disorders, Neurologic] explode all trees

#18 (hemipleg* or hemipar* or paresis or paraparesis or paretic):ti,ab,kw (Wordvariationshave been searched)

#19 (or #1-#18)

#20 MeSH descriptor: [Physical Therapy Modalities] this term only

#21 MeSH descriptor: [Physical Therapy Specialty] this term only

#22 MeSH descriptor: [Exercise Movement Techniques] explode all trees

#23 MeSH descriptor: [Exercise Therapy] explode all trees

#24 MeSH descriptor: [Hydrotherapy] this term only

#25 MeSH descriptor: [Kinesiology, Applied] this term only

#26 MeSH descriptor: [Rehabilitation] this term only

#27 MeSH descriptor: [Activities of Daily Living] this term only

#28 MeSH descriptor: [Occupational Therapy] this term only

#29 MeSH descriptor: [Recreation Therapy] explode all trees

#30 MeSH descriptor: [Rehabilitation, Vocational] this term only

#31 MeSH descriptor: [Recovery of Function] this term only

#32 MeSH descriptor: [Movement] this term only

#33 MeSH descriptor: [Motor Activity] this term only

#34 MeSH descriptor: [Exercise] this term only

#35 MeSH descriptor: [Circuit-Based Exercise] this term only

#36 MeSH descriptor: [Muscle Stretching Exercises] this term only

#37 MeSH descriptor: [Physical Conditioning, Human] this term only

#38 MeSH descriptor: [Plyometric Exercise] this term only

#39 MeSH descriptor: [Resistance Training] this term only

#40 MeSH descriptor: [Running] explode all trees

#41 MeSH descriptor: [Swimming] this term only

#42 MeSH descriptor: [Walking] this term only

#43 MeSH descriptor: [Warm-Up Exercise] this term only

#44 MeSH descriptor: [Exercise Test] this term only

#45 MeSH descriptor: [Sports] explode all trees

#46 MeSH descriptor: [Physical Exertion] this term only

#47 MeSH descriptor: [Physical Endurance] explode all trees

#48 MeSH descriptor: [Physical Fitness] this term only

#49 MeSH descriptor: [Muscle Stretching Exercises] this term only

#50 MeSH descriptor: [Resistance Training] this term only

#51 MeSH descriptor: [Muscle Contraction] this term only

#52 MeSH descriptor: [Isometric Contraction] this term only

#53 MeSH descriptor: [Isotonic Contraction] this term only

#54 (exercise near/3 (train* or intervention* or protocol* or program* or therap*or activit* orregim*)):ti,ab,kw (Word variations have been searched)

#55 (fitness near/3 (train* or intervention* or protocol* or program* or therap*or activit* orregim* or centre* or center*)):ti,ab,kw (Word variations have beensearched)

#56 ((training or conditioning) near/3 (intervention* or protocol* or program*or activit* orregim*)):ti,ab,kw (Word variations have been searched)

#57 (sport* or recreation* or leisure or cycling or bicycl* or rowing or treadmill* or running or circuit training or swim* or walk* or dance* or dancing or tai ji or tai chi or yoga):ti,ab,kw (Word variations have been searched)

#58 ((endurance or aerobic or cardio*) near/3 (fitness or train* or intervention* or protocol* or program* or therap* or activit* or regim*)):ti,ab,kw (Word variations have been searched)

#59 (muscle strengthening or progressive resist*):ti,ab,kw (Word variations have been searched)

#60 ((weight or strength* or resistance) near/3 (train* or lift* or exercise*)):ti,ab,kw (Word variations have been searched)

#61 ((isometric or isotonic or eccentric or concentric) near/3 (action* or contraction* or exercise*)):ti,ab,kw (Word variations have been searched)

#62 (or #20-#61)

#63 MeSH descriptor: [Cerebrovascular Disorders] this term only and with qualifier(s): [Rehabilitation - RH]

#64 MeSH descriptor: [Basal Ganglia Cerebrovascular Disease] explode all trees and with qualifier(s): [Rehabilitation - RH]

#65 MeSH descriptor: [Brain Ischemia] explode all trees and with qualifier(s): [Rehabilitation - RH]

#66 MeSH descriptor: [Carotid Artery Diseases] explode all trees and with qualifier(s): [Rehabilitation - RH]

#67 MeSH descriptor: [Intracranial Arterial Diseases] explode all trees and with qualifier(s): [Rehabilitation - RH]

#68 MeSH descriptor: [Intracranial Embolism and Thrombosis] explode all trees and with qualifier(s): [Rehabilitation - RH]

#69 MeSH descriptor: [Intracranial Hemorrhages] explode all trees and with qualifier(s): [Rehabilitation - RH]

#70 MeSH descriptor: [Brain Infarction] explode all trees and with qualifier(s): [Rehabilitation - RH]

Appendix E

#71 MeSH descriptor: [Stroke, Lacunar] this term only and with qualifier(s): [Rehabilitation - RH]

#72 MeSH descriptor: [Vasospasm, Intracranial] this term only and with qualifier(s): [Rehabilitation - RH]

#73 MeSH descriptor: [Vertebral Artery Dissection] this term only and with qualifier(s): [Rehabilitation - RH]

#74 MeSH descriptor: [Hemiplegia] this term only and with qualifier(s): [Rehabilitation - RH]

#75 MeSH descriptor: [Paresis] explode all trees and with qualifier(s): [Rehabilitation - RH]

#76 (or #63-#75)

#77 (time or timing or intensive or intensity or augment* or accelerate* or additional or dosage or dose or frequency or amount or quantity):ti,ab,kw (Word variations have been searched)

#78 #76 and #77

#79 #19 and #62 and #77

#80 #78 or #79

Appendix F MEDLINE Search Strategy

1. cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or stroke, lacunar/ or vasospasm, intracranial/ or vertebral artery dissection/

2. (stroke or poststroke or post-stroke or cerebrovasc$ or brain vasc$ or cerebral vasc$ or cva$ or apoplex$ or SAH).tw.

3. ((brain$ or cerebr$ or cerebell$ or intracran$ or intracerebral) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$)).tw.

4. ((brain$ or cerebr$ or cerebell$ or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage$ or hemorrhage$ or haematoma$ or hematoma$ or bleed$)).tw.

5. hemiplegia/ or exp paresis/

6. (hemipleg$ or hemipar$ or paresis or paretic).tw.

7. 1 or 2 or 3 or 4 or 5 or 6

8. physical therapy modalities/ or physical therapy specialty/ or exp exercise movement techniques/ or exp exercise therapy/ or hydrotherapy/ or kinesiology, applied/

9. "Physical and Rehabilitation Medicine"/

10. rehabilitation/ or "activities of daily living"/ or occupational therapy/ or recreation therapy/ or rehabilitation, vocational/ or "Recovery of Function"/

11. movement/ or motor activity/ or exercise/ or circuit-based exercise/ or cool-down exercise/ or muscle stretching exercises/ or physical conditioning, human/ or plyometric exercise/ or resistance training/ or exp running/ or swimming/ or walking/ or warm-up exercise/ or exercise test/

12. exp sports/

13. physical exertion/ or exp physical endurance/ or physical fitness/

14. muscle stretching exercises/ or resistance training/

15. muscle contraction/ or isometric contraction/ or isotonic contraction/

16. (physiotherap$ or (physical adj3 (mobilis$ or mobiliz$ or exercise$ or exertion or endurance or therap$ or conditioning or activit$ or fitness))).tw.

17. (rehabilitation or recovery of function or exercise$ or mobilis$ or mobiliz$ or motion therap$ or motor activit$ or motor skill$ or activities of daily living or adl or manipulat$ or (occupational adj3 (train$ or rehab$ or therap$ or activit$ or regim$))).tw.

18. (exercise adj3 (train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$)).tw.

19. (fitness adj3 (train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$ or centre$ or center$)).tw.

20. ((training or conditioning) adj3 (intervention$ or protocol$ or program$ or activit$ or regim$)).tw.

21. (sport$ or recreation$ or leisure or cycling or bicycl$ or rowing or treadmill$ or running or circuit training or swim$ or walk$ or dance$ or dancing or tai ji or tai chi or yoga).tw.

22. ((endurance or aerobic or cardio$) adj3 (fitness or train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$)).tw.

23. (muscle strengthening or progressive resist$).tw.
24. ((weight or strength$ or resistance) adj3 (train$ or lift$ or exercise$)).tw.

25. ((isometric or isotonic or eccentric or concentric) adj3 (action$ or contraction$ or exercise$)).tw.

26. or/8-25

27. cerebrovascular disorders/rh or exp basal ganglia cerebrovascular disease/rh or exp brain ischemia/rh or exp carotid artery diseases/rh or cerebrovascular accident/rh or exp brain infarction/rh or exp cerebrovascular trauma/rh or exp hypoxia-ischemia, brain/rh or exp intracranial arterial diseases/rh or intracranial arteriovenous malformations/rh or exp "intracranial embolism and thrombosis"/rh or exp intracranial hemorrhages/rh or vasospasm, intracranial/rh or vertebral artery dissection/rh or (hemiplegia/rh or exp paresis/rh)

28. (intensive or intensity or augment$ or accelerate$ or additional or dosage or dose-response or frequency or amount or quantity).tw.

29. 27 and 28

30. 7 and 26 and 28

31. 29 or 30

32. Randomized Controlled Trials as Topic/

33. random allocation/

34. Controlled Clinical Trials as Topic/

35. control groups/

36. clinical trials as topic/ or clinical trials, phase i as topic/ or clinical trials, phase ii as topic/ or clinical trials, phase iii as topic/ or clinical trials, phase iv as topic/

37. double-blind method/

38. single-blind method/

39. Therapies, Investigational/

40. Research Design/

41. randomized controlled trial.pt.

42. controlled clinical trial.pt.

43. clinical trial.pt.

44. random$.tw.

45. (controlled adj5 (trial$ or stud$)).tw.

46. (clinical$ adj5 trial$).tw.

47. ((control or treatment or experiment$ or intervention or surgical) adj5 (group$ or subject$ or patient$)).tw.

48. (quasi-random$ or quasi random$ or pseudo-random$ or pseudo random$).tw.

49. ((control or experiment$ or conservative) adj5 (treatment or therapy or procedure or manage$)).tw.

50. ((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw. 51. (coin adj5 (flip or flipped or toss$)).tw.
52. latin square.tw.
53. versus.tw.

54. controls.tw. 55. or/32-54 56. 31 and 55

Appendix G Embase Search Strategy

1. cerebrovascular disease/ or exp basal ganglion hemorrhage/ or exp brain hemangioma/ or exp brain hematoma/ or exp brain hemorrhage/ or exp brain infarction/ or exp brain ischemia/ or exp carotid artery disease/ or exp cerebral artery disease/ or exp cerebrovascular accident/ or exp cerebrovascular malformation/ or exp intracranial aneurysm/ or exp occlusive cerebrovascular disease/ or exp vertebrobasilar insufficiency/

2. (stroke$ or poststroke or apoplex$ or cerebral vasc$ or brain vasc$ or cerebrovasc$ or cva$ or SAH).tw.

3. ((brain or cerebr$ or cerebell$ or vertebrobasil$ or hemispher$ or intracran$ or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA$ or anterior circulation or posterior circulation or basilar artery or vertebral artery or space-occupying) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$ or hypoxi$)).tw.

4. ((brain$ or cerebr$ or cerebell$ or intracerebral or intracran$ or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli$ or putaminal or putamen or posterior fossa or hemispher$ or subarachnoid) adj5 (h?emorrhag$ or h?ematoma$ or bleed$)).tw.

5. exp hemiplegia/ or exp paresis/ or neurologic gait disorder/

6. (hemipleg$ or hemipar$ or paresis or paraparesis or paretic).tw.

7. 1 or 2 or 3 or 4 or 5 or 6

8. therapy/

9. exp kinesiotherapy/

10. exp exercise/

11. rehabilitation/ or cognitive rehabilitation/ or community based rehabilitation/ or constraint induced therapy/ or functional training/ or home rehabilitation/ or muscle training/ or exp neurorehabilitation/ or occupational therapy/ or psychosocial rehabilitation/ or recreational therapy/ or rehabilitation care/ or sociotherapy/ or exp "speech and language rehabilitation"/ or telerehabilitation/ or vocational rehabilitation/

12. exp muscle exercise/

13. physical activity/ or climbing/ or cycling/ or jogging/ or running/ or stretching/ or swimming/ or exp walking/ or weight lifting/

14. sport/

15. exp muscle contraction/

16. (physiotherap$ or (physical adj3 (mobilis$ or mobiliz$ or exercise$ or exertion or endurance or therap$ or conditioning or activit$ or fitness))).tw.

17. (rehabilitation or recovery of function or exercise$ or mobilis$ or mobiliz$ or motion therap$ or motor activit$ or motor skill$ or activities of daily living or adl or manipulat$ or (occupational adj3 (train$ or rehab$ or therap$ or activit$ or regim$))).tw.

18. (exercise adj3 (train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$)).tw.

19. (fitness adj3 (train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$ or centre$ or center$)).tw.

20. ((training or conditioning) adj3 (intervention$ or protocol$ or program$ or activit$ or regim$)).tw.

21. (sport$ or recreation$ or leisure or cycling or bicycl$ or rowing or treadmill$ or running or circuit training or swim$ or walk$ or dance$ or dancing or tai ji or tai chi or yoga).tw.

22. ((endurance or aerobic or cardio$) adj3 (fitness or train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$)).tw.

23. (muscle strengthening or progressive resist$).tw.

24. ((weight or strength$ or resistance) adj3 (train$ or lift$ or exercise$)).tw.

25. ((isometric or isotonic or eccentric or concentric) adj3 (action$ or contraction$ or exercise$)).tw.

26. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25

27. cerebrovascular disease/rh or exp basal ganglion hemorrhage/rh or exp brain hemangioma/rh or exp brain hematoma/rh or exp brain hemorrhage/rh or exp brain infarction/rh or exp brain ischemia/rh or exp carotid artery disease/rh or exp cerebral artery disease/rh or exp cerebrovascular accident/rh or exp cerebrovascular malformation/rh or exp intracranial aneurysm/rh or exp occlusive cerebrovascular disease/rh or exp vertebrobasilar insufficiency/rh

28. time factor/ or treatment duration/

29. (time or timing or intensive or intensity or augment$ or accelerate$ or additional or dosage or dose or frequency or amount or quantity).tw.

30. 28 or 29

31. 7 and 26 and 30

32. 27 and 30

33. 31 or 32

34. Randomized Controlled Trial/ or "randomized controlled trial (topic)"/

35. Randomization/

36. Controlled clinical trial/ or "controlled clinical trial (topic)"/

37. control group/ or controlled study/

38. clinical trial/ or "clinical trial (topic)"/ or phase 1 clinical trial/ or phase 2 clinical trial/ or phase 3 clinical trial/ or phase 4 clinical trial/

39. Crossover Procedure/

40. Double Blind Procedure/

41. Single Blind Procedure/ or triple blind procedure/

42. placebo/ or placebo effect/

43. (random$ or RCT or RCTs).tw.

44. (controlled adj5 (trial$ or stud$)).tw.

45. (clinical$ adj5 trial$).tw.

46. ((control or treatment or experiment$ or intervention) adj5 (group$ or subject$ or patient$)).tw.

47. (quasi-random$ or quasi random$ or pseudo-random$ or pseudo random$).tw.

48. ((control or experiment$ or conservative) adj5 (treatment or therapy or procedure or manage$)).tw.

49. ((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw.

50. (cross-over or cross over or crossover).tw.

51. (placebo$ or sham).tw.

52. trial.ti.

53. (assign$ or allocat$).tw.

54. controls.tw.

55. or/34-54

56. 33 and 55

Appendix H CINAHL Search Strategy

S1 (MH "Cerebrovascular Disorders") OR (MH "Basal Ganglia Cerebrovascular Disease+") OR (MH "Carotid Artery Diseases+") OR (MH "Cerebral Ischemia+") OR (MH "Cerebral Vasospasm") OR (MH "Intracranial Arterial Diseases+") OR ((MH "Intracranial Embolism and Thrombosis")) OR (MH "Intracranial Hemorrhage+") OR (MH "Stroke") OR (MH "Vertebral Artery Dissections") OR (MH "Stroke Patients") OR (MH "Stroke Units")

S2 TI (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc or cva or apoplex or SAH) or AB (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc or cva or apoplex or SAH)

S3 TI ((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA* or anterior circulation or posterior circulation or basilar artery or vertebral artery or space-occupying) N5 (ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus*)) OR AB ((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA* or anterior circulation or posterior circulation or basilar artery or vertebral artery or space-occupying) N5 (ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus*))

S4 TI ((brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or putaminal or putamen or posterior fossa or hemispher* or subarachnoid) N5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)) OR AB ((brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or putaminal or putamen or posterior fossa or hemispher* or subarachnoid) N5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*))

S5 (MH "Hemiplegia") or (MH "Gait Disorders, Neurologic+")

S6 TI (hemipleg* or hemipar* or paresis or paretic) OR AB (hemipleg* or hemipar* or paresis or paretic)

S7 S1 OR S2 OR S3 OR S4 OR S5 OR S6

S8 (MH "Therapeutic Exercise+")

S9 (MH "Applied Kinesiology")

S10 (MH "Recreational Therapy") OR (MH "Rehabilitation+")

S11 (MH "Movement") OR (MH "Motor Activity")

S12 (MH "Exercise+")

Appendix H

S13 (MH "Sports")

S14 (MH "Physical Endurance+") OR (MH "Exertion") OR (MH "Exercise Intensity")

S15 (MH "Physical Fitness")

S16 TI ((exercise n3 (train* or intervention* or protocol* or program* or therap* or activit* or regim*))) OR AB ((exercise n3 (train* or intervention* or protocol* or program* or therap* or activit* or regim*)))

S17 TI ((fitness n3 (train* or intervention* or protocol* or program* or therap* or activit* or regim* or centre* or center*))) OR AB ((fitness n3 (train* or intervention* or protocol* or program* or therap* or activit* or regim* or centre* or center*)))

S18 TI (((training or conditioning) n3 (intervention* or protocol* or program* or activit* or regim*)) OR AB (((training or conditioning) n3 (intervention* or protocol* or program* or activit* or regim*))

S19 TI ((sport* or recreation* or leisure or cycling or bicycl* or rowing or treadmill* or running or circuit training or swim* or walk* or dance* or dancing or tai ji or tai chi or yoga)) OR AB ((sport* or recreation* or leisure or cycling or bicycl* or rowing or treadmill* or running or circuit training or swim* or walk* or dance* or dancing or tai ji or tai chi or yoga))

S20 TI (((endurance or aerobic or cardio*) n3 (fitness or train* or intervention* or protocol* or program* or therap* or activit* or regim*))) OR AB (((endurance or aerobic or cardio*) n3 (fitness or train* or intervention* or protocol* or program* or therap* or activit* or regim*)))

S21 TI ((muscle strengthening or progressive resist*)) OR AB ((muscle strengthening or progressive resist*))

S22 TI (((weight or strength* or resistance) n3 (train* or lift* or exercise*))) OR AB (((weight or strength* or resistance) n3 (train* or lift* or exercise*)))

S23 TI (((isometric or isotonic or eccentric or concentric) n3 (action* or contraction* or exercise*))) OR AB (((isometric or isotonic or eccentric or concentric) n3 (action* or contraction* or exercise*)))

S24 S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23

S25 TI ((time or timing or intensive or intensity or augment* or accelerate* or additional or dosage or dose or frequency or amount or quantity)) OR AB ((time or timing or intensive or intensity or augment* or accelerate* or additional or dosage or dose or frequency or amount or quantity))

S26 S24 AND S25

S27 MH Random Assignment or MH Single-blind Studies or MH Double-blind Studies or MH Triple-blind Studies or MH Crossover design or MH Factorial Design

S28 TI ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or AB ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or SU ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study")

S29 TI random* or AB random*

S30 AB "latin square" or TI "latin square"

S31 TI (crossover or cross-over) or AB (crossover or cross-over) or SU (crossover or cross-over)

S32 MH Placebos

S33 TI (((singl* or doubl* or trebl* or tripl*) N3 (blind* or mask*))) OR AB (((singl* or doubl* or trebl* or tripl*) N3 (blind* or mask*)))

S34 TI Placebo* or AB Placebo* or SU Placebo*

S35 MH Clinical Trials

S36 TI (Clinical AND Trial) or AB (Clinical AND Trial) or SU (Clinical AND Trial)

S37 S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36

S38 S7 AND S26 AND S37

Appendix I AMED Search Strategy

1. cerebrovascular disorders/ or cerebral hemorrhage/ or cerebral infarction/ or cerebral ischemia/ or cerebrovascular accident/ or stroke/

2. (stroke or poststroke or post-stroke or cerebrovasc$ or brain vasc$ or cerebral vasc$ or cva$ or apoplex$ or SAH).tw.

3. ((brain$ or cerebr$ or cerebell$ or intracran$ or intracerebral) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$)).tw.

4. ((brain$ or cerebr$ or cerebell$ or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage$ or hemorrhage$ or haematoma$ or hematoma$ or bleed$)).tw.

5. hemiplegia/

6. (hemipleg$ or hemipar$ or paresis or paraparesis or paretic).tw.

7. or/1-6

8. physical therapy modalities/ or exp exercise therapy/ or hydrotherapy/ or physical medicine/ or physical therapy speciality/

9. exp applied kinesiology/ or rehabilitation/ or "activities of daily living"/ or therapy/

10. rehabilitation modalities/ or exp occupational therapy modalities/ or rehabilitation psychosocial/ or exp rehabilitation vocational/ or rehabilitation techniques/

11. exp movement/

12. exercise/ or weight training/ or physical fitness/ or exp sports/ or exp exercise testing/

13. exertion/ or exp physical endurance/

14. exp muscle contraction/

15. (physiotherap$ or (physical adj3 (mobilis$ or mobiliz$ or exercise$ or exertion or endurance or therap$ or conditioning or activit$ or fitness))).tw.

16. (rehabilitation or recovery of function or exercise$ or mobilis$ or mobiliz$ or motion therap$ or motor activit$ or motor skill$ or activities of daily living or adl or manipulat$ or (occupational adj3 (train$ or rehab$ or therap$ or activit$ or regim$))).tw.

17. (exercise adj3 (train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$)).tw.

18. (fitness adj3 (train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$ or centre$ or center$)).tw.
19. ((training or conditioning) adj3 (intervention$ or protocol$ or program$ or activit$ or regim$)).tw.

20. (sport$ or recreation$ or leisure or cycling or bicycl$ or rowing or treadmill$ or running or circuit training or swim$ or walk$ or dance$ or dancing or tai ji or tai chi or yoga).tw.

21. ((endurance or aerobic or cardio$) adj3 (fitness or train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$)).tw.

22. (muscle strengthening or progressive resist$).tw.

23. ((weight or strength$ or resistance) adj3 (train$ or lift$ or exercise$)).tw.

24. ((isometric or isotonic or eccentric or concentric) adj3 (action$ or contraction$ or exercise$)).tw.

25. or/8-24

26. (time or timing or intensive or intensity or augment$ or accelerate$ or additional or dosage or dose or frequency or amount or quantity).tw.

27. 25 and 26

28. clinical trials/

29. randomized controlled trial.pt.

30. controlled clinical trial.pt.

31. placebo.ab.

32. random$.ab.

33. trial.ab.

34. groups.ab.

35. or/28-34

36. 7 and 27 and 35

Appendix J PsycINFO Search Strategy

1. cerebrovascular disorders/ or cerebral hemorrhage/ or exp cerebral ischemia/ or cerebral small vessel disease/ or cerebrovascular accidents/ or subarachnoid hemorrhage/

2. (stroke$ or poststroke or apoplex$ or cerebral vasc$ or brain vasc$ or cerebrovasc$ or cva$ or SAH).tw.

3. ((brain or cerebr$ or cerebell$ or vertebrobasil$ or hemispher$ or intracran$ or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA$ or anterior circulation or posterior circulation or basilar artery or vertebral artery or space-occupying) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$ or hypoxi$)).tw.

4. ((brain$ or cerebr$ or cerebell$ or intracerebral or intracran$ or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli$ or putaminal or putamen or posterior fossa or hemispher$ or subarachnoid) adj5 (h?emorrhag$ or h?ematoma$ or bleed$)).tw.

5. hemiparesis/ or hemiplegia/

6. 1 or 2 or 3 or 4 or 5

7. rehabilitation/ or cognitive rehabilitation/ or neuropsychological rehabilitation/ or neurorehabilitation/ or occupational therapy/ or physical therapy/ or exp psychosocial rehabilitation/

8. "activities of daily living"/

9. recreation therapy/ or psychotherapy/

10. exp exercise/

11. exp motor performance/

12. exp sports/

13. physical fitness/ or physical endurance/ or physical strength/

14. (physiotherap$ or (physical adj3 (mobilis$ or mobiliz$ or exercise$ or exertion or endurance or therap$ or conditioning or activit$ or fitness))).tw.

15. (rehabilitation or recovery of function or exercise$ or mobilis$ or mobiliz$ or motion therap$ or motor activit$ or motor skill$ or activities of daily living or adl or manipulat$ or (occupational adj3 (train$ or rehab$ or therap$ or activit$ or regim$))).tw.

16. (exercise adj3 (train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$)).tw.

17. (fitness adj3 (train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$ or centre$ or center$)).tw.

18. ((training or conditioning) adj3 (intervention$ or protocol$ or program$ or activit$ or regim$)).tw.

19. (sport$ or recreation$ or leisure or cycling or bicycl$ or rowing or treadmill$ or running or circuit training or swim$ or walk$ or dance$ or dancing or tai ji or tai chi or yoga).tw.

20. ((endurance or aerobic or cardio$) adj3 (fitness or train$ or intervention$ or protocol$ or program$ or therap$ or activit$ or regim$)).tw.

21. (muscle strengthening or progressive resist$).tw.

22. ((weight or strength$ or resistance) adj3 (train$ or lift$ or exercise$)).tw.

23. ((isometric or isotonic or eccentric or concentric) adj3 (action$ or contraction$ or exercise$)).tw.

24. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23

25. (time or timing or intensive or intensity or augment$ or accelerate$ or additional or dosage or dose or frequency or amount or quantity).tw.

26. 24 and 25

27. clinical trials/ or treatment effectiveness evaluation/ or placebo/

28. (random$ or RCT or RCTs).tw.

29. (controlled adj5 (trial$ or stud$)).tw.

30. (clinical$ adj5 trial$).tw.

31. ((control or treatment or experiment$ or intervention) adj5 (group$ or subject$ or patient$)).tw.

32. (quasi-random$ or quasi random$ or pseudo-random$ or pseudo random$).tw.

33. ((control or experiment$ or conservative) adj5 (treatment or therapy or procedure or manage$)).tw.

34. ((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw.

35. (cross-over or cross over or crossover).tw.

36. (placebo$ or sham).tw.

37. trial.ti.

38. (assign$ or allocat$).tw.

39. controls.tw.

40. or/27-39

41. 6 and 26 and 40

Appendix K Open Grey Search Strategy

(stroke OR cereb* OR cva* OR subarachnoid OR brain) AND (physio* OR physical OR exercise* OR therap* OR rehab*) AND (Intens* OR augment* OR additional OR dosage OR dose OR frequen* OR amount OR quantity)

Appendix L OT Seeker Search Strategy

(stroke OR cereb* OR cva* OR subarachnoid OR brain) AND (physio* OR physical OR exercise* OR therap* OR rehab*) AND (Intens* OR augment* OR additional OR dosage OR dose OR frequen* OR amount OR quantity)

Appendix M PEDro Search Strategy

1. neurology in the <Subdiscipline> field 2. clinical trial in the <Method> field

3. (tim* OR intens* OR augment* OR accelerate* OR additional* OR dosage OR dose OR frequency OR amount OR quantity) in the <Title & Abstract> field

4. 1 AND 2 AND 3

Appendix N REHABDATA Search Strategy

Key Concept 1 - Stroke:

stroke OR cereb* OR cva* OR subarachnoid OR brain

Key Concept 2 - Physio/ OT/Rehab Exercise Interventions

physiotherap* OR physical OR exercise* OR therap* OR rehab*

Key Concept 3 - Frequency/Intensity

Intens* OR augment* OR additional OR dosage OR dose OR frequen* OR amount OR quantity

The method for search was to run the three key concept searches, then combined the queries. This had to be done by the staff at the company who manage REHABDATA, as it was a 'back end' search – the website doesn't currently have the functionality to conduct a search using the method required.

Appendix O ProQuest Dissertations and Theses Search Strategy

Set#: S1

Searched for: ti,ab(stroke or poststroke or "post-stroke" or cerebrovasc* or brain next vasc* or cerebral next vasc* or cva* or apoplex* or SAH) OR ti,ab((brain* or cerebr* or cerebell* or intracran* or intracerebral) NEAR/5 (isch*emi* or infarct* or thrombo* or emboli* or occlus*)) OR ti,ab((brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid) NEAR/5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)) OR ti,ab(hemipleg* or hemipar* or paresis or paretic)

Set#: S2

Searched for: ti,ab(exercise OR rehabilit* OR physiotherapy OR therapy)

Set#: S3

Searched for: ti,ab(time OR timing OR intensive OR intensity OR dosage OR dose OR quantity OR amount)

Set#: S4

Searched for: S1 AND S2 AND S3

Appendix P ClinicalTrials.gov Search Strategy

(exercise OR physical therapy OR rehabilitation) AND (time OR timing OR intensive OR intensity OR quantity OR amount OR dose) AND (Brain Infarction OR Intracranial Hemorrhages OR Carotid Artery Diseases OR Brain Ischemia OR Cerebral Hemorrhage OR Cerebrovascular Disorders OR Stroke) [DISEASE]

Appendix Q Stroke Trials Registry Search Strategy

Keywords:

Intensity Intensive Augment Augmented Additional Dosage Dose Frequent Frequency Amount Quantity Duration

Conditions:

Stroke, Cerebral Vascular Accident, CVA (cerebrovascular Accident), Cerebellar Stroke, Subarachnoid Hemorrhage (SAH), SAH, Brain Infarction, Ischemic Brain Injury, Cerebral Hemorrhage, Carotid Artery Disease

Interventions:

Physiotherapy, Occupational Therapy, Exercise, Rehabilitation, Rehabilitation program, rehabilitation therapy, therapy.

Appendix R EU Clinical Trials Register Search Strategy

Six separate searched run:

Stroke AND Rehabilitation AND Intensity

Stroke AND Rehabilitation AND Amount

Stroke AND Rehabilitation AND Dose

Stroke AND therapy AND Intensity

Stroke AND therapy AND Amount

Stroke AND therapy AND Dose

Appendix S ISRCTN Registry

Filtered the database for all “Nervous system diseases” and included all results. Unable to run a more precise search

Appendix T WHO ICTRP Search Strategy

stroke AND therapy AND dose:

Synonyms: stroke, ACCIDENT CEREBROVASCULAR, accident; cerebral, accident; cerebrovascular, Apoplexy, Apoplexy Cerebrovascular, apoplexy; cerebral, Brain Attack, Brain Vascular Accident, Brain Vascular Accidents, Cerebral vascular accident, Cerebral vascular events, cerebral; accident, cerebral; apoplexy, Cerebrovascular accident, Cerebrovascular accident (disorder), Cerebrovascular accident NOS, Cerebrovascular accident NOS, Cerebrovascular Accidents, Cerebrovascular Apoplexy, cerebrovascular; accident, CVA, CVA (cerebral vascular accident), CVA (Cerebrovascular Accident), CVA NOS, CVAs (Cerebrovascular Accident), Neuro: Cerebrovascular accident, Vascular Accident Brain, Vascular Accidents Brain AND therapy, disease management, THER, Therapeutic, therapeutic aspects, therapeutic method, Therapeutic proced, Therapeutic procedure, Therapeutic procedure (procedure), Therapeutic procedure NOS, Therapeutic Procedures, Therapeutics, therapies, TREAT, treatment, treatment method, Treatments AND dose, Dosage, Dosage (attribute), Dosages, Dosages (qualifier value), TRTDOS

stroke AND rehabilitation AND dose

Synonyms: stroke, ACCIDENT CEREBROVASCULAR, accident; cerebral, accident; cerebrovascular, Apoplexy, Apoplexy Cerebrovascular, apoplexy; cerebral, Brain Attack, Brain Vascular Accident, Brain Vascular Accidents, Cerebral vascular accident, Cerebral vascular events, cerebral; accident, cerebral; apoplexy, Cerebrovascular accident, Cerebrovascular accident (disorder), Cerebrovascular accident NOS, Cerebrovascular accident NOS, Cerebrovascular Accidents, Cerebrovascular Apoplexy, cerebrovascular; accident, CVA, CVA (cerebral vascular accident), CVA (Cerebrovascular Accident), CVA NOS, CVAs (Cerebrovascular Accident), Neuro: Cerebrovascular accident, Vascular Accident Brain, Vascular Accidents Brain AND rehabilitation, Physical Therapy, rehab.asistnce, REHABIL AND dose, Dosage, Dosage (attribute), Dosages, Dosages (qualifier value), TRTDOS

stroke AND therapy AND intensity

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stroke AND rehabilitation AND intensity

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Synonyms: stroke, ACCIDENT CEREBROVASCULAR, accident; cerebral, accident; cerebrovascular, Apoplexy, Apoplexy Cerebrovascular, apoplexy; cerebral, Brain Attack, Brain Vascular Accident, Brain Vascular Accidents, Cerebral vascular accident, Cerebral vascular events, cerebral; accident, cerebral; apoplexy, Cerebrovascular accident, Cerebrovascular accident (disorder), Cerebrovascular accident NOS, Cerebrovascular accident NOS, Cerebrovascular Accidents, Cerebrovascular Apoplexy, cerebrovascular; accident, CVA, CVA (cerebral vascular accident), CVA (Cerebrovascular Accident), CVA NOS, CVAs (Cerebrovascular Accident), Neuro: Cerebrovascular accident, Vascular Accident Brain, Vascular Accidents Brain AND therapy, disease management, THER, Therapeutic, therapeutic aspects, therapeutic method, Therapeutic proced, Therapeutic procedure, Therapeutic procedure (procedure), Therapeutic procedure NOS, Therapeutic Procedures, Therapeutics, therapies, TREAT, treatment, treatment method, Treatments AND amount, 050-051 QUANTITIES, QUANTITIES, Quantity, Quantity (attribute), Quantity finding, Quantity finding (finding)

Appendix U Characteristics of included studies

Abdullahi 2018	
Methods	Randomised Controlled Trial Consent Baseline testing of cohorts of 15 Stratification of walking speed organized into triplets and then randomised into group Assessment Intervention Assessment and Retention
Participants	102 participants in 3 study arms Experimental Group 1: n=34, 70(11) years old, 71% male, 53% right sided weakness, chronicity 22(16)months Experimental Group 2: n=34, 64(12) years old, 82% male, 41% right sided weakness, chronicity 20(15)months All Participants were within 5 years of their first stroke and had been discharged from formal rehabilitation. Community Setting in Australia
Interventions	Intervention was a treadmill and over ground walking program Experimental Group 1: Intervention was provided for 30minutes, 3 times-a-week for 16 weeks Experimental Group 2: Intervention was provided for 30minutes, 3 times-a-week for 16 weeks Control Group: No intervention
Outcomes	Six Minute walk test 10 meter walk test EuroQol EQ-5D-5L Adelaide Activities Profile Walking self-efficacy scale Number of Falls Measurements were taken at baseline, 2 months, 4 months, 6 months & 12 months
Notes	Control group is excluded from analysis, as they received no intervention This study controlled the rehabilitation duration. The number of minutes per-session and the frequency of sessions were the same for each group. Conflict of Interest: The authors declare there is no conflict of interest. Funding: This study was funded by the Heart Foundation of Australia and the University of Sydney.
Burgar 2011	
Methods	Randomised Controlled Trial Medical clearance to participate Eligibility Consent Baseline testing Stratification by FMA upper extremity score and randomised at each site into 3 groups. Hi dose Robot, Lo dose Robot and control (all extra to existing therapy) Intervention Testing and 6 month retention For the purpose of the Cochrane review, we can only compare the two robot groups.
Participants	54 participants, in three study arms, completed the pre-intervention testing and at least 5 hours of treatment: Robot-Lo: n = 19, mean age 62.5 years, 17.3 days since stroke (mean) Robot-Hi: n = 17, mean age 58.6 years, 16.6 days since stroke (mean) No information given re: gender of participants.

	No significant difference between the sites, other than in time since stroke. There was a significant difference in age between the groups. Three inpatient settings in the USA
Interventions	The intervention was Robot therapy. The Robot-lo group (and the CG) were eligible to receive up to 15 one-hour therapy sessions over a three week period. The robot-hi group were eligible to receive 30 one-hour therapy sessions over the same time period. Intervention was terminated when the participant received the maximum amount of sessions, of when they were discharged from acute inpatient rehabilitation.
Outcomes	Fugl-Meyer upper limb Upper limb portion of the Functional Independence Measure Modified Ashworth Scale Wolf Motor Function Test Measurements were taken before study initiation, after completion of training and at 6-month follow-up.
Notes	Very few of the participants received the maximum amount of additional input, as planned. Early discharges, scheduling conflicts, and patient tolerance were among the factors that reduced the total amount of therapy. Conflict of Interest: Authors declared no competing financial interests. Funding: Study was supported by VA Rehabilitation and Service Development (B2695)
Cooke 2010	
Methods	Randomised controlled Trial Potential participants assessed for eligibility consented to the study obtained baseline measurements taken Allocation was stratified by baseline scores for unilateral visual spatial neglect 6 weeks of intervention Post intervention and follow-up measurements taken
Participants	109 participants in three study arms (only 2 of the study arms meet the criteria for this review): CPT Group: n = 38, mean days since stroke = 36.76 (SD 22.4), mean age = 66.37 (SD 13.7), males = 55% CPT + CPT Group: n = 35, mean days since stroke = 32.43 (SD 21.29), mean age = 67.46 (SD 11.3), males = 63% Participants were initially seen as inpatients, but intervention was completed as outpatients, if they were discharged before the end of the intervention period. Four clinical settings in the UK
Interventions	Intervention was Conventional Physiotherapy (CPT), for the lower limbs. There was no pre-specified schedule for routine CPT. Additional CPT was provided for up to one hour, 4 days-a-week, for six weeks. The study authors report that the CPT group received a mean of 9.2 (SD 6.9) cumulative hours of treatment and the CPT + CPT group received a mean of 23 (SD10.4) cumulative hours of treatment.
Outcomes	Walking speed (meters/second) Ability to walk at 0.8 m/s or more Torque around the paretic knee Modified Rivermead mobility index Temporal-spatial gait parameters EuroQuol Measurements were taken at baseline, end of intervention and at 12 week follow-up
Notes	Conflict of Interests: The authors have no conflicts of interest to declare with regard to this article. Funding: Funding was provided by the Healthcare Foundation and the Dowager Countess Eleanor Peel Trust.

Donaldson 2009	
Methods	Randomised Controlled Trial Baseline measurements taken, randomisation (Group allocation was stratified by baseline ARAT scores), intervention began the following day. Participants were randomised into three groups, two Conventional Physiotherapy (CPT) groups and one group that received Functional Strength Training (FST) and CPT. For the purpose of the Cochrane review, we only compare the two CPT groups.
Participants	30 participants in three study arms CPT group: mean age 72.6, 5 male, mean 13.4 days since stroke CPT+CPT group: mean age 73.3, 5 male, mean 25.6 days since stroke Inpatient setting in the UK
Interventions	Intervention was Conventional Physiotherapy (CPT) Conventional Physiotherapy was provided to all participants in the study, using a standardised treatment schedule. There is no evidence that there was a planned amount of CPT. The CPT+CPT group received additional CPT provided for up to an hour, 4 days-a-week for 6 weeks. This was also recorded using a standardised treatment schedule.
Outcomes	Action Research Arm Test 9 Hole Peg test Upper Limb strength (measured with a myometer) - grip, pinch, elbow flexion & extension Recorded at baseline; 6 weeks (end of intervention) and 12 weeks (follow-up).
Notes	Conflict of Interest: No conflicts of interest declared Funding: Study was funded by The Wellcome Trust
Dromerick 2009	
Methods	Randomised Controlled Trial Adaptively randomised balancing age, NIHSS score, pre-test ARAT and days from stroke Study compared 2 different Constraint Induced Movement Therapy (CIMT) protocols to control. For the purpose of the Cochrane review, we are interested in the two different protocols for CIMT only (excluding control)
Participants	52 participants in three study arms. Low CIMT: n=19. Mean age 62.8, days since stroke 8.8, 68% female High CIMT: n=16. Mean age 64.5, days since stroke 9.94, 44% female Inpatient rehabilitation Setting
Interventions	Intervention was CIMT Pre-specified treatment (pre-empted OT) based on Excite + routine physio Received extensive verbal and written feedback and review of prior day's achievements, day's goals and reinforcement of new gains and maintenance. Low CIMT: 2 hours of shaping therapy a day and padded constraint mitt for 6 hours per day. High CIMT: 3 hours of shaping therapy a day and padded constraint mitt for 90% of waking hours. Study treatment occurred 5 days-a-week for 2 weeks (consecutively).
Outcomes	NIHSS ARAT FIM SIS Hand function sub-scale Pain Ratings Geriatric Depression Scale All measures were taken on baseline, at 14 days (post-intervention) and at 90 days.
Notes	Conflict of Interests: Authors have disclosed the following: Dr. Dromerick has received research support from NIH, NINDS, and United States Veterans Affairs, and Intramural support from the United States Army, Department of Defense. Dr. Lang has received

	research support from NIH, NINDS, and the Missouri Physical Therapy Association. Dr. Miller has served on the Data and Safety Monitoring Board for Ethicon. Dr. Powers has received research support from University of North Carolina, Washington University, University of Iowa, University of Kentucky, Harvard University, Bowdoin College, NIH, Legatus Emergency Services, LLC, Neutral, LLC, EDJ Associates, Hitchcock Foundation, Dartmouth-Hitchcock Clinic, Certus International, Inc., Companion Baking Company, and Union Square Hospitality Group. Dr. Wolf is supported by NIH, Allergan, and AMES. Funding: This study was funded by NIH grant 1 RO1 NS41261-01A1 and James S. McDonnell Foundation grant 21002032.
English 2015	
Methods	Randomised Controlled Trial Participants were recruited into the study, and randomised into one of three treatment arms Assessment Intervention Post-intervention and follow-up assessment
Participants	283 participants in 3 study arms (only 2 of the study arms meet the criteria for this review): Usual Care (5 day): n = 94, mean age 68.2years, time between stroke & randomization: 28.7 days, 52 males 7 day: n = 96, mean age 71.9 years, time between stroke & randomization: 25.0 days, 59 males All participants were between 5 and 197 days post-stroke on entry to the study In-patient setting in Australia
Interventions	7-day therapy: Therapy was provided 7 days-a-week for a maximum of 90 minutes/day (maximum of 630 minutes/week) Usual Care (5-day therapy): Therapy was provided 5 days-a-week for a maximum of 90 minutes/day (maximum of 450 minutes/week) Intervention was provided over a 4 week period.
Outcomes	FIM WMFT 6-minute walk test Walking speed Functional Ambulation Classification SIS physical subscale Length of Stay Australian Quality of Life (AQoL) Scale Adverse events Assessed at baseline, 4-weeks, 3 and 6-months post randomisation (SIS and the AQoL no baseline)
Notes	This study controlled for the number of minutes of rehabilitation provided each week and the frequency of rehabilitation intervention. Conflict of Interests: None Funding: This project was supported by a National Health and Medical Research Project Council Grant #631904.
GAPS 2004	
Methods	Randomised Controlled Trial Informed consent, randomised, stratified by study site, age and level of severity Randomised to Augmented Physio (AP) or Standard Physio (SP) Patients in both groups had normal access to all other interventions
Participants	70 participants in two study arms Augmented Physiotherapy group: n=35, 68(11) years old, 31% female, 46% right

	hemisphere stroke Standard Physiotherapy group: n=35, 67(10) years old, 51% female, 43% right hemisphere stroke All participants were between 6 and 71 days post-stroke on entry into the study In-patient settings in Scotland
Interventions	Intervention was routine Physiotherapy, based on the Normal Movement (Bobath) approach. Ambition was to provide the Augmented Physiotherapy group double the amount (60-80 minutes) of physiotherapy compared to the Standard Physiotherapy group (30 - 40 minutes), five days-a-week. Intervention continued for the duration of the participants' inpatient stay.
Outcomes	Trunk Control Test Motricity Index Achievement of mobility milestones RMI Walking Speed Barthel Index. NEADL EuroQuol Discharge home, length of stay in hospital, delays to discharges Complications Measures taken – baseline, four weeks, three months and six months.
Notes	This study controlled for daily amount and frequency of rehabilitation, but not overall duration. Although the ambition was for the Augmented Physiotherapy group to receive double the amount of therapy to the Standard Physiotherapy group, the reality was they only received 62% more therapy. Conflict of Interest: None declared. Funding: This project was supported by a National Health and Medical Research Project Council Grant #631904.
Han 2013	
Methods	Randomised Controlled Trial Eligibility Consent Randomization by random number tables and sealed envelopes Baseline Testing, Intervention motor relearning for 5 days a week, for 6 weeks.
Participants	32 participants in three study arm. Two dropped out, so data analysed for 30. Group A: n=10, 7 male, Mean age 52.4 years, mean days to randomisation 41.4 Group B: n=10, 8 male, Mean age 53.7 years, mean days to randomisation 42.9 Group C: n=10, 8 male, Mean age 44.6 years, mean days to randomisation 38.3 No significant difference between the groups
Interventions	Intervention was upper limb rehabilitation Group A: 1 hour per day Group B: 2 hours per day Group C: 3 hours per day Duration could be distributed throughout the day. All intervention was provided 5 days a week, for 6 weeks.
Outcomes	Fugl Meyer Assessment Action Research Arm Test Barthel Index Measured at baseline, 2weeks, 4weeks and post at 6 weeks
Notes	The following pair-wise comparison are included: Han 2013a - Group A (1 hour) (n=5) vs. Group B (2 hours) (n=10) Han 2013b – Group A (1 hour) (n=5) vs. Group C (3 hours) (n=10)

	Conflict of Interest: No conflicts of interest declared Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.
Hsieh 2012	
Methods	Randomized block-controlled trial Randomized using random numbers; stratification based on lesion side and motor deficit level. Robot Therapt (RT) is Bi-Manu-Track (allows forearm supination/pronation and wrist flexion/extension) with duration control of 3 groups (90-105mins). Repetitions were high or low intensity with high having twice the number of repetitions per unit time than lower. Before RT, 5 mins mobilization and afterwards 15-20 mins of functional activities practice. Control group had intensive standard therapy. For the purpose of the Cochrane review, we will only compare the two robot groups.
Participants	54 participants in three study arms High RT: n 18; Age 56.5 (10) yrs; Time 28.7 (13.7) mo; male n 11. Low RT = n 18; Age 52.2 (12) yrs; Time 23.3 (15.4) mo; male n 13. No differences between these or other characteristics Participants were all more than 6 months post-stroke.
Interventions	Intervention was Robot Therapy All participants received a duration-matched intervention for 90 – 105 minutes of therapy/ day, for 5 days/week for 4 weeks. Higher-intensity RT – 600–800 repetitions of modes 1 and 2 for 15–20 minutes and 150–200 reps of mode 3 for 3-5 minutes Lower-intensity RT – received half the number of repetitions as the high intensity group.
Outcomes	Upper Extremity items of the Fugl-Meyer assessment Medical Research Council Scale (Muscle power from 0-5) Motor Activity Log (Amount of use and quality of movement) The 4 physical domains on the Stroke Impact Scale (Strength, ADLs, Mobility and hand function) Pain (scale of 0-10) Fatigue (scale of 0-10) All measures were administered at baseline and immediately after the intervention. The primary outcome was also administered 2 weeks after the treatment began.
Notes	Authors provided mean and standard deviations for the post-treatment MAL (AoU) and SIS Hand function, as these were presented as change scores in the paper. Conflict of Interest: None Funding: This project was supported in part by the National Health Research Institutes (NHRI-EX101-9920PI and NHRI-EX101-10010PI), the National Science Council (NSC-100-2314-B-002-008-MY3 and NSC 99-2314-B-182-014-MY3), and the Healthy Ageing Research Center at Chang Gung University (EMRPD1A0891) in Taiwan.
Hsu 2010	
Methods	Randomised Controlled Trial Participants who satisfied selection criteria were randomised into 3 groups: High-NMES, Low-NMES or Control. For the purpose of the Cochrane review, we will exclude the control group.
Participants	66 participants in three study arms; 22 in each group High-NMES group: Mean age 60.2, 15% male, mean time since stroke – 23.3 days Low-NMES group: Mean age 62, 15% male, mean time since stroke – 21 days Study setting was not reported, but presumed to be inpatient.

Interventions	Intervention was Neuromuscular Electrical Simulation (NMES) All participants received standard rehabilitation. In addition to this, the two NMES groups received an additional 4 weeks of NMES, five days a week. The high- NMES group received 60 minutes of treatment per day, and the low-NMES group received 30 minutes of treatment per day.
Outcomes	Fugl-Meyer – upper extremity motor section ARAT Motor Activity Log (only assessed at follow-up) Measurements were taken at baseline, after 4 weeks of treatment and at 2 months
Notes	Conflict of Interests: None . Funding: This study was partially supported by the Bureau of Health Promotion, Department of Health, ROC (Taiwan), through grants DOH93-HP-1114DOH94- HP-1114
Hunter 2011	
Methods	Randomised Controlled Trial Randomised (independent, concealed) to 4 groups. Three groups received different amounts of the intervention and the 4th was a control group. For the purpose of the Cochrane review, we will exclude the control group. Stratified by clinical centre, severity of paresis and spatial neglect
Participants	76 participants in 4 study arms. All participants were within 8 – 84 days post-event Group 2 – 18 participants. 61% male, mean age 73.3 Group 3 – 19 participants. 42% male, mean age 72.9 Group 4 – 20 participants. 45% male, mean age 72.5 Inpatient setting (or at home if discharged), in the UK
Interventions	Intervention was Mobilization and tactile stimulation (MTS) of forearm and hand. This intervention has specific components that can be adapted to individual presentation. Group 2 – up to 30 minutes/day of MTS Group 3 – up to 60 minutes/day of MTS Group 4 – up to 120 minutes/day of MTS Intervention was provided for 14 consecutive working days
Outcomes	Primary outcome was the arm section of the Motricity Index Secondary outcome was the ARAT. Measurements were at baseline, and at the end of the intervention phase. Adverse events were monitored on each working day.
Notes	Hunter 2011 reports the following pair-wise comparison: Hunter 2011a - Group 2 (n=9) vs. Group 3 (n=18) Hunter 2011b - Group 2 (n=9) vs. Group 4 (n=20) Both the planned amount of minutes and the actual amount of minutes of therapy provided are recorded. Paper reports change scores, but authors kindly sent raw data, so Mean and Standard Deviation could be calculated. Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the authorship and/or publication of this article. Funding: The author(s) disclosed receipt of the following financial support for the research and/or authorship of this article: We are grateful to The Stroke Association for the provision of funding for this study. The Stroke Association had no role in the design, conduction, or interpretation of the results of this study.
Kowalczewski 2007	
Methods	Randomised Controlled Trial

	Participants who met the eligibility criteria for the study were randomised into either a low-intensity Functional Electrical Stimulation-assisted exercise therapy (FES-ET) group or a high intensity FES-ET group. As well as the experimental treatment, participants also received regular hand function therapy.
Participants	19 participants in two study arms High Intensity FES-ET: n=10, male = 4, mean age = 59.4 years, mean time since stroke = 1.6 months Low Intensity FES-ET: n=9, male = 6, Mean age = 61.7 years, mean time since stroke = 1.6 months Canadian in-patient rehabilitation unit
Interventions	Intervention was FES-ET Both groups received intervention for 3-4-weeks in addition to regular hand therapy (1 hour/day 3-4 days/week) Low intensity group: 15 mins sensory stimulation x 4 days/week and 60 mins on day 5. High intensity group: 60 mins for 15-20 consecutive days on the workstation
Outcomes	Wolf Motor Function Test Upper Extremity Fugl Meyer Motor Activity Log Assessed at baseline, post-treatment and at 3 and 6 month follow-up: Kinematic data generated by the workstation not reported at follow-up for logistical reasons
Notes	Conflict of Interests: No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit upon the author(s) or upon any organization with which the author(s) is/are associated. Funding: The author(s) disclosed receipt of the following financial support for the research and/or authorship of this article: We are grateful to The Stroke Association for the provision of funding for this study. The Stroke Association had no role in the design, conduction, or interpretation of the results of this study.
Lang 2016	
Methods	Randomised Controlled Parallel trial Participants who met the selection criteria were randomised into 4 groups, each received different number of repetitions.
Participants	85 participants in 4 study arms 3.2k reps Group: 21, mean age 59.9, time since stroke 12.0 months, 7 Female 6.4k reps Group: 22, mean age 62.1, time since stroke 13.0 months, 5 Female 9.6k reps Group: 21, mean age 60.0, time since stroke 13.0 months, 10 Female Individualized Max Group: 21, mean age 60.9, time since stroke 11.5 months, 8 Female Outpatient setting.
Interventions	Intervention was supervised, massed practice of functional UL daily tasks e.g. reaching, grasping, moving/manipulating and releasing object. The participants in the 4 groups were encouraged to perform a certain amount of repetitions of exercise, dependent on their group allocation. Number of reps /session were: 100, 200, or 300. The Individualized maximum group aimed for 300 reps per session, but to continue receiving therapy until certain criteria had been met.
Outcomes	ARAT (primary outcome measurement) Stroke Impact Scale (hand and ADL sub scales) COPM 7 point Likert scale to evaluate if the participant though they had changed, and if that

	change was meaningful. Measures were taken at baseline (prior to randomisation, post-intervention, and then two-months later
Notes	Lang 2016 refers to the following pair-wise comparison: Lang 2016a - 3.2k rep (n=7) vs. 6.4k rep (n=19) Lang 2016b – 3.2k rep (n= 6) vs. 9.6k reps (n=17) Lang 2016c - 3.2k rep (n=6) vs. IM group (n=18) This study specified repetitions of exercise, as opposed to time spent, but also report the amount of minutes of 'active practice' undertaken in each group Conflict of Interest: There are no potential conflicts of interest between the authors and any commercial sponsors. Funding: Funding was provided by NIH R01 HD068290.
Lincoln 1999	
Methods	Randomised Controlled Trial Participants who met the inclusion criteria for the study were assessed and then randomise into one of three groups; a Routine Phsyiotherapy Group (RPT), a Qualified Physiotherapy Group (QPT) and an Assistant Physiotherapy Group (APT). For the purpose of the Cochrane review we will exclude the group treated by the assistant.
Participants	282 Participants in three study arms. RPT – n = 95, male n = 45, median age = 73 QPT - n = 94, male n = 51, median age = 73 All participants were between 1 and 5 weeks post-stroke on entry to the study.
Interventions	Intervention was physiotherapy, using a Bobath approach The RPT group received approximately 30-45 minutes 5 days/week for 5 weeks – analysed for amount of UL therapy post-hoc from notes. The QPT group received an additional 2 hours of therapy, 5 days-a-week
Outcomes	Rivermead Motor Assessment arm scale ARAT Ten-hole peg test Grip strength (dynamometer) RMA gross function scale Barthel Index Extended ADL Scale Measurements taken at baseline; five weeks (Post treatment); 3 and 6 months post-stroke.
Notes	Only 56% of participants in the QPT group completed the intervention (46% in the APT group). The most common reasons for this were inability to tolerate the additional therapy and full upper limb recovery. Conflict of Interest: Not reported Funding: This study was supported by the National Health Service (NHS) Executive, NHS Research and Development Programme on Cardiovascular Disease and Stroke.
Page 2011	
Methods	Randomised Controlled Trial Participants were screened for inclusion and signed consent. Baseline assessments were performed on two occasions, one week apart. Randomized using computer generated method Each group received repetitive task-specific practice and then varying amounts of mental practice. For the purpose of the Cochrane Review we will exclude the sham Mental Practice group
Participants	29 participants in four treatment arms Mean age 61(12)yrs, 23 males, time since stroke 35 months

	Groups did not differ except gender MP 40 n=6 females; MP 60 n = 7 with 6 males. The distribution of participants across the treatment groups were as follows: MP20 – 8 MP40 – 6 MP60 – 7 Outpatient/laboratory setting
Interventions	Experimental intervention was Mental Practice All subjects received 30minutes of Repetitive Task Practice, 3 days-a-week for 10 weeks (15-30 mins with optional 1-10 mins stretching). The treatment groups then received 20, 40 or 60 minutes of mental practice, as per their group allocation.
Outcomes	Upper limb section of the Fugl-Meyer assessment. ARAT Measurements were taken pre (average of 2 measures) and post intervention Only within-group analyses reported
Notes	Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the authorship and/or publication of this article. Funding: The author(s) disclosed receipt of the following financial support for the research and/or authorship of this article: We are grateful to The Stroke Association for the provision of funding for this study. The Stroke Association had no role in the design, conduction, or interpretation of the results of this study.
Page 2012	
Methods	Randomised Controlled Trial Power analysis undertaken Recruitment via adverts. 2 baselines Randomization from computer generated random numbers table (concealed envelope). 4 groups (three different amounts of intervention and a Home Exercise group) Education Session COPM and H200 fitted For the purpose of the Cochrane review we will exclude the group who only received a home exercise program
Participants	36 participants in 4 study arms. Four participants did not complete, so analysis is of 32. 30m/day – 9 60m/day - 8 120m/day - 8 Overall characteristics are as follows: 15 men; mean age 57.6y; age range, 38–75y; mean time since stroke onset 53.8m; range of onset, 7–324mo; 19 subjects exhibiting left-sided lesions. Outpatient setting.
Interventions	Intervention was repetitive task specific practice with Electrical stimulation neuroprosthesis (ESN). The participant carried out majority of the intervention. However, they did also participate in a 30minute, 1 hour or 2 hour home-based therapy session (based on their group allocation) and subsequent therapy session for 30 minutes 2 days-a-week, every other week, during the intervention phase of the study. The groups received: RTP & ESN for 30m/day RTP & ESN for 60m/day RTP & ESN for 120m/day All intervention was undertaken every weekday for 8 weeks.

Outcomes	Upper Extremity section of the Fugl-Meyer Arm Motor Ability Test (AMAT) Box and Blocks Action Research Arm Test Measurements were taken one week before and one week after the period of intervention. Only within-group analysis reported
Notes	Page 2012 reports the following pair-wise comparison from this study: Page 2012a - 30min group (n=5) vs. 60min group (n=8) Page 2012b - 30min group (n=4) vs. 120min group (n=8) Conflicts of Interest: No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated. Funding: Supported by an award from the American Heart Association.
Partridge 2000	
Methods	Randomised Controlled Trial Participants were deemed eligible for the study by applying the selection criteria. They then undertook baseline assessments, before randomisation
Participants	144 participants in two study arms Mean age 76.5 years (range 60–94), 62 (54%) female 30 min group: n=60 60 min group: n=54 Stroke Unit setting in Canterbury (UK)
Interventions	Intervention was Physiotherapy, based on Bobath principles 30 minutes or 60 minutes / day Although not explicitly stated, it is assumed that the treatment was 5 days-per-week. It appears that duration of treatment was not controlled (i.e. participants continued to receive the treatment to which they were allocated for the duration of their inpatient stay).
Outcomes	Profiles of Recovery (POR) Scale (gross body movement and underlying function). Functional Reach Step:time ratio Five meter timed walk Timed Sit to stand HADS Recovery Locus of Control Scale. Measurements were taken at baseline, at 6 weeks and at 6 months.
Notes	Study authors believe that it would be beneficial to identify subgroups of patients, who would benefit most from intensive input. Conflicts of Interest: Not reported Funding: The project was funded jointly by South East Thames R&D Directorate and East Kent Health Authority.
Smith 1981	
Methods	Randomised Controlled Trial Recruited post-discharge and randomised to one of 3 groups to receive variable intensities of rehab 1. Intensive 4 days / week. 2. Conventional 3 half-days / week. 3. No attendance but visited by health visitor at home encouraged to do exercises For the purpose of the Cochrane review, we will exclude the group that were visited at home.

Participants	133 Participants in three study arms Group 1 n=46 67% male, mean age 63, mean time since stroke 35 days. Group 2 n=43 patients, 73% male, mean age 66, mean time since stroke 41 days. Outpatient setting in the UK
Interventions	Intervention was Physiotherapy and Occupational Therapy Participants were required to attend the Out Patient dept for whole or half days, for up to 6-months, but shorter if full recovery achieved Group 1: 4 days /week. Group 2 3 half days / week Group 1 received double amount as Group 2
Outcomes	Activities of Daily Living (ADL) index. (17 item covering mobility, self-care and household tasks) Clinical exam Outcome Measures recorded at Baseline, 3, 6 and 12 months -i.e. one follow-up at 12 months Deaths and re-occurrences of stroke are also recorded.
Notes	Written in 1981 when there was little evidence from RCTs about effect of stroke rehab. Study indicates that intensive therapy may only be tolerated by a small percentage of stroke survivors (11% in this instance) Conflict of Interest: Not reported Funding: Not reported
Tong 2019	
Methods	Randomised controlled trial Patients screened for inclusion Baseline characteristic collected for eligible participants Eligible participants randomized into three groups, Very Early Intensive Mobilisation (VEIM), Early Intensive Mobilisation (EIM), Early Routine Mobilisation (ERM). For the purpose of this review we can only compare the EIM group and the ERM group. Delivery of intervention, depending on group, commenced 24-48 hours post stroke for 10 - 14 days duration Data collection 3 months post-stroke
Participants	100 participants randomised to each of the three trial arms, but data reported only for those who a) were confirmed diagnosis of stroke and b) received the intervention as planned. ERM: n = 80. Time since stroke to first mobilization 41.0 hrs (mean). Mean age: 62.1 years. 71.3% male. Baseline NIHSS 6.0 (0-16) EIM: n = 86. Time since stroke to first mobilization 38.0 hrs (mean). Mean age: 60.9 years. 76.7% males. Baseline NIHSS 5.8 (0-16) The study was conducted at the Stroke Unit of the Department of Neurology, Beijing Luhe Hospital, China
Interventions	Intervention was out of bed mobilization included sitting, standing and walking with or without assistance. No special equipment. Individualized to patient. Intervention was provided according to the AVERT protocol.
Outcomes	Modified Rankin Scale
Notes	Very Early Intensive Mobilisation (VEIM) group is excluded from this review, as they have received something different (i.e. earlier intervention). Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. Funding: The work was supported in part by Beijing Municipal Science Technology Commission (Z151100003915134), the National Natural Science Foundation of China (81501141), Science and Technology Project of Beijing Municipal Education Commission (KM201610025028), the Beijing NOVA program (xx2016061), and Science and Technology Plan of Beijing Tongzhou District (KJ2017CX043).

Wang 2004	
Methods	Randomised Controlled Trial Pre and post measurement.
Participants	74 participants in two treatment arms. Exp Group: n=38, 11 aphasic, mean age 65.13 ±8.86, 21 male. Control group: n=36, 9 aphasic, mean age 65.72±8.68, 19 male. Acute inpatient setting
Interventions	Intervention was rehabilitation therapy In the first month, the two groups of patients were given the same rehabilitation intensity, 2 times /d and 40 minutes/time; Starting from the second month, treatment group: once or twice a day, 40 min/ time; Control group :3 times/week, 40 min/ time. Treatment lasted for 6 months
Outcomes	Functional rating scale National Institue of Health Stroke Scale Fugl Meyer Assessment Modified Barthel Index Western Aphasia Battery Measurements taken before rehabilitation and at the end of 6 months after treatment
Notes	It is not certain if the intervention was provided 7 days-a-week or five days-a-week. Conflict of Interest: Not reported Funding: Not reported
Wang 2011	
Methods	Randomised Controlled Trial Participants were recruited into study and randomised Baseline assessment Intervention - All groups received OT, no mention of PT Assessment 2 weeks post-randomisation (half way through the intervention) Assessment post-intervention
Participants	30 participants in 3 study arms Conventional Rehabilitation: n=10, 67(7.45) years old, 50% male, 80% infarct, 9.4 (5.38) weeks since stroke Intensive Conventional Rehabilitation: n=10, 63.5(9.63) years old, 70% male, 80% infarct, 12.7 (9.72) weeks since stroke In-patient setting in China
Interventions	The purpose of this study was to compare modified Constraint Induced Movement Therapy to intensive conventional rehab (ICR), using conventional rehab (CR) as a control. For this Cochrane review we are interested in comparing the ICR and the CR only. All intervention took place five days a week, over 4 weeks. Amount per-day was as follows: CR Group – 45 minutes ICR Group – 3 hours
Outcomes	Wolf Motor Function Test Measurement taken at baseline and at 2 and 4 weeks after initiation of treatment.
Notes	Conflict of Interest: Not reported Funding: This research was supported by a grant from the Ministry of Human Resources and Social Security of the People's Republic of China.
Winstein 2019	

Methods	Randomised Controlled Trial Randomisation was stratified by severity (Fugl-Meyer) and Chronicity (time since stroke). Intervention was provided following a train-wait-train-wait-train pattern. Testing was undertaken pre, post and during intervention
Participants	41 participants in 4 study arms (for the purpose of this review, we only include 3 of these study arms) 15 hours group: n=10, age = 57.0±12.77, time since stroke (y) = 2.93±2.68, m/f = 9/1 30 hours group: n=10, age = 61.3±13.69, time since stroke (y) = 2.45±2.01, m/f = 7/3 60 hours group: n=11, age = 60.64±14.12, time since stroke (y) = 1.96±1.49, m/f = 8/3
Interventions	Intervention was the accelerated skill acquisition program (ASAP), a "personalized task-oriented training program that incorporates elements of skill acquisition, capacity building, with intrinsic motivational enhancements." Intervention was provided in 3 weeklong bouts of 4 consecutive visits each separated by 1 month. Intervention was provided at different durations – 0, 15, 30, or 60 hours, depending on group allocation. These figures are the total amount of intervention provided in the study.
Outcomes	Motor activity log WMFT time score Measurements were taken at baseline and at the end of intervention. Further measures were taken at the end of each weeklong bout of treatment.
Notes	Winstein 2019 reports the following pair-wise comparisons: Winstein 2019a - 15hour group (n=5) vs. 30 hour group (n=10) Winstein 2019b - 15hour group (n=5) vs.60 hour group (n=11) For the purpose of the Cochrane review, we have excluded the group that receive no therapy Conflict of Interest: No conflict of interest Funding: The research reported here was supported by the National Institute of Neurological Disorders and Stroke of the National Institutes of Health under R01 HD065438 and R56 NS100528.

Appendix V Characteristics of excludes studies

Study	Reason for exclusion
Abdullahi 2021	Does not compare different time spent in rehabilitation
Abraha 2017	Not an RCT
Afridi 2021	Compares time spent in rehabilitation to repetitions
Agarwal 2008	Not an RCT
Ardestani 2020	Compares different types of intervention (dose-matched)
Askim 2004	Compares different interventions
Askim 2010	Compares different interventions
Bai 2008	Control group received no intervention
Bowden 2020	Compares different interventions
Boyd 2016	Compares different interventions
Brusco 2014	Includes non-stroke participants
Byblow 2020	Compares different types of therapy
Byl 2008	Not an RCT
Chen 2006	Control group received no intervention
Daly 2019	Compares different interventions
De Sousa 2019	Compares different interventions
Di Lauro 2003	Compares different interventions
Duff 2013	Compares different interventions
Duncan 2003	Compares different interventions
Fasoli 2004	Compares different interventions
Forster 1992	Compares different interventions
Galloway 2017	Not an RCT
Gobbato 2012	Compares early onset to later onset therapy
Green 2004	Does not investigate dose-response in terms of time spent
Gremeaux 2017	Control group received no intervention
Henriksen 1992	Compares different interventions
Hesse 2011	Compares different interventions
Hogg 2020	Compares different interventions
Hornby 2015	Does not investigate dose-response in terms of time spent
Hornby 2016	Compares different interventions

Host 2014	Includes non-stroke participants
Hsu 2016	Does not compare different amounts of the same intervention. Uses a different definition of 'intensity'
Hubbard 2010	Compares different interventions
Huijben-Schoenmakers 2014	Not an RCT
Kissela 2013	Does not investigate dose-response in terms of time spent
Klassen 2020	Compares different interventions - The difference in the two treatment arms that were considered for this review were not only amount of time, but also intensity, in terms of exercise repetitions
Kosak 1998	Compares different interventions
Krebs 1997	Compares different interventions
Lamberti 2017	Compares different interventions
Langhammer 2007	Some control group participants received no therapy
Langhammer 2014	Control group received no intervention
Langhorne 2010	Compares different interventions
Langhorne 2017	Compares different interventions (Early as well as more intensive)
Lee 2012	Compares different interventions
Lewthwaite 2018	Some of the control participants received no therapy. We considered comparing the usual Care with the dose-matched usual care. However, although the DMUC group received a standard amount of therapy (30 hours over 16 weeks), the UC group did not (0-46 hours range over 16 weeks)
Li 2000	Compares different interventions
Lin 2017	Compares different interventions
Lo 2010	Compares different interventions
Logan 1997	Intervention group received input earlier than control group
Malouin 1992	Not an RCT (Case report)
Malouin 1993	Compares different interventions (Early as well as more intensive)
Martinsson 2003	Compares different interventions
Marzolini 2016	Compares different (dose-matched) interventions
McDonnell 2017	Compares different interventions
Mickelborough 1999	Compares different interventions
Mikulecka 2005	Compares different interventions
Outermans 2010	Compares different interventions
Ozdemir 2001	Compares different interventions

Raghavan 2016	Compares different interventions
Richards 2006	Compares different interventions
Richards 2006b	Study withdrawn
Roderick 2001	Compares different interventions
Rodgers 2019	Compares different interventions
Ruff 1999	Not an RCT
Ryan 2006	Includes non-stroke participants
Sanchez-Sanchez 2015	Compares different (dose-matched) interventions
Scrivener 2012	Not an RCT
Sheil 2001	Non-stroke participants
Sivenius 1985	Compares different interventions
Slade 2002	Includes non-stroke participants
Sonoda 2004	Not an RCT
Sterr 2002	Includes non-stroke participants
Sunderland 1992	Compares different interventions
Tomic 2017	Compares different interventions
Unknown 2021	Compares different interventions
Van Wijck 2020	Compares different interventions
Wu 2016	Compares different interventions
Wuennemann 2020	Includes non-stroke participants
Xu 2008	Compares different interventions
Yau 2010	Compares different interventions
Yelnik 2017	Compares different interventions
Yu 2008	Control group receives no intervention
Zhang 2005	Compares different interventions – early vs. later

Appendix W Characteristics of studies awaiting classification

Aksu 2001	
Methods	Randomised Controlled Trial
Participants	20 acute stroke patients in three study arms
Interventions	Exercies chosen from a Bobath neurodevelopmental approach Group 1 received four exercises Group 2 received six exercises Group 3 received eight exercises
Outcomes	Stroke Rehabilitation Assessment of Movement (STREAM)
Notes	The above is taken from conference proceedings and there is not enough information available to include at this stage. The authors have been contacted for full details of the study and we are awaiting their response.
Cauraugh 2006	
Methods	Randomised Controlled Trial
Participants	30 participants in three study arms
Interventions	Intervention is Bilateral movements and neuromuscular electrical stimulation (or sham stimulation) High Intensity Group: Bilateral training moving both arms coupled with neuromuscular electrical stimulation; four 90-minute sessions/week for 2 weeks. Low Intensity Group: Bilateral training moving both arms coupled with neuromuscular electrical stimulation; two 90-minute sessions/week for 2 weeks. Control Group: Bilateral training moving both arms coupled with sham neuromuscular electrical stimulation; two sessions/week for 2 weeks.
Outcomes	Box and Block Test Fugl-Meyer Upper Extremity Motor Test Fractionated Reaction Time Measurements were taken before and after intervention and outcomes reported for 14 of the participants recruited
Notes	This study is reported on ClinicalTrials.gov as completed, however, unable to locate a full paper and available information is limited. Authors contacted regarding publication of full paper; currently awaiting a response.
Hsieh 2011	
Methods	Pilot Randomised Controlled Trial
Participants	18 Participants in three study arms All participants were more than 6 months post-stroke Recruited from 3 medical centres in Taiwhan

Interventions	High Intensity Robot Therapy: Using the robot-assisted arm trainer, Bi-Manu-Track participants practiced 600 to 800 repetitions of mode1 for 15 minutes, 600 to 800 repetitions of mode 2 for 15 to 20 minutes, and 150 to 200 repetitions of mode 3 for 5 minutes, respectively, for forearm and wrist movements. Low Intensity Robot Therapy: Intervention for this group was the same as for the High Intensity group, but half the amount of repetitions were practiced. Control: Structured protocol of conventional Occupational Therapy All participants received training sessions (90-105 min/day, 5 days/wk for 4 weeks).
Outcomes	Upper Extremity Subscale of the Fugl Meyer Assessment Medical Research Council Scale Motor Activity Log ABILHAND scale Urinary 8-OHdG General sub-scale of the Multidimensional Fatigue Symptom Inventory Assessments were administered before and after treatment
Notes	Unable to include, as it appears that the recruitment dates of this study may cross with the study described in Hsieh 2012. We are waiting for confirmation from the authors regarding whether there was any participant overlap between these two studies.
Jung 2008	
Methods	Possibly a Randomised Controlled Trial
Participants	89 participants in two study arms
Interventions	Conventional rehabilitation (Occupational Therapy and Physiotherapy) Group I: Received one session of rehabilitation training per day Group II: Received two sessions of rehabilitation training per day
Outcomes	Korean Berg Balance Scale (K-BBS) Functional Independence Measure (FIM) Mini Mental State Examination-Korea (MMSE-K) Measurements were taken at 2-week intervals and between group differences were assessed at the beginning of treatment and at the peak of K-BBS.
Notes	The above is taken from conference proceedings and there is not enough information available to include at this stage. The authors have been contacted for full details of the study and we are awaiting their response.
Kreisel 2005	
Methods	Randomised Controlled Trial
Participants	55 participants in 2 study arms
Interventions	Intervention was conventional Physiotherapy Intensive Group: 10 to no more than 14 sessions of physiotherapy over a period of 10 days Conventional Group: No more than 5 sessions)
Outcomes	NIHSS Motricity Index
Notes	The above is taken from conference proceedings and there is not enough information available to include at this stage. The authors have been contacted for full details of the study and we are awaiting their response.

Rimmer 2004	
Methods	Randomised Controlled Trial
Participants	25 subjects in 3 study arms
Interventions	Group 1: Intensity-oriented exercise program, Group 2: Duration-oriented exercise program, Group 3: standard care group.
Outcomes	Peak Vo2 Time to exhaustion Maximum workload Submaximal oxygen cost Blood pressure Heart rate Lipid profile
Notes	The above is taken from conference proceedings and there is not enough information available to include or exclude. The authors have been contacted and we are awaiting their response.
Takebayashi 2015	
Methods	Probably a Randomised Controlled Trial
Participants	30 participants in two treatment arms
Interventions	Intervention was robotic therapy using the Reo Go therapy system, comparing a Low Intensity Training Group with a High Intensity Training Group.
Outcomes	Unspecified upper limb measurements
Notes	The above is taken from conference proceedings and there is not enough information available to include or exclude. The authors have been contacted and we are awaiting their response.
Wu 2013	
Methods	Randomised Controlled Trial
Participants	32 Participants planned, in three study arms
Interventions	Intervention is Robot Assisted Training (RT) High Intensity Robot Therapy Group: Each RT session will include 400-600 repetitions of mode 1 and 800-1000 repetitions of mode 2, totalling 1200-1600 repetitions, respectively for the forearm and the wrist movements. In addition, the patients will practice 100-200 repetitions in mode 3. In addition, this group received functional training. Low Intensity Robot Therapy Group: This group received the same intervention as the High Intensity Robot Therapy Group, but half the number of repetitions. Conventional Therapy Group: Functional training (no robot therapy)
Outcomes	Fugl-Meyer Assessment (FMA) Motor Status Scale (MSS) Modified Ashworth Scale (MAS) MyotonPRO Muscle metabolism (NIRS) Box and Block Test (BBT) Revised Nottingham Sensory Assessment (RNSA) Functional Independence Measure (FIM)

	Motor Activity Log (MAL)* ABILHAND Questionnaire* Adelaide Activities Profile (AAP)* EQ-5D-5L Accelerometers* Functional magnetic resonance imaging (fMRI) Kinematic analysis Inflammatory markers Oxidative stress markers Erythrocyte deformability Blood glucose indicators All measures were taken at baseline and at completion of intervention. Those marked with a * were also taken at 6-month follow-up.
Notes	The above is taken from ClinicalTrials.gov, which reports that the study was completed in May 2015. However, there are no results nor full publication available. The authors have been contacted and we are awaiting their response.

Appendix X Characteristics of ongoing studies

Bernhardt 2019	
Study name	AVERT DOSE
Methods	Randomised Controlled Trial
Participants	Study aims to recruit 2,700 participants
Interventions	Intervention was mobility training, delivered at an intensity tolerable to the participant, noted as mild, moderate or vigorous as determined by BORG and physiological measures (heart rate, respiratory rate, oxygen saturations and blood pressure) Group 1 - 1 session per day Group 2 - 2 sessions per day Group 3 - 3 sessions per day Group 4 - 4 sessions per day
Outcomes	modified Rankin Scale, safety (adverse events or serious adverse events), six meter walk test, EQ-5D-5L, HADS or SADsH10
Starting date	01/05/2019
Contact information	julie.bernhardt@florey.edu.au
Notes	This study is currently ongoing. It's inclusion will likely depend upon there being a similar proportion of intensity of training (mild, moderate or vigorous) across the 4 intervention groups.
Dukelow 2019	
Study name	RESTORE
Methods	Randomised Controlled Trial
Participants	132 participants planned in five study arms
Interventions	Intervention is robotic rehabilitation using a robotic exoskeleton Group 1 - Early low intensity (1 hour/day) Group 2 - Early high intensity (2 hours/day) Group 3 - Late low intensity (1 hour/day) Group 4 - Late high intensity (2 hours/day) Group 5 - Control For the purpose of this review, we would include a comparison of the two early groups and a separate comparison of the two late groups
Outcomes	Fugl-Meyer upper extermity Functional Independence Measure modified Rankin Scale Action Research Arm Test Robotic assessments
Starting date	01/05/2019

Contact information	spdukelo@ucalgary.ca, mark.piitz@albertahealthservices.ca
Notes	Above information is taken from www.ClinicalTrial.gov.
Holmstedt 2021	
Study name	Impact of More Frequent PT Services
Methods	Randomised controlled trial
Participants	150
Interventions	Group A - Increased frequency of PT services within the first 3-5 days of admission, followed by daily PT services for the duration of their inpatient stay. Group B - PT services 3-5 times per week during their hospitalization.
Outcomes	None yet reported
Starting date	March 2021
Contact information	holmstedt@musc.edu
Notes	
Kanlaya 2018	
Study name	
Methods	Randomised controlled trial
Participants	14 planned
Interventions	Group 1: task oriented training of Upper extremity for 2 hours Group 2: task oriented training of Upper extremity for 1 hour
Outcomes	Corticospinal excitability and kinematics
Starting date	
Contact information	
Notes	Limited availability from trial registries. Have contacted authors and awaiting response.
Kim 2017	
Study name	
Methods	Randomised Controlled Trial (according to clinicaltrials.gov)
Participants	150 participants planned in 2 study arms
Interventions	Intervention is cognitive rehabilitation Group 1: Cognitive rehabilitation for 1 hour, every working day for 4 weeks Group 2: Cognitive rehabilitation for 30 minutes, every working day for 4 weeks
Outcomes	Korean-Montreal Cognitive Assessment (K-MoCA)
Starting date	
Contact information	

Notes	Above information is taken from www.ClinicalTrial.gov. There is an associated paper for this study, which states it is a prosective cohort study (not RCT). Until the study is published, we will not know if it meets the criteria for this review.
Kinoshita 2020	
Study name	Dose-response of rPMS for Upper Limb Hemiparesis after stroke
Methods	Randomised Controlled Trial
Participants	Target sample size of 50
Interventions	The intervention is Repetitive peripheral magnetic stimulation (rPMS) Group 1 - Control Group 2 - 2400 pulses group Group 3 - 4800 pulses group Groups 2 and 3 could be included in the analysis
Outcomes	Fugl-Meyer upper extremity, modified Ashworth Scale, Active ROM Goniometry, Functional Independence Measure
Starting date	20th Janurary 2020
Contact information	kinoshita@jikei.ac.jp
Notes	Although amount is measures in number of pulses of rPMS, the protocol explains that "Each train of rPMS stimuli will be applied at 20 Hz for 3 seconds followed by a 27 second rest interval. Eighty such trains of rPMS stimuli will be applied as the daily 4800 pulses of rPMS therapy, and 40 such trains of rPMS stimuli will be applied as the daily 2400 pulses of rPMS, in the respective treatment groups." Therefore, intervention for group 3 will take twice as long as intervention for groups 2.
Ling 2018	
Study name	Effect of different intensity rehabilitation training on hemiplegic patients after stroke
Methods	Uncertain - possibly a Randomised Controlled Trial
Participants	24 participants planned in two study arms
Interventions	Intervention is 'Rehabilitation Training" Group 1: Low-intensity rehabilitation training Group 2: High-intensity rehabilitation training
Outcomes	Sicam 1n (svcam1n) D- dimer Cardiopulmonary exercise test 6-minute walking distance (6MWD) Quality of life (SF-36) Walking speed (10-meter walking test) Balance (Berg balance scale) Evaluation index of lower limb strength and FMA scale
Starting date	
Contact information	
Notes	This information is taken from a trial registries. There is not enough information to make a decision regarding inclusion of this study and currently no results available. We have contacted the study authors and await their response.

Mansfield 2020	
Study name	Determining the optimal dose of reactive balance training after stroke
Methods	Randomised Controlled Trial
Participants	36 planned - 12 in each intervention group
Interventions	Intervention was Reactive Balance Training (RBT) Group 1 - 1 session of RBT Group 2 - 3 sessions of RBT Group 3 - 6 sessions of RBT Each session will be 45 minutes long
Outcomes	Chedoke-McMaster Stroke Assessment, mini-Balance Evaluation Systems Test, Activities-specific Balance Confidence, Novel unpredictable perturbation.
Starting date	June 2020 (according to clinicaltrials.gov)
Contact information	Dr Avril Mansfield - avril.mansfield@uhn.ca
Notes	Above information taken from published protocol and registration of study on www.clinicaltrials.gov

Appendix Y Amount of intervention provided by studies

Study	Minutes per session	Session frequency	Duration of rehabilitation
Abdullahi 2018	Not reported (control received half the number of repetitions to the intervention group)	5 days-a-week	Four weeks
Ada 2013	30 minutes	3 x weekly	8 weeks (control) 16 weeks (intervention)
Burgar 2011	60 minutes	Up to 15 over 3 weeks (control) Up to 30 over 3 weeks (intervention)	3 weeks
Cooke 2010	23 minutes (control) 57.5 minutes (intervention)	4 days-a-week	6 weeks
Donaldson 2009	6.4 minutes (control) 36.4 minutes (intervention)	4 days-a-week	6 weeks
Dromerick 2009	120 minutes (control) 180 minutes (intervention)	5 days-a-week	2 weeks
English 2015	Up to 90 minutes	5 days-a-week (control) 7 days-a-week (intervention)	4 weeks
GAPS 2004	35 minutes (control) 63 minutes (intervention)	5 days-a-week	Uncontrolled
Han 2013	60 minutes (control) 120 minutes (intervention 1) 180 minutes (intervention 2)	5 days-a-week	6 weeks
Hsieh 2012	90 - 105 minutes (control received half the number of repetitions to the intervention group)	5 days-a-week	4 weeks
Hsu 2010	30 minutes (control) 60 minutes (intervention)	5 days-a-week	4 weeks
Hunter 2011	30 minutes (control) 60 minutes (intervention 1) 120 minutes (intervention 2)	7 days-a-week	2 weeks
Kowalczewski 2007	60 minutes	1 day-a-week (control) 5 days-a-week (intervention)	3-4 weeks

Lang 2016	25.5 minutes (control) 37.5 minutes (intervention 1) 49.3 minutes (intervention 2) 54.7 minutes (intervention 3)	4 days-a-week	8 weeks (control, intervention 1 & 2) 9 weeks (median - intervention group 3)
Lincoln 1999	30-45 minutes (control) 54-69 minutes (intervention)	5 days-a-week	5 weeks
Page 2012	30 minutes (control) 60 minutes (intervention 1) 120 minutes (intervention 2)	5 days-a-week	8 weeks
Partridge 2000	30 minutes (control) 60 minutes (intervention)	5 days-a-week	Uncontrolled
Smith 1981	3 half-days 4 full days	3 days-a-week 4 days-a-week	Up to 6 months
Tong 2019	<90 minutes (control) 180+ minutes (intervention)	7 days-a-week	10 – 14 days
Wang 2004	40 minutes (control) 40-80 minutes (intervention)	3 days-a-week (control) 5 days-a-week (intervention)	5 months
Winstein 2019	60 minutes (control) 120 minutes (intervention 1) 240 minutes (intervention 2)	5 days-a-week (for one week in every month	3 months

Appendix Z Characteristics of study participants

Study	Mean age (years)	Gender (% male)	Mean time post-stroke	Side of weakness (% right sided weakness)
Abdullahi 2018	300 reps: 59.42 600 reps: 57.60	Unable to establish from the information given	300 reps: 22days 600 reps: 14days	Unable to establish from the information given
Ada 2013	2 month group: 64 4 month group: 70	2 month group: 28% 4 month group: 24%	2 month group: 20 months 4 month group: 22 months	2 month group: 14% 4 month group: 18%
Burgar 2011	Robot Low: 62.5 Robot High: 58.6	No information	Robot Low: 17.3 days Robot High: 16.6 days	Robot Low: 53% Robot High: 47%
Cooke 2010	CPT: 66.37 CPT+CPT: 67.46	CPT: 55% CPT+CPT: 63%	CPT: 36.76 days CPT + CPT: 32.43 days	CPT: 45% CPT + CPT: 37%
Donaldson 2009	CPT: 72.6 CPT+CPT: 73.3	CPT: 50% CPT+CPT: 50%	CPT: 13.4 days CPT+CPT: 25.6 days	CPT: 50% CPT+CPT: 40%
Dromerick 2009	Low CIMT: 62.8 High CIMT: 64.5	Low CIMT: 32% High CIMT: 56%	Low CIMT: 8.8 days High CIMT: 9.94 days	Low CIMT: 47.4% High CIMT: 56.3%
English 2015	5 day: 68.2 7 day: 71.9	5 day: 55% 7 day: 61%	5 day: 28.7 days 7 day: 25.0 days	5 day: 40.4% 7 day: 42.7%
GAPS 2004	Standard Physio: 67 Augmented Physio: 68	Standard Physio: 49% Augmented Physio: 69%	Standard Physio: 25 days Augmented Physio: 22 days	Standard Physio: 57% Augmented Physio: 54%
Han 2013	Group A (1 hour): 52.4 Group B (2 hours): 53.7 Group C (3 hours): 44.6	Group A: 70% Group B: 80% Group C: 80%	Group A: 41.4 days Group B: 42.9 days Group C: 38.3 days	Group A: 10% Group B: 10% Group C: 20%
Hsieh 2012	Low RT: 52.2 High RT: 56.5	Low RT: 72% High RT: 61%	Low RT: 23.3 months High RT: 28.7 months	Low RT: 50% High RT: 50%
Hsu 2010	Low-NMES: 62 High-NMES: 60.2	Low-NMES: 15% male High-NMES: 15% male	Low-NMES: 21 days High-NMES: 23.3 days	Low-NMES: 54.5% High-NMES: 40.9%
Hunter 2011	30 mins: 73.3 60 mins: 72.9 120 mins: 72.5	30 mins: 61% 60 mins: 42% 120 mins: 45%	All participants were within 8 – 84 days post-event	30 mins: 22% 60 mins: 21% 120 mins: 35%

Kowalczewski 2007	Low Intensity FES-ET: 61.7 High Intensity FES-ET: 59.4	Low Intensity FES-ET: 67% High Intensity FES-ET: 40%	Low Intensity FES-ET: 1.6 months High Intensity FES-ET: 1.6 months	Low Intensity FES-ET: 22% High Intensity FES-ET: 40%
Lang 2016	3.2k reps Group: 59.9 6.4k reps Group: 62.1 9.6k reps Group: 60.0 Individualized Maximum Group: 60.9	3.2k reps Group: 67% 6.4k reps Group: 77% 9.6k reps Group: 52% Individualized Max Group: 62%	3.2k reps Group: 12.0 months 6.4k reps Group: 13.0 months 9.6k reps Group: 13.0 months Individualized Max Group: 11.5 months	3.2k reps Group: 52% 6.4k reps Group: 45% 9.6k reps Group: 48% Individualized Max Group: 62%
Lincoln 1999	Routine Physio: 73 Qualified Physio: 73	Routine Physio: 47% Qualified Physio: 54%	All participants were between one and five weeks post-stroke on entry to the study	Routine Physio: 40% Qualified Physio: 50%
Page 2012	57.6	47%	53.8 months	59%
Partridge 2000	76.3	46%	Unable to establish, but setting was acute inpatient	46%
Smith 1981	Group 1: 63 Group 2: 66	Group 1: 67% Group 2: 73%	Group 1: 35 days Group 2: 41 days	Unable to establish from information given
Tong 2019	ERM: 62.1 EIM: 60.9	ERM: 71.3% EIM: 76.7%	RM: 41.0 hrs EIM: 38.0 hrs	Unable to establish from information given
Wang 2004	Experimental: 65.13 Control: 65.72	Experimental: 55% Control: 53%	Unable to establish, but setting was acute inpatient	Unable to establish from information given
Winstein 2019	15 hours: 57.0 30 hours: 61.3 60 hours: 60.64	15 hours: 90% 30 hours: 70% 60 hours: 73%	15 hours: 2.93 years 30 hours: 2.45 years 60 hours: 1.96 years	15 hours: 60% 30 hours: 70% 60 hours: 27%

Information provided either by included study group, or overall study, dependent on what was reported in the paper.

Reps = Repetitions, CPT = Conventional Physiotherapy, CIMT = Constraint Induced Movement Therapy, RT = Robot assisted therapy, NMES = Neuromuscular electrical stimulation, FES- ET = Functional electric stimulation assisted exercise therapy, ERM = Early routine mobilisation, EIM = Early intensive mobilisation,

Appendix AA Assessment of non-reporting bias in studies

Study ID	Greater amount n=	Lesser amount n=	Synthesis assessed for risk of non-reporting bias											
			ADL Outcomes		Activity Measures – UL		Activity Measures – LL		Motor Impairment - UL		Motor Impairment - LL		SAE/Death	
			Imm	FU	Imm	FU	Imm	FU	Imm	FU	Imm	FU	Imm	FU
Ada 2013	34	34	+	+	-	-	+	+	-	-	-	-	-	-
GAPS 2004	35	35	+	+	?	?	+	+	-	-	-	-	-	+
English 2015	96	94	+	-	-	-	+	-	-	-	-	-	+	-
Lang 2016a	21 (3.2)	22 (6.4) 21 (9.6) 21 (IM)	+	+	+	+	-	-	-	-	-	-	-	-
Abdullahi 2018	11	12	+	+	+	+	-	-	+	+	-	-	-	-
Dromerick 2009	16	19	+	+	+	+	-	-	-	-	-	-	-	-
Hunter 2011a	19 (60) 20 (120)	12 (30)	-	-	+	-	-	-	+	-	-	-	-	-
Hsu 2010	22	22	-	+	+	+	-	-	+	+	-	-	-	-
Partridge 2000	54	60	?	?	?	?	+	+	?	?	?	?	-	-
Lincoln 1999	94	95	+	+	-	-	-	-	?	?	-	-	+	+
Page 2012a	8 (60) 8 (120)	9 (30)	+	?	+	?	-	-	+	?	-	-	-	-
Han 2013a	10 (120) 10 (180)	10 (60)	+	?	+	?	-	-	+	?	-	-	-	-
Wang 2004	36	38	+	?	?	?	?	?	-	?	-	?	-	-
Donaldson 2009	10	10	-	-	+	+	-	-	+	+	-	-	-	-
Cooke 2010a	35	38	?	?	-	-	+	+	-	-	+	+	-	-
Burgar 2011	17	19	+	+	+	+	-	-	+	+	-	-	-	-
Kowalczewski 2007	10	9	+	+	+	+	-	-	+	+	-	-	-	-
Smith 1981	46	43	-	-	?	?	-	-	-	-	-	-	-	+
Hsieh 2012	18	18	+	?	+	?	-	-	+	?	-	-	-	-
Winstein 2019a	11 (60hrs) 10 (30hrs)	10 (15hrs)	+	0	+	0	-	-	0	0	-	-	-	-
Tong 2019	86	80	?	+	?	0	?	0	?	0	?	0	-	-

Key:

+ = A study result is available for inclusion in the synthesis

0 = No study result is available for inclusion, (probably) because the p value, magnitude or direction of the results generated were considered unfavourable to the study investigators

- = No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the p value, magnitude or direction of the results

? = No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

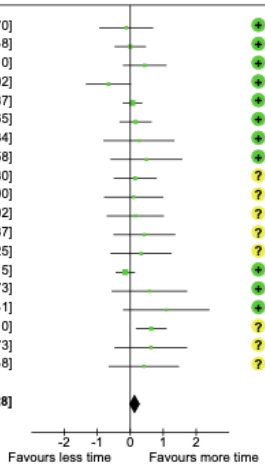
Appendix BB Forest plots for comparison 1

Analysis 1.1

Comparison 1: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Immediate outcomes, Outcome 1: ADL Outcomes

Study or Subgroup	More time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Abdullahi 2018	3.47	0.64	11	3.57	0.9	12	3.1%	-0.12 [-0.94 , 0.70]
Ada 2013	22	10	34	22	9	33	8.4%	0.00 [-0.48 , 0.48]
Burgar 2011	21.5	8.66	17	17.7	8.28	19	4.7%	0.44 [-0.22 , 1.10]
Dromerick 2009	26.93	4.84	16	30.21	4.84	19	4.4%	-0.66 [-1.35 , 0.02]
English 2015	96.2	20.3	88	94.8	20.4	85	18.5%	0.07 [-0.23 , 0.37]
GAPS 2004	16.6	2.8	32	16.1	3.3	33	8.2%	0.16 [-0.33 , 0.65]
Han 2013a	88	10.33	10	85	11.79	5	1.8%	0.26 [-0.82 , 1.34]
Han 2013b	89.5	6.85	10	85	11.79	5	1.8%	0.49 [-0.60 , 1.58]
Hsieh 2012	1.08	0.72	18	0.95	0.96	18	4.8%	0.15 [-0.50 , 0.80]
Kowalczewski 2007	0.04	0.054	10	0.035	0.036	9	2.6%	0.10 [-0.80 , 1.00]
Lang 2016a	61.5	22.24	19	58	21.8	7	2.8%	0.15 [-0.71 , 1.02]
Lang 2016b	67.8	22.25	17	58	21.8	6	2.4%	0.43 [-0.51 , 1.37]
Lang 2016c	65.4	22.05	18	58	21.8	6	2.4%	0.32 [-0.60 , 1.25]
Lincoln 1999	12	5.93	87	13	7.41	90	18.8%	-0.15 [-0.44 , 0.15]
Page 2012a	1.62	0.71	8	1.25	0.29	5	1.6%	0.58 [-0.57 , 1.73]
Page 2012b	2.19	0.93	8	1.25	0.29	4	1.2%	1.09 [-0.22 , 2.41]
Wang 2004	88.24	17.95	38	74.42	24.7	36	8.8%	0.64 [0.17 , 1.10]
Winstein 2019a	3.66	0.71	10	3.11	1.05	5	1.7%	0.62 [-0.48 , 1.73]
Winstein 2019b	3.5	0.82	11	3.11	1.05	5	1.9%	0.41 [-0.66 , 1.48]
Total (95% CI)			**462**			**402**	**100.0%**	**0.13 [-0.02 , 0.28]**

Heterogeneity: Tau² = 0.01; Chi² = 19.38, df = 18 (P = 0.37); I² = 7%
Test for overall effect: Z = 1.71 (P = 0.09)
Test for subgroup differences: Not applicable



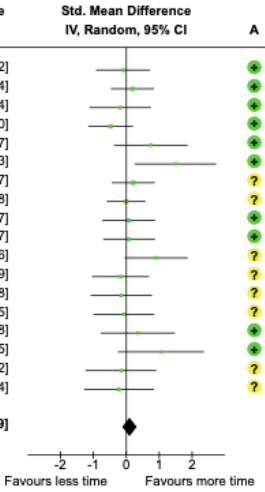
Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.2

Comparison 1: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Immediate outcomes, Outcome 2: Activity measures of the Upper Limb

Study or Subgroup	More time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Abdullahi 2018	3.71	0.54	11	3.79	0.92	12	6.0%	-0.10 [-0.92 , 0.72]
Burgar 2011	0.9	1.24	17	0.7	0.87	19	9.4%	0.18 [-0.47 , 0.84]
Donaldson 2009	41.8	17.83	10	45	13.93	8	4.6%	-0.19 [-1.12 , 0.74]
Dromerick 2009	33.93	16.64	16	42.1	16.66	19	8.8%	-0.48 [-1.16 , 0.20]
Han 2013a	8.7	4.62	10	5.3	3.4	5	3.2%	0.75 [-0.37 , 1.87]
Han 2013b	10.9	3.6	10	5.3	3.4	5	2.6%	1.49 [0.25 , 2.73]
Hsieh 2012	51.14	23.07	18	46.14	23.24	18	9.4%	0.21 [-0.44 , 0.87]
Hsu 2010	8.5	13.2	22	8.6	11.3	22	11.5%	-0.01 [-0.60 , 0.58]
Hunter 2011a	13.72	16.03	18	12.44	19.25	9	6.3%	0.07 [-0.73 , 0.87]
Hunter 2011b	14.1	19.09	20	12.44	19.25	9	6.5%	0.08 [-0.70 , 0.87]
Kowalczewski 2007	1.87	0.44	10	1.39	0.57	9	4.4%	0.91 [-0.05 , 1.86]
Lang 2016a	35.3	14.9	19	37.8	8.8	7	5.3%	-0.18 [-1.05 , 0.69]
Lang 2016b	35.7	14.3	17	37.8	8.8	6	4.6%	-0.15 [-1.09 , 0.78]
Lang 2016c	36.9	12.6	18	37.8	8.8	6	4.7%	-0.07 [-1.00 , 0.85]
Page 2012a	13	14.9	8	8.3	6.5	5	3.2%	0.35 [-0.78 , 1.48]
Page 2012b	22.3	14.1	8	8.3	6.5	4	2.4%	1.05 [-0.26 , 2.35]
Winstein 2019a	7.87	14.55	10	10.12	9.64	5	3.5%	-0.16 [-1.24 , 0.92]
Winstein 2019b	7.47	11.9	11	10.12	9.64	5	3.6%	-0.22 [-1.28 , 0.84]
Total (95% CI)			**253**			**173**	**100.0%**	**0.09 [-0.11 , 0.29]**

Heterogeneity: Tau² = 0.00; Chi² = 16.18, df = 17 (P = 0.51); I² = 0%
Test for overall effect: Z = 0.92 (P = 0.36)
Test for subgroup differences: Not applicable



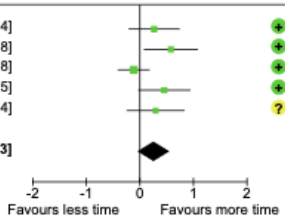
Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.3

Comparison 1: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Immediate outcomes, Outcome 3: Activity measures of the Lower Limb

Study or Subgroup	More time Mean	More time SD	More time Total	Less time Mean	Less time SD	Less time Total	Weight	Std. Mean Difference IV, Random, 95% CI
Ada 2013	289	131	34	253	137	34	18.9%	0.27 [-0.21 , 0.74]
Cooke 2010a	0.55	0.49	32	0.3	0.35	31	17.8%	0.58 [0.07 , 1.08]
English 2015	134.8	106.6	88	150.1	154.1	85	28.6%	-0.12 [-0.41 , 0.18]
GAPS 2004	9.7	3.3	32	8.1	3.6	34	18.4%	0.46 [-0.03 , 0.95]
Partridge 2000	49.2	32	33	39.9	29.9	22	16.3%	0.29 [-0.25 , 0.84]
Total (95% CI)			**219**			**206**	**100.0%**	**0.25 [-0.03 , 0.53]**

Heterogeneity: Tau² = 0.05; Chi² = 7.68, df = 4 (P = 0.10); I² = 48%
Test for overall effect: Z = 1.77 (P = 0.08)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.4

Comparison 1: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Immediate outcomes, Outcome 4: Motor impairment measures of the Upper Limb

Study or Subgroup	More time Mean	More time SD	More time Total	Less time Mean	Less time SD	Less time Total	Weight	Std. Mean Difference IV, Random, 95% CI
Abdullahi 2018	49.27	6.23	11	52.5	8.54	12	8.7%	-0.41 [-1.24 , 0.42]
Burgar 2011	14.4	14.83	17	6.8	8.28	19	12.5%	0.63 [-0.04 , 1.30]
Donaldson 2009	52.6	45.218	10	30	25.9	8	6.7%	0.57 [-0.39 , 1.52]
Han 2013a	19.7	7.09	10	13	6.38	5	4.8%	0.92 [-0.22 , 2.06]
Han 2013b	24.5	7.96	10	13	6.38	5	4.2%	1.44 [0.21 , 2.67]
Hsieh 2012	48	8.22	18	46.33	10.27	18	13.1%	0.18 [-0.48 , 0.83]
Hsu 2010	25.5	20	22	28.1	18	22	15.5%	-0.13 [-0.73 , 0.46]
Hunter 2011a	38.89	25.42	18	32.06	31.27	9	9.2%	0.24 [-0.56 , 1.04]
Hunter 2011b	35.75	30	20	32.06	31.27	9	9.5%	0.12 [-0.67 , 0.91]
Kowalczewski 2007	14.2	8.22	10	9.6	8.85	9	7.2%	0.52 [-0.40 , 1.43]
Page 2012a	26.6	10.4	8	21	3.3	5	4.7%	0.61 [-0.54 , 1.76]
Page 2012b	27.1	7.5	8	21	3.3	4	3.9%	0.86 [-0.41 , 2.13]
Total (95% CI)			**162**			**125**	**100.0%**	**0.32 [0.06 , 0.58]**

Heterogeneity: Tau² = 0.02; Chi² = 12.17, df = 11 (P = 0.35); I² = 10%
Test for overall effect: Z = 2.44 (P = 0.01)
Test for subgroup differences: Not applicable

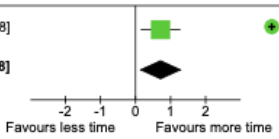
Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.5

Comparison 1: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Immediate outcomes, Outcome 5: Motor impairment measures of the lower limb

Study or Subgroup	More Time Mean	SD	Total	Less Time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F
Cooke 2010a (1)	34	23.1	26	19	17.8	25	100.0%	0.71 [0.15 , 1.28]	+ + - + ? -
Total (95% CI)			**26**			**25**	**100.0%**	**0.71 [0.15 , 1.28]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 2.47 (P = 0.01)
Test for subgroup differences: Not applicable



Footnotes
(1) Cooke 2010 - knee flexion peak torque

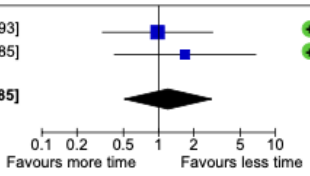
Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.6

Comparison 1: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Immediate outcomes, Outcome 6: Serious Adverse Events/Death

Study or Subgroup	More time Events	Total	Less time Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F
English 2015	6	96	6	94	62.1%	0.98 [0.33 , 2.93]	+ + + + + +
Lincoln 1999	5	94	3	95	37.9%	1.68 [0.41 , 6.85]	+ ? + + ? ?
Total (95% CI)		**190**		**189**	**100.0%**	**1.20 [0.51 , 2.85]**	
Total events:	11		9				

Heterogeneity: Tau² = 0.00; Chi² = 0.36, df = 1 (P = 0.55); I² = 0%
Test for overall effect: Z = 0.42 (P = 0.68)
Test for subgroup differences: Not applicable



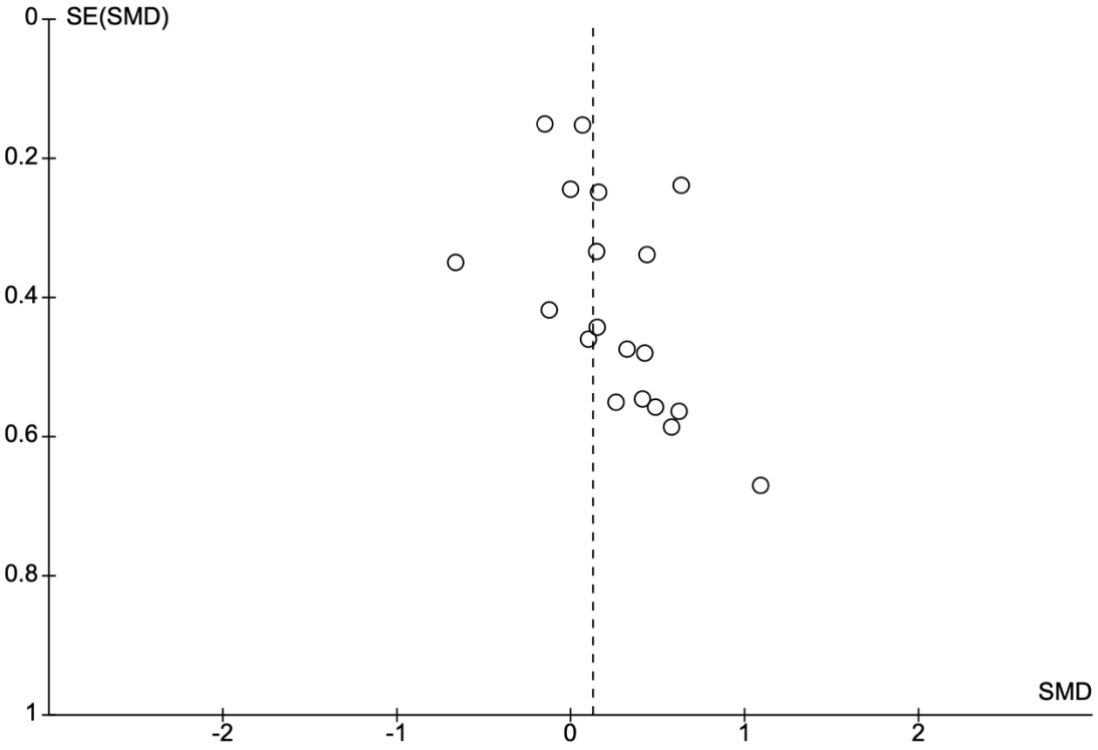
Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Appendix CC Sensitivity analyses to assess the effect of excluding studies at high risk of bias

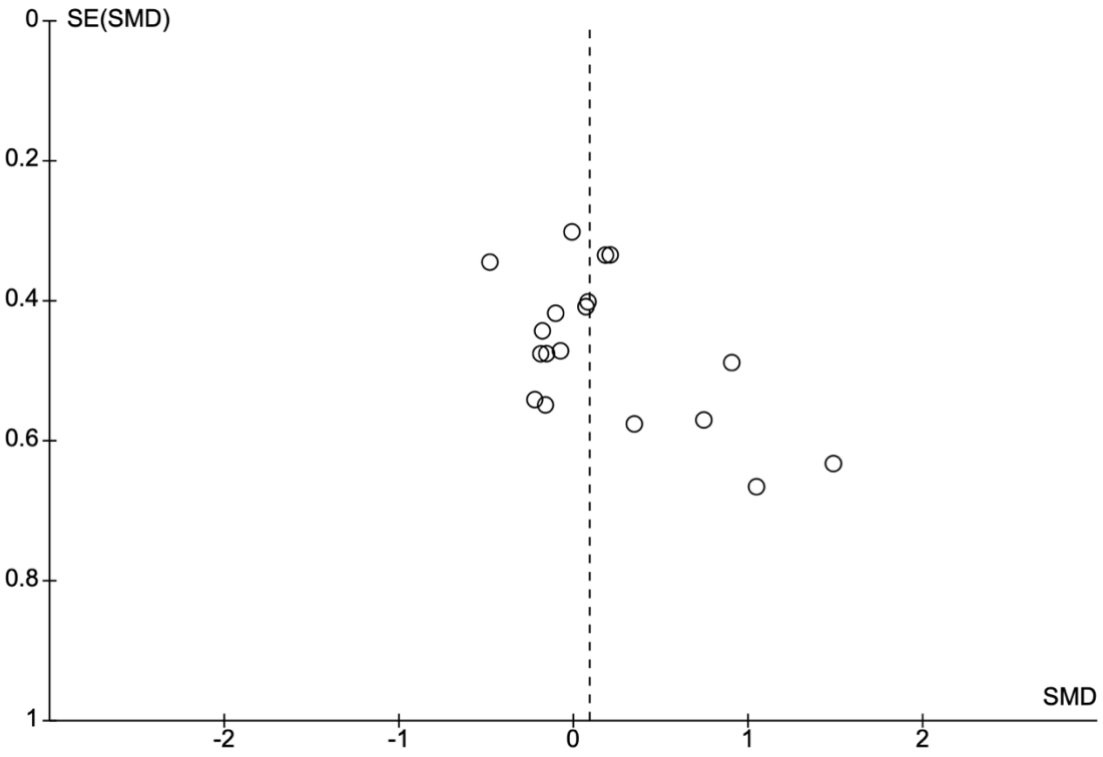
	High overall risk excluded	**High risk due to effect of adherence excluded**	**Both high overall risk and high risk due to effect of adherence excluded**
1.1 ADL Outcomes	SMD 0.15, 95% CI -0.04 to 0.33; 9 studies, 469 participants; p = 0.12; I^2 = 0%	SMD 0.32, 95% CI 0.11 to 0.52; 8 studies, 401 participants; p = 0.002; I^2 = 0%	SMD 0.26, 95% CI -0.04 to 0.55; 5 studies, 189 participants; p = 0.09; I^2 = 0%
1.2 Activity measures of the upper limb	SMD 0.18, 95% CI -0.05 to 0.41; 9 studies, 324 participants; p = 0.13; I^2 = 0%	SMD 0.20, 95% CI -0.11 to 0.52; 5 studies, 195 participants; p = 0.21; I^2 = 4%	SMD 0.30, 95% CI -0.07 to 0.67; 4 studies, 164 participants; p = 0.12; I^2 = 14%
1.3 Activity measures of the lower limb	SMD 0.26, 95% CI -0.09 to 0.60; 4 studies, 370 participants; p = 0.14; I^2 = 60%	SMD 0.36, 95% CI 0.02 to 0.70; 2 studies, 134 participants; p = 0.04; I^2 = 0%	SMD 0.36, 95% CI 0.02 to 0.70; 2 studies, 134 participants; p = 0.04; I^2 = 0%
1.4 Motor impairment measures of the upper limb	SMD 0.28, 95% CI 0.00 to 0.56; 8 studies, 251 participants; p = 0.05; I^2 = 10%	SMD 0.60, 95% CI 0.15 to 1.05; 3 studies, 91 participants; p = 0.008; I^2 = 0%	SMD 0.60, 95% CI 0.15 to 1.05; 3 studies, 91 participants; p = 0.008; I^2 = 0%
1.5 Motor impairment measures of the lower limb	N/A	N/A	N/A
1.6 Serious Adverse Events/Death	RR 1.20, 95% CI 0.51 to 2.85; two studies, 379 participants; p = 0.68; I^2 = 0%	N/A	N/A

SMD = Standardised mean difference, CI = Confidence interval, N/A = Not applicable, RR = Risk ratio

Appendix DD Funnel plot for analysis 1.1



Appendix EE Funnel plot for analysis 1.2



Appendix FF Minimal clinically important difference for analysis 1.4

Study	Subacute/ Chronic	Measure	MCID for measure	More therapy group change from baseline	MCID reached?	Less therapy group change from baseline	MCID reached?
Abudullahi 2008	Subacute	Fugl-Meyer (UE)	9	18.82	Yes	17.33	Yes
Burgar 2011	Subacute	Fugl-Meyer (UE)	9	14.4	Yes	6.8	No
Donaldson 2009	Subacute	Upper Limb Strength (Myometer)	5kg	19.3kg	Yes	34.75kg	Yes
Han 2013 (1 hour vs. 2 hours)	Subacute	Fugl-Meyer (UE)	9	11.5	Yes	6.3	No
Han 2013 (1 hour vs. 3 hours)	Subacute	Fugl-Meyer (UE)	9	18	Yes	6.3	No
Hsieh 2012	Chronic	Fugl-Meyer (UE)	4.25	5.22	Yes	3.22	No
Kowalczewski 2007	Subacute	Fugl-Meyer (UE)	9	6.4	No	3.6	No
Page 2012 (30mins vs. 60mins)	Chronic	Fugl-Meyer (UE)	4.25	1.3	No	1.9	No
Page 2012 (30mins vs. 120 mins)	Chronic	Fugl-Meyer (UE)	4.25	4.2	No	1.9	No
Hsu 2010	Subacute	Fugl-Meyer (UE)	9	18	Yes	19.8	Yes

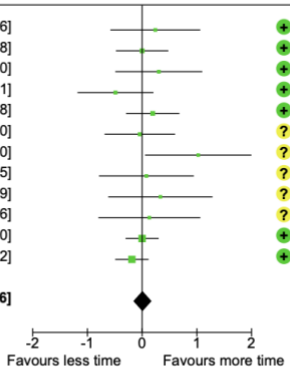
MCID = Minimal clinically important difference, Fugl-Meyer (UE) = Fugl-Meyer upper extremity

Appendix GG Forest plots for comparison 2

Analysis 2.1

Comparison 2: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Medium-term outcomes, Outcome 1: ADL Outcomes - Medium-term outcomes

Study or Subgroup	More time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F
Abdullahi 2018	4.65	0.43	11	4.55	0.37	12	3.5%	0.24 [-0.58 , 1.06]	+ + + + + +
Ada 2013	21	10	34	21	10	33	10.3%	0.00 [-0.48 , 0.48]	+ + + + + +
Burgar 2011	27.5	9.96	11	24.2	10.85	14	3.7%	0.30 [-0.49 , 1.10]	+ - - + ? -
Dromerick 2009	29.12	4.64	16	31.41	4.53	17	4.9%	-0.49 [-1.18 , 0.21]	+ + + + - -
GAPS 2004	16.9	2.7	31	16.2	4.2	34	9.9%	0.19 [-0.29 , 0.68]	+ + + + ? ?
Hsu 2010	0.56	0.87	19	0.6	1	18	5.7%	-0.04 [-0.69 , 0.60]	? + + + ? ?
Kowalczewski 2007	0.073	0.085	10	0.006	0.012	9	2.5%	1.03 [0.05 , 2.00]	? + + + ? ?
Lang 2016a	69	24	19	67	27	7	3.1%	0.08 [-0.79 , 0.95]	? + + - ? -
Lang 2016b	74	17	15	67	27	6	2.6%	0.33 [-0.62 , 1.29]	? + + - ? -
Lang 2016c	70	20	17	67	27	6	2.7%	0.13 [-0.80 , 1.06]	? + + - ? -
Lincoln 1999	14	7.41	84	14	6.67	84	25.8%	0.00 [-0.30 , 0.30]	+ - ? + ? -
Tong 2019	2.41	1.12	86	2.63	1.22	80	25.3%	-0.19 [-0.49 , 0.12]	+ + + + - -
Total (95% CI)			**353**			**320**	**100.0%**	**0.01 [-0.15 , 0.16]**	



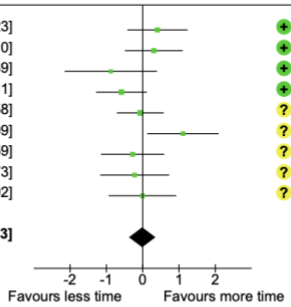
Heterogeneity: Tau² = 0.00; Chi² = 9.71, df = 11 (P = 0.56); I² = 0%
Test for overall effect: Z = 0.07 (P = 0.94)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 2.2

Comparison 2: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Medium-term outcomes, Outcome 2: Activity measures of the Upper Limb - Medium-term outcomes

Study or Subgroup	More time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F
Abdullahi 2018	4.97	0.07	11	4.9	0.22	12	11.7%	0.41 [-0.42 , 1.23]	+ + + + + +
Burgar 2011	1.8	2.32	11	1.2	1.5	14	12.3%	0.31 [-0.49 , 1.10]	+ - - + ? -
Donaldson 2009	41.83	15.02	6	53.4	6.71	5	6.0%	-0.88 [-2.15 , 0.39]	+ + ? + ? ?
Dromerick 2009	38	15.04	16	46.86	14.46	17	14.5%	-0.59 [-1.29 , 0.11]	+ + + + - -
Hsu 2010	15.9	18.4	19	17.2	19.1	18	16.0%	-0.07 [-0.71 , 0.58]	? + + + ? ?
Kowalczewski 2007	1.96	0.54	10	1.35	0.51	9	9.1%	1.11 [0.12 , 2.09]	? + + + ? ?
Lang 2016a	33.3	14.7	19	37.2	9.2	7	10.9%	-0.28 [-1.15 , 0.59]	? + + + ? ?
Lang 2016b	34	15.2	15	37.2	9.2	6	9.6%	-0.22 [-1.17 , 0.73]	? + + + ? ?
Lang 2016c	37.1	13.2	17	37.2	9.2	6	9.9%	-0.01 [-0.94 , 0.92]	? + + + ? ?
Total (95% CI)			**124**			**94**	**100.0%**	**-0.02 [-0.36 , 0.33]**	

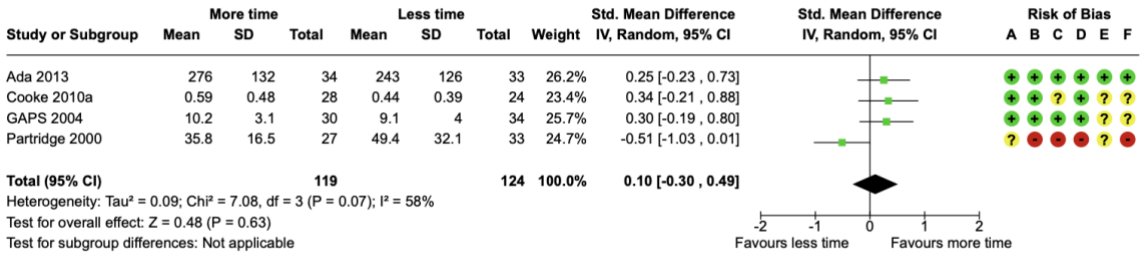


Heterogeneity: Tau² = 0.08; Chi² = 11.51, df = 8 (P = 0.17); I² = 30%
Test for overall effect: Z = 0.09 (P = 0.93)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 2.3

Comparison 2: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Medium-term outcomes, Outcome 3: Activity measures of the Lower Limb - Medium-term outcomes



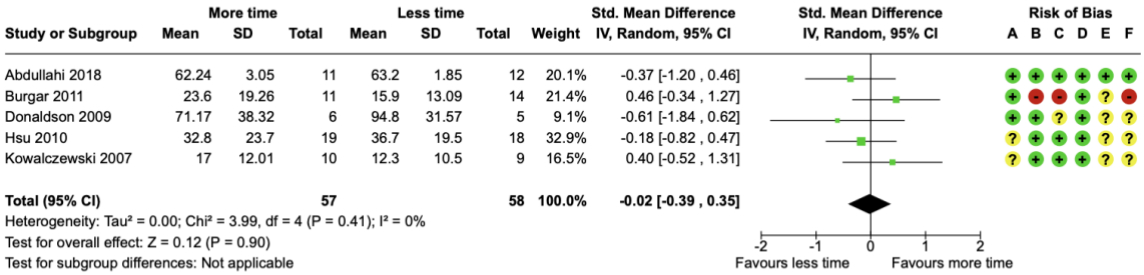
Study or Subgroup	More time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Ada 2013	276	132	34	243	126	33	26.2%	0.25 [-0.23 , 0.73]
Cooke 2010a	0.59	0.48	28	0.44	0.39	24	23.4%	0.34 [-0.21 , 0.88]
GAPS 2004	10.2	3.1	30	9.1	4	34	25.7%	0.30 [-0.19 , 0.80]
Partridge 2000	35.8	16.5	27	49.4	32.1	33	24.7%	-0.51 [-1.03 , 0.01]
Total (95% CI)			**119**			**124**	**100.0%**	**0.10 [-0.30 , 0.49]**

Heterogeneity: Tau² = 0.09; Chi² = 7.08, df = 3 (P = 0.07); I² = 58%
Test for overall effect: Z = 0.48 (P = 0.63)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 2.4

Comparison 2: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Medium-term outcomes, Outcome 4: Motor impairment measures of the Upper Limb - Medium-term outcomes



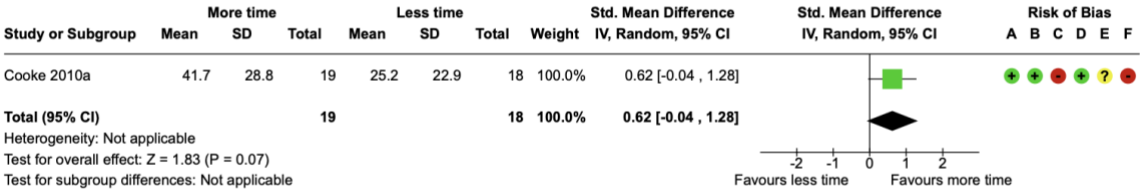
Study or Subgroup	More time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Abdullahi 2018	62.24	3.05	11	63.2	1.85	12	20.1%	-0.37 [-1.20 , 0.46]
Burgar 2011	23.6	19.26	11	15.9	13.09	14	21.4%	0.46 [-0.34 , 1.27]
Donaldson 2009	71.17	38.32	6	94.8	31.57	5	9.1%	-0.61 [-1.84 , 0.62]
Hsu 2010	32.8	23.7	19	36.7	19.5	18	32.9%	-0.18 [-0.82 , 0.47]
Kowalczewski 2007	17	12.01	10	12.3	10.5	9	16.5%	0.40 [-0.52 , 1.31]
Total (95% CI)			**57**			**58**	**100.0%**	**-0.02 [-0.39 , 0.35]**

Heterogeneity: Tau² = 0.00; Chi² = 3.99, df = 4 (P = 0.41); I² = 0%
Test for overall effect: Z = 0.12 (P = 0.90)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 2.5

Comparison 2: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Medium-term outcomes, Outcome 5: Motor impairment measures of the Lower Limb - Medium-term outcomes



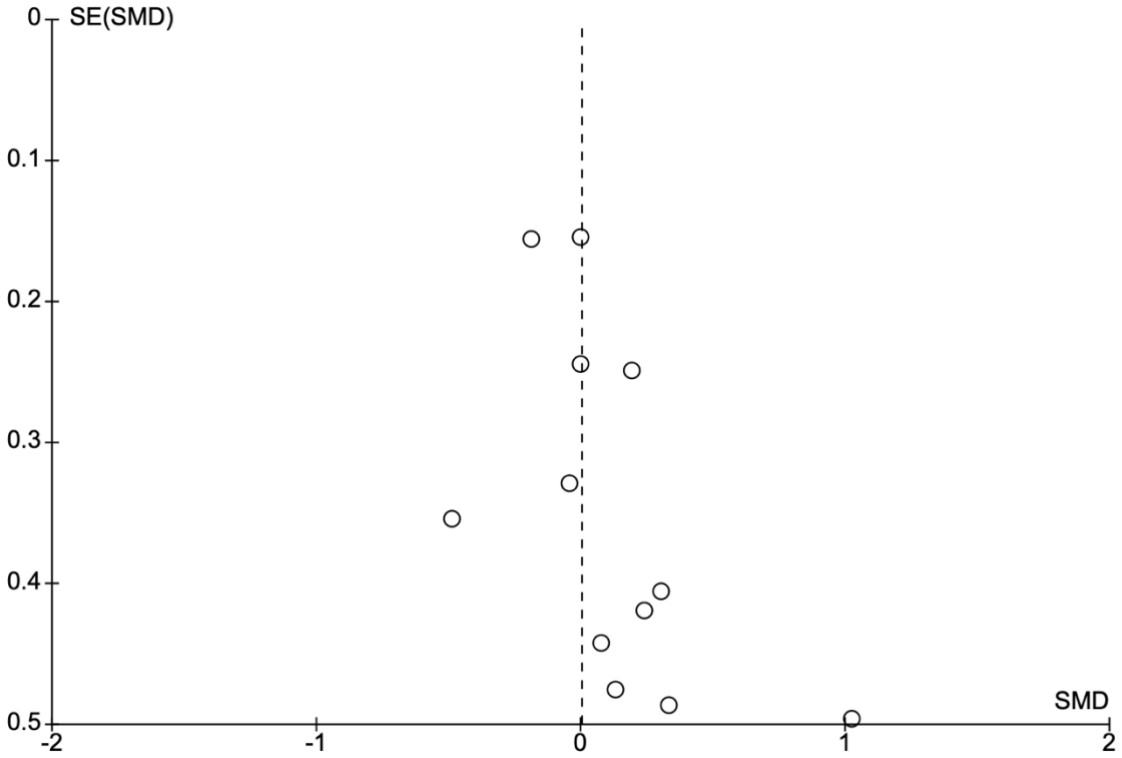
Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 2.6

Comparison 2: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Medium-term outcomes, Outcome 6: Serious Adverse Events/Death - Medium-term outcomes

Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

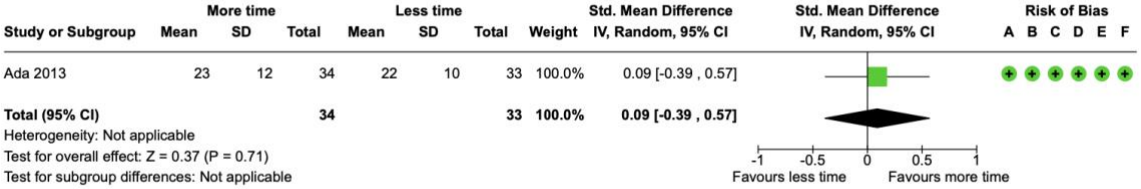
Appendix HH Funnel plot for analysis 2.1



Appendix II Forest plots for comparison 3

Analysis 3.1

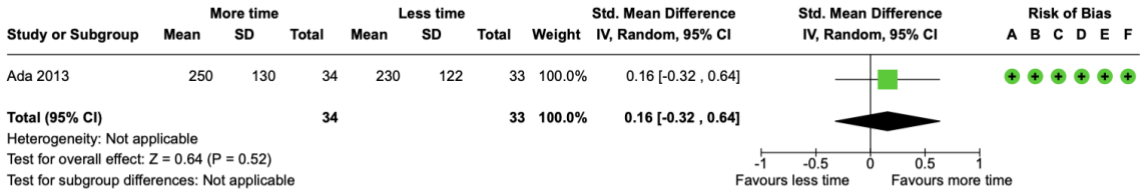
Comparison 3: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Long-term outcomes, Outcome 1: ADL Outcomes - Long-term outcomes



Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 3.2

Comparison 3: Objective One - More time spent in rehabilitation vs Less time spent in rehabilitation - Long-term outcomes, Outcome 2: Activity measures of the Lower Limb - Long-term outcomes



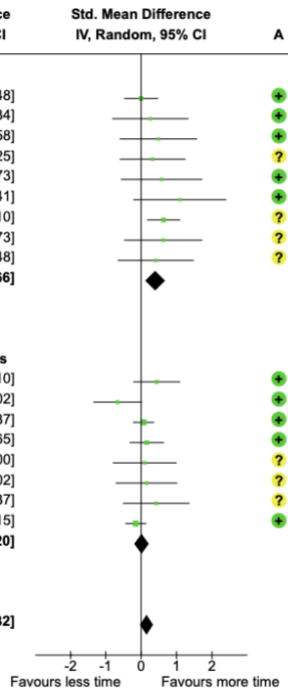
Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Appendix JJ Forest plots for objective 2

Analysis 4.1

Comparison 4: Objective Two - Effect of total time spent in rehabilitation, Outcome 1: ADL Outcomes - Immediately after intervention

Study or Subgroup	More time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
4.1.1 Median Split — Studies with a larger difference in total amount of therapy between treatment arms								
Ada 2013	22	10	34	22	9	33	9.4%	0.00 [-0.48 , 0.48]
Han 2013a	88	10.33	10	85	11.79	5	2.3%	0.26 [-0.82 , 1.34]
Han 2013b	89.5	6.85	10	85	11.79	5	2.2%	0.49 [-0.60 , 1.58]
Lang 2016c	65.4	22.05	18	58	21.8	6	3.0%	0.32 [-0.60 , 1.25]
Page 2012a	1.62	0.71	8	1.25	0.29	5	2.0%	0.58 [-0.57 , 1.73]
Page 2012b	2.19	0.93	8	1.25	0.29	4	1.6%	1.09 [-0.22 , 2.41]
Wang 2004	88.24	17.95	38	74.42	24.7	36	9.8%	0.64 [0.17 , 1.10]
Winstein 2019a	3.66	0.71	10	3.11	1.05	5	2.2%	0.62 [-0.48 , 1.73]
Winstein 2019b	3.5	0.82	11	3.11	1.05	5	2.3%	0.41 [-0.66 , 1.48]
Subtotal (95% CI)			**147**			**104**	**34.8%**	**0.40 [0.14 , 0.66]**
Heterogeneity: Tau² = 0.00; Chi² = 5.09, df = 8 (P = 0.75); I² = 0%								
Test for overall effect: Z = 2.99 (P = 0.003)								
4.1.2 Median Split — Studies with a smaller difference in total amount of therapy between treatment arms								
Burgar 2011	21.5	8.66	17	17.7	8.28	19	5.5%	0.44 [-0.22 , 1.10]
Dromerick 2009	26.93	4.84	16	30.21	4.84	19	5.2%	-0.66 [-1.35 , 0.02]
English 2015	96.2	20.3	88	94.8	20.4	85	17.7%	0.07 [-0.23 , 0.37]
GAPS 2004	16.6	2.8	32	16.1	3.3	33	9.2%	0.16 [-0.33 , 0.65]
Kowalczewski 2007	0.04	0.054	10	0.035	0.038	9	3.2%	0.10 [-0.80 , 1.00]
Lang 2016a	61.5	22.24	19	58	21.8	7	3.4%	0.15 [-0.71 , 1.02]
Lang 2016b	67.8	22.25	17	58	21.8	6	3.0%	0.43 [-0.51 , 1.37]
Lincoln 1999	12	5.93	87	13	7.41	90	17.9%	-0.15 [-0.44 , 0.15]
Subtotal (95% CI)			**286**			**268**	**65.2%**	**0.01 [-0.18 , 0.20]**
Heterogeneity: Tau² = 0.01; Chi² = 7.82, df = 7 (P = 0.35); I² = 10%								
Test for overall effect: Z = 0.11 (P = 0.91)								
Total (95% CI)			**433**			**372**	**100.0%**	**0.15 [-0.02 , 0.32]**
Heterogeneity: Tau² = 0.02; Chi² = 19.04, df = 16 (P = 0.27); I² = 16%								
Test for overall effect: Z = 1.78 (P = 0.08)								
Test for subgroup differences: Chi² = 5.53, df = 1 (P = 0.02), I² = 81.9%								

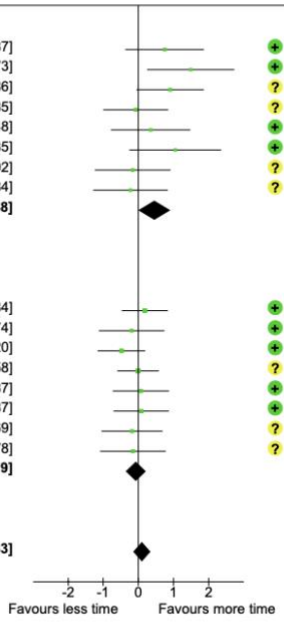


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 4.2

Comparison 4: Objective Two - Effect of total time spent in rehabilitation, Outcome 2: Activity measures of the Upper Limb - Immediately after intervention

Study or Subgroup	More time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
4.2.1 Median Split - Studies with a larger difference in total amount of therapy between treatment arms								
Han 2013a	8.7	4.62	10	5.3	3.4	5	3.9%	0.75 [-0.37 , 1.87]
Han 2013b	10.9	3.6	10	5.3	3.4	5	3.2%	1.49 [0.25 , 2.73]
Kowalczewski 2007	1.87	0.44	10	1.39	0.57	9	5.3%	0.91 [-0.05 , 1.86]
Lang 2016c	36.9	12.6	18	37.8	8.8	6	5.7%	-0.07 [-1.00 , 0.85]
Page 2012a	13	14.9	8	8.3	6.5	5	3.9%	0.35 [-0.78 , 1.48]
Page 2012b	22.3	14.1	8	8.3	6.5	4	2.9%	1.05 [-0.26 , 2.35]
Winstein 2019a	7.87	14.55	10	10.12	9.64	5	4.2%	-0.16 [-1.24 , 0.92]
Winstein 2019b	7.47	11.9	11	10.12	9.64	5	4.4%	-0.22 [-1.28 , 0.84]
Subtotal (95% CI)			**85**			**44**	**33.5%**	**0.45 [0.03 , 0.88]**
Heterogeneity: Tau² = 0.07; Chi² = 8.69, df = 7 (P = 0.28); I² = 19%								
Test for overall effect: Z = 2.08 (P = 0.04)								
4.2.2 Median Split - Studies with a smaller difference in total amount of therapy between treatment arms								
Burgar 2011	0.9	1.24	17	0.7	0.87	19	10.7%	0.18 [-0.47 , 0.84]
Donaldson 2009	41.8	17.83	10	45	13.93	8	5.6%	-0.19 [-1.12 , 0.74]
Dromerick 2009	33.93	16.64	16	42.1	16.66	19	10.2%	-0.48 [-1.16 , 0.20]
Hsu 2010	8.5	13.2	22	8.6	11.3	22	13.0%	-0.01 [-0.60 , 0.58]
Hunter 2011a	13.72	16.03	18	12.44	19.25	9	7.4%	0.07 [-0.73 , 0.87]
Hunter 2011b	14.1	19.09	20	12.44	19.25	9	7.7%	0.08 [-0.70 , 0.87]
Lang 2016a	35.3	14.9	19	37.8	8.8	7	6.4%	-0.18 [-1.05 , 0.69]
Lang 2016b	35.7	14.3	17	37.8	8.8	6	5.6%	-0.15 [-1.09 , 0.78]
Subtotal (95% CI)			**139**			**99**	**66.5%**	**-0.07 [-0.34 , 0.19]**
Heterogeneity: Tau² = 0.00; Chi² = 2.45, df = 7 (P = 0.93); I² = 0%								
Test for overall effect: Z = 0.53 (P = 0.59)								
Total (95% CI)			**224**			**143**	**100.0%**	**0.10 [-0.13 , 0.33]**
Heterogeneity: Tau² = 0.01; Chi² = 15.84, df = 15 (P = 0.39); I² = 5%								
Test for overall effect: Z = 0.87 (P = 0.38)								
Test for subgroup differences: Chi² = 4.19, df = 1 (P = 0.04), I² = 76.2%								

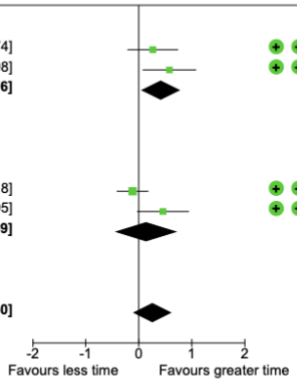


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 4.3

Comparison 4: Objective Two - Effect of total time spent in rehabilitation, Outcome 3: Activity measures of the lower limb - immediately after intervention

Study or Subgroup	Greater time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
4.3.1 Median Split - Studies with a larger difference in total amount of therapy between treatment arms								
Ada 2013	289	131	34	253	137	34	23.2%	0.27 [-0.21 , 0.74]
Cooke 2010a	0.55	0.49	32	0.3	0.35	31	22.1%	0.58 [0.07 , 1.08]
Subtotal (95% CI)			**66**			**65**	**45.3%**	**0.41 [0.07 , 0.76]**
Heterogeneity: Tau² = 0.00; Chi² = 0.78, df = 1 (P = 0.38); I² = 0%								
Test for overall effect: Z = 2.33 (P = 0.02)								
4.3.2 Median Split - Studies with a smaller difference in total amount of therapy between treatment arms								
English 2015	134.8	106.6	88	150.1	154.1	85	32.0%	-0.12 [-0.41 , 0.18]
GAPS 2004	9.7	3.3	32	8.1	3.6	34	22.7%	0.46 [-0.03 , 0.95]
Subtotal (95% CI)			**120**			**119**	**54.7%**	**0.14 [-0.42 , 0.69]**
Heterogeneity: Tau² = 0.12; Chi² = 3.83, df = 1 (P = 0.05); I² = 74%								
Test for overall effect: Z = 0.48 (P = 0.63)								
Total (95% CI)			**186**			**184**	**100.0%**	**0.26 [-0.09 , 0.60]**
Heterogeneity: Tau² = 0.07; Chi² = 7.50, df = 3 (P = 0.06); I² = 60%								
Test for overall effect: Z = 1.46 (P = 0.14)								
Test for subgroup differences: Chi² = 0.68, df = 1 (P = 0.41), I² = 0%								

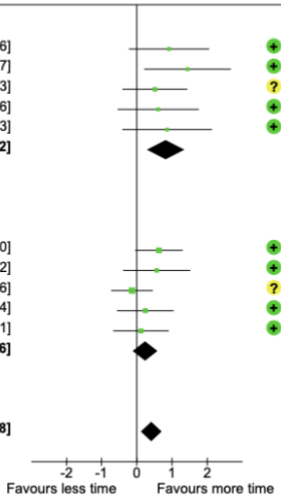


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 4.4

Comparison 4: Objective Two - Effect of total time spent in rehabilitation, Outcome 4: Motor impairment measures of the Upper Limb - Immediately after intervention

Study or Subgroup	More time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F
4.4.1 Median Split - Studies with a larger difference in total amount of therapy between treatment arms									
Han 2013a	19.7	7.09	10	13	6.38	5	5.8%	0.92 [-0.22 , 2.06]	+ + + + ? ?
Han 2013b	24.5	7.96	10	13	6.38	5	5.0%	1.44 [0.21 , 2.67]	+ + + + ? ?
Kowalczewski 2007	14.2	8.22	10	9.6	8.85	9	8.9%	0.52 [-0.40 , 1.43]	? + + + ? ?
Page 2012a	26.6	10.4	8	21	3.3	5	5.7%	0.61 [-0.54 , 1.76]	+ + + + ? ?
Page 2012b	27.1	7.5	8	21	3.3	4	4.6%	0.86 [-0.41 , 2.13]	+ + + + ? ?
Subtotal (95% CI)			**46**			**28**	**29.9%**	**0.82 [0.32 , 1.32]**	
Heterogeneity: Tau² = 0.00; Chi² = 1.56, df = 4 (P = 0.82); I² = 0%									
Test for overall effect: Z = 3.20 (P = 0.001)									
4.4.2 Median Split - Studies with a smaller difference in total amount of therapy between treatment arms									
Burgar 2011	14.4	14.83	17	6.8	8.28	19	16.6%	0.63 [-0.04 , 1.30]	+ - + + ? -
Donaldson 2009	52.6	45.218	10	30	25.9	8	8.3%	0.57 [-0.39 , 1.52]	+ + + + ? ?
Hsu 2010	25.5	20	22	28.1	18	22	21.4%	-0.13 [-0.73 , 0.46]	? + + + ? ?
Hunter 2011a	38.89	25.42	18	32.06	31.27	9	11.6%	0.24 [-0.56 , 1.04]	+ + + + ? ?
Hunter 2011b	35.75	30	20	32.06	31.27	9	12.1%	0.12 [-0.67 , 0.91]	+ + + + ? ?
Subtotal (95% CI)			**87**			**67**	**70.1%**	**0.24 [-0.09 , 0.56]**	
Heterogeneity: Tau² = 0.00; Chi² = 3.36, df = 4 (P = 0.50); I² = 0%									
Test for overall effect: Z = 1.41 (P = 0.16)									
Total (95% CI)			**133**			**95**	**100.0%**	**0.41 [0.14 , 0.68]**	
Heterogeneity: Tau² = 0.00; Chi² = 8.57, df = 9 (P = 0.48); I² = 0%									
Test for overall effect: Z = 2.93 (P = 0.003)									
Test for subgroup differences: Chi² = 3.65, df = 1 (P = 0.06), I² = 72.6%									



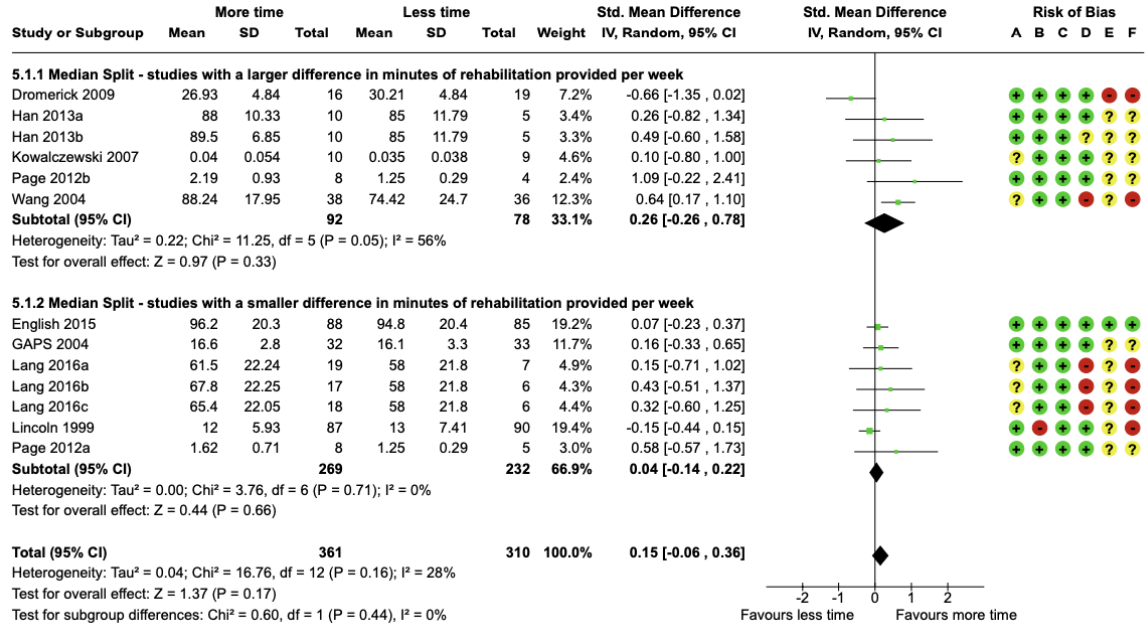
Risk of bias legend

(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Appendix KK Forest plots for objective 3

Analysis 5.1

Comparison 5: Objective Three - The effect of rehabilitation schedule , Outcome 1: ADL Outcomes - Immediately after intervention

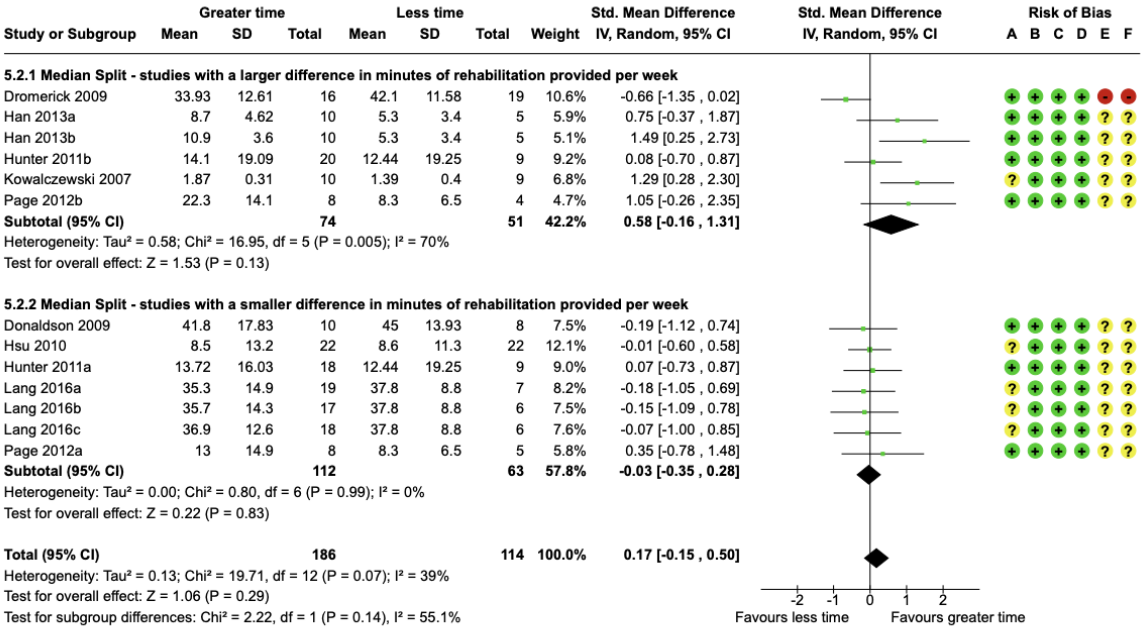


Risk of bias legend

(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 5.2

Comparison 5: Objective Three - The effect of rehabilitation schedule , Outcome 2: Activity measures of the Upper Limb - Immediately after intervention

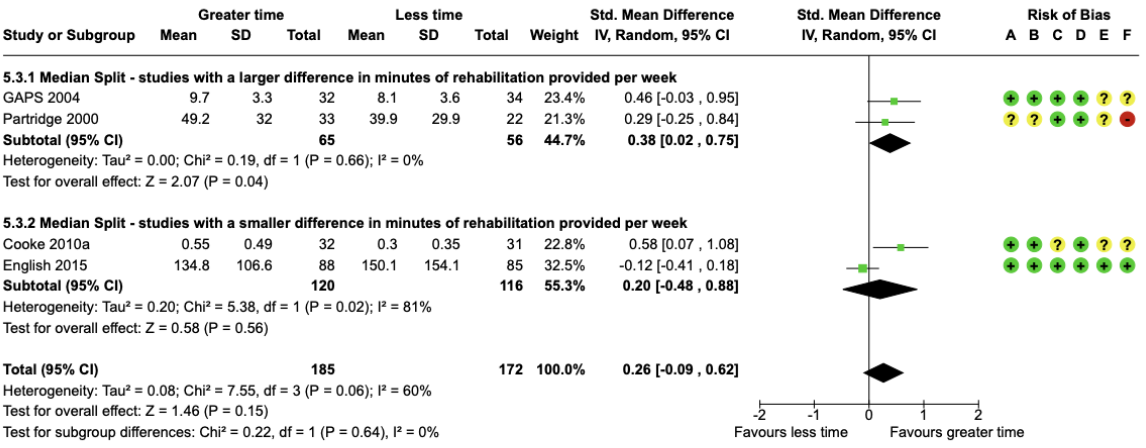


Study or Subgroup	Greater time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
5.2.1 Median Split - studies with a larger difference in minutes of rehabilitation provided per week								
Dromerick 2009	33.93	12.61	16	42.1	11.58	19	10.6%	-0.66 [-1.35 , 0.02]
Han 2013a	8.7	4.62	10	5.3	3.4	5	5.9%	0.75 [-0.37 , 1.87]
Han 2013b	10.9	3.6	10	5.3	3.4	5	5.1%	1.49 [0.25 , 2.73]
Hunter 2011b	14.1	19.09	20	12.44	19.25	9	9.2%	0.08 [-0.70 , 0.87]
Kowalczewski 2007	1.87	0.31	10	1.39	0.4	9	6.8%	1.29 [0.28 , 2.30]
Page 2012b	22.3	14.1	8	8.3	6.5	4	4.7%	1.05 [-0.26 , 2.35]
Subtotal (95% CI)			**74**			**51**	**42.2%**	**0.58 [-0.16 , 1.31]**
Heterogeneity: Tau² = 0.58; Chi² = 16.95, df = 5 (P = 0.005); I² = 70%								
Test for overall effect: Z = 1.53 (P = 0.13)								
5.2.2 Median Split - studies with a smaller difference in minutes of rehabilitation provided per week								
Donaldson 2009	41.8	17.83	10	45	13.93	8	7.5%	-0.19 [-1.12 , 0.74]
Hsu 2010	8.5	13.2	22	8.6	11.3	22	12.1%	-0.01 [-0.60 , 0.58]
Hunter 2011a	13.72	16.03	18	12.44	19.25	9	9.0%	0.07 [-0.73 , 0.87]
Lang 2016a	35.3	14.9	19	37.8	8.8	7	8.2%	-0.18 [-1.05 , 0.69]
Lang 2016b	35.7	14.3	17	37.8	8.8	6	7.5%	-0.15 [-1.09 , 0.78]
Lang 2016c	36.9	12.6	18	37.8	8.8	6	7.6%	-0.07 [-1.00 , 0.85]
Page 2012a	13	14.9	8	8.3	6.5	5	5.8%	0.35 [-0.78 , 1.48]
Subtotal (95% CI)			**112**			**63**	**57.8%**	**-0.03 [-0.35 , 0.28]**
Heterogeneity: Tau² = 0.00; Chi² = 0.80, df = 6 (P = 0.99); I² = 0%								
Test for overall effect: Z = 0.22 (P = 0.83)								
Total (95% CI)			**186**			**114**	**100.0%**	**0.17 [-0.15 , 0.50]**
Heterogeneity: Tau² = 0.13; Chi² = 19.71, df = 12 (P = 0.07); I² = 39%								
Test for overall effect: Z = 1.06 (P = 0.29)								
Test for subgroup differences: Chi² = 2.22, df = 1 (P = 0.14), I² = 55.1%								

Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 5.3

Comparison 5: Objective Three - The effect of rehabilitation schedule , Outcome 3: Activity measures of the lower limb - immediately after intervention

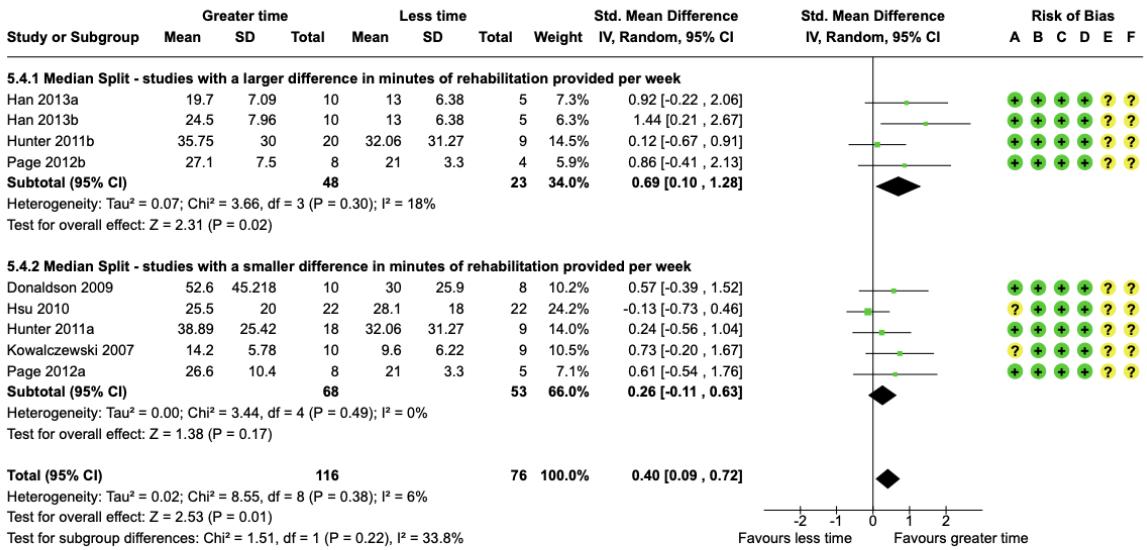


Study or Subgroup	Greater time Mean	SD	Total	Less time Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
5.3.1 Median Split - studies with a larger difference in minutes of rehabilitation provided per week								
GAPS 2004	9.7	3.3	32	8.1	3.6	34	23.4%	0.46 [-0.03 , 0.95]
Partridge 2000	49.2	32	33	39.9	29.9	22	21.3%	0.29 [-0.25 , 0.84]
Subtotal (95% CI)			**65**			**56**	**44.7%**	**0.38 [0.02 , 0.75]**
Heterogeneity: Tau² = 0.00; Chi² = 0.19, df = 1 (P = 0.66); I² = 0%								
Test for overall effect: Z = 2.07 (P = 0.04)								
5.3.2 Median Split - studies with a smaller difference in minutes of rehabilitation provided per week								
Cooke 2010a	0.55	0.49	32	0.3	0.35	31	22.8%	0.58 [0.07 , 1.08]
English 2015	134.8	106.6	88	150.1	154.1	85	32.5%	-0.12 [-0.41 , 0.18]
Subtotal (95% CI)			**120**			**116**	**55.3%**	**0.20 [-0.48 , 0.88]**
Heterogeneity: Tau² = 0.20; Chi² = 5.38, df = 1 (P = 0.02); I² = 81%								
Test for overall effect: Z = 0.58 (P = 0.56)								
Total (95% CI)			**185**			**172**	**100.0%**	**0.26 [-0.09 , 0.62]**
Heterogeneity: Tau² = 0.08; Chi² = 7.55, df = 3 (P = 0.06); I² = 60%								
Test for overall effect: Z = 1.46 (P = 0.15)								
Test for subgroup differences: Chi² = 0.22, df = 1 (P = 0.64), I² = 0%								

Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 5.4

Comparison 5: Objective Three - The effect of rehabilitation schedule , Outcome 4: Motor impairments of the upper limb - Immediately after intervention



Risk of bias legend

(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Appendix LL Summary of subgroup analyses

Subgroup Analysis	Outcome	Studies included	Significance of subgroup difference
Effect of time since stroke (studies within the first six months since stroke vs. studies after after six months since stroke)	ADL Outcomes	First six months: Abdullahi 2018; Burgar 2011; Dromerick 2009; English 2015; GAPS 2004; Han 2013a; Kowalczewski 2007; Lincoln 1999; Wang 2004 After six months: Ada 2013; Hsieh 2012; Lang 2016a; Page 2012a; Winstein 2019a	p = 0.39
	Activity measures of the Upper Limb	First six months: Abdullahi 2018; Burgar 2011; Donaldson 2009; Dromerick 2009; Han 2013a; Hsu 2010; Hunter 2011a; Kowalczewski 2007 After six months: Hsieh 2012; Lang 2016a; Page 2012a; Winstein 2019a	p = 0.71
	Activity measures of the Lower Limb	First six months: Cooke 2010a; English 2015; GAPS 2004; Partridge 2000 After six months: Ada 2013	p = 1.00
	Motor impairment measures of the Upper Limb	First six months: Abdullahi 2018; Burgar 2011; Donaldson 2009; Han 2013a; Hsu 2010; Hunter 2011a; Kowalczewski 2007 After six months: Hsieh 2012; Page 2012a	p = 0.85
Hours of intervention provided per week Grouped as follows: <5 hrs, 5 hrs - <10 hrs, 10 hrs - <20 hrs, 20 hrs + interventional therapy to the experimental group per week.	ADL Outcomes	<5 hrs: Ada 2013; English 2015; Kowalczewski 2007; Lang 2016a 5 hrs - <10 hrs: Burgar 2011; GAPS 2004; Lincoln 1999; Wang 2004 10 hrs - <20 hrs: Dromerick 2009; Han 2013a; Page 2012a 20 hrs+: Winstein 2019a	p = 0.72
	Activity measures of the Upper Limb	<5 hrs: Donaldson 2009; Kowalczewski 2007; Lang 2016a 5 hrs - <10 hrs: Burgar 2011; Hsu 2010; Hunter 2011a 10 hrs - <20 hrs: Dromerick 2009; Han 2013a; Page 2012a 20 hrs+: Winstein 2019a	p = 0.61
	Activity measures of the Lower Limb	<5 hrs: Ada 2013; Cooke 2010a; English 2015 5 hrs - <10 hrs: GAPS 2004; Partridge 2000 10 hrs - <20 hrs: None 20 hrs+: None	p = 0.52
	Motor impairment measures of the Upper Limb	<5 hrs: Donaldson 2009; Kowalczewski 2007 5 hrs - <10 hrs: Burgar 2011; Hsu 2010; Hunter 2011a 10 hrs - <20 hrs: Han 2013a; Page 2012a 20 hrs+: None	p = 0.09
Upper limb therapy vs. other therapy	ADL Outcomes	Upper limb therapy: Abdullahi 2018; Burgar 2011; Dromerick 2009; Han 2013a; Hsieh 2012; Kowalczewski 2007; Lang 2016a; Lincoln 1999; Page 2012a; Winstein 2019a Other therapy: Ada 2013; English 2015; GAPS 2004; Wang 2004	p = 0.41
Electro-mechanical technology vs. No electro-mechanical technology	ADL Outcomes	Electro-mechanical technology: Ada 2013; Burgar 2011; Hsieh 2012; Kowalczewski 2007; Page 2012a No electro-mechanical technology: Abdullahi 2018; Dromerick 2009; English 2015; GAPS 2004; Han 2013a; Lang 2016a; Lincoln 1999; Wang 2004; Winstein 2019a	p = 0.56
	Activity measures of the Upper Limb	Electro-mechanical technology: Burgar 2011; Hsieh 2012; Hsu 2010; Kowalczewski 2007; Page 2012a No electro-mechanical technology: Abdullahi 2018; Donaldson 2009; Dromerick 2009; Han 2013a; Hunter 2011a; Lang 2016a; Winstein 2019a	p = 0.14
	Activity measures of the Lower Limb	Electro-mechanical technology: Ada 2013 No electro-mechanical technology: Cooke 2010a; English 2015; GAPS 2004; Partridge 2000	p = 1.00
	Motor impairment measures of the Upper Limb	Electro-mechanical technology: Burgar 2011; Hsieh 2012; Hsu 2010; Kowalczewski 2007; Page 2012a No electro-mechanical technology: Abdullahi 2018; Donaldson 2009; Han 2013a; Hunter 2011a	p = 0.84

ADL = Activities of daily living

Appendix MM Summary of other systematic reviews with meta-analyses to address time spent in rehabilitation

Review	Type of rehabilitation	Key findings (in relation to time spent in rehabilitation)	Agreement/ disagreement with this review
Langhorne 1996	Physiotherapy	There was a non-significant reduction in the chance of death The pooled measures of impairment and disability did not show any significant results.	This review found no difference in the risk of SAE/Death with additional therapy. There is limited comparison with the pooled measures.
Kwakkel 1997	Rehabilitation	Small effect in favour of additional treatment seen for ADLs Effect seen for functional outcomes in favour of additional treatment No effect seen for neuromuscular outcomes, however, following post-hoc analysis to control for organisational setting and blinding, an effect was seen	This review found no effect for ADLs and no effect for activity measures of the upper and lower limbs. This is in disagreement with Kwakkel 1997.
Kwakkel 2004	Exercise therapy	Small effect found for ADL and walking speed. No effect seen for upper limb outcomes (measured with the Action Research Arm Test) For the ADL outcomes, a cumulative meta-analysis was undertaken. This found that at least an additional 16 hours of exercise therapy is required to elicit a 4/5% change in outcome measure.	This review found no effect for ADL and lower limb activity measures (such as walking), in disagreement with Kwakkel 2004 This review found no effect for activity measures of the upper limb (such as the Action Research Arm Test), in agreement with Kwakkel 2004
Galvin 2008	Exercise therapy	No effect found for upper limb measures (pooled functional and impairment measures) No effect found for lower limb measures (pooled functional and impairment measures) Effect seen in favour of additional therapy for ADL measures (as measured with the Barthel Index).	This review split functional and impairment measures of the upper and lower, so this outcome is not comparable This review saw no effect for ADL measures, in contrast with the Galvin 2008 review
Cooke 2010	Exercise-based therapy	Meta analysis was undertaken for hand grip force/strength at end of treatment. This favoured the control treatment For motricity arm measured at first follow-up, there was an effect in favour of experimental treatment No effect was found for measures of upper limb function (Action Research Arm Test) Comfortable walking speed showed an effect in favour of control treatment at first time point, but a non-significant finding at second time point.	This review found an effect for motor impairment of the upper limb, which is in contrast with some findings of Cooke 2010 (which split measures of motor impairment of the upper limb). This review found no effect for measures of upper limb function, in agreement with Cooke 2010 This review found no effect for activity measures of the lower

		Rivermead mobility showed a non-significant effect	limb, which is in contrast to the findings of Cooke 2010 at the first time point.
Veerbeek 2011	Lower-limb exercise therapy	Beneficial effect of more therapy seen for walking ability, comfortable walking speed and maximum walking speed. No effect seen for basic ADLs, but an effect seen for extended ADLs.	This review did not find an effect for lower limb activity or ADLs, as Veerbeek did.
Lohse 2014	Therapy	There was an overall beneficial effect of receiving more therapy than receiving less (all outcomes combined) A meta regression was performed using 4 different models, which controlled for the linear and non-linear effects of time and time since stroke They concluded that there was a significant, positive relationship between amount of time scheduled for therapy and improvement on outcome measures. This relationship was not effected by time since stroke, but there was a potentially non-linear effect of time.	There is limited comparison with this review, as Lohse 2014 combined outcomes. The findings of the scatter diagrams in this review are in agreement with the findings of Lohse 2014.
Pollock 2014	Physiotherapy	Greater amount of therapy lead to greater improvements in UL activity. No significant difference in measures of mobility with increased amount of therapy No significant difference in ADL	This study did not find evidence that supported a specific therapy schedule
Sehatzadeh 2015	Physiotherapy	Greater amount of therapy lead to greater improvements in UL activity. No significant difference in measures of mobility with increased amount of therapy No significant difference in ADL	This review did not find an effect for upper limb activity with more rehabilitation, as Sehatzadeh did. This review agrees with Sehatzadeh about lack of effect for mobility (lower limb activity) and ADL.
Schneider 2016	Rehabilitation	Found that additional therapy had a beneficial effect on UL and LL activity immediately after training Subgroup analysis showed that there was a greater effect in studies that provided a large increase in therapy, compared to a small increase.	This review did not find a beneficial effect on upper limb and lower limb activity, as Schneider 2016 did. This review found a greater effect when there was a larger difference in amount of rehabilitation between study arms, which is in agreement with Schneider 2016.
French 2016	Repetitive task training	No difference found between subgroups for trials that delivered 0-20 hours of therapy or 20 + hours of therapy for upper limb function or lower limb function.	This trial found no effect for additional time spend in rehabilitation for activity measures of the upper and lower limb, which is in agreement with French 2016.

ADL = Activities of daily living, UL = Upper limb, LL = Lower limb

Appendix NN COREQ Checklist

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	Page 119
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Page 119
3. Occupation	What was their occupation at the time of the study?	Page 119/120
4. Gender	Was the researcher male or female?	Page 119

5. Experience and training	What experience or training did the researcher have?	Page 119/120
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Page 119 .
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	See participant information sheet and invitation email (appendices OO and QQ, pages 337 and 345)
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	See participant information sheet and invitation email (appendices OO and QQ, pages 337 and 345))
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content	P. 118 - Reflective thematic analysis, from

	analysis	an interpretivist approach
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 119
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 119
12. Sample size	How many participants were in the study?	Table 6 – page 121
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Page 119
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Page 119 .
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Page 119
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Table 6 – page 121

Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Table 5 – Page 119 and 120
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	No, inferred in methodology section
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 120
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Page 120
21. Duration	What was the duration of the inter views or focus group?	Page 119
22. Data saturation	Was data saturation discussed?	Page 120
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No - Page 12
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Page 120
25. Description of the coding tree	Did authors provide a description of the coding tree?	Appendix RR – page 347

26. Derivation of themes	Were themes identified in advance or derived from the data?	Derived from the data – page 120
27. Software	What software, if applicable, was used to manage the data?	N/A
28. Participant checking	Did participants provide feedback on the findings?	Page 120
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Pages 122 - 136
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes, there was. Pages 122 - 136
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes. Page 122
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes – pages 122 - 136

Appendix OO Focus group participant information sheet

Participant Information Sheet for Focus Group

(Version 3 – 10th April 2016)

Title of Study

Examining the recommendation for 45 minutes of therapy following Stroke

Researcher: Beth Clark **Ethics Number: 17994**

Invitation:

You are invited to take part in a study that examines the recommendation for 45 minutes of each relevant therapy following Stroke. This phase of the study examines the reasons why some stroke survivors receive this level of input and some do not. This research forms part of a Doctoral level research project at the University of Southampton, undertaken by Beth Clark, an Occupational Therapist, and student at the University of Southampton.

It is important that you are aware of what your participation in this research will entail. Please read this information sheet thoroughly, to ensure you understand what your participation will involve.

What is the research about?

The National Institute of Health and Care Recommend that stroke services should:

"Offer initially at least 45 minutes of each relevant stroke rehabilitation therapy for a minimum of 5 days per week, to people who have the ability to participate, and where functional goals can be achieved"

Evidence from the Stroke Sentinel National Audit Programme (SSNAP) indicates that this recommendation is not well achieved. The reasons for this are unclear, but could potentially relate to service's inability to provide this level of input, or that some stroke survivors are not suitable for this level of input. This research will examine and explore the reasons why some

stroke survivors receive the recommended amount of therapy in the first three-months following stroke and some do not.

Why have I been invited to take part?

As an Occupational Therapist or Physiotherapist with experience in Stroke rehabilitation, you make decisions regarding how much therapy you provide to stroke survivors within the first three-months. I would like to find out more from you regarding how you make these decisions.

Do I have to take part?

No. Your participation is voluntary. If you do decide to take part, you will be asked to sign a consent form. If you do not wish to take part, or decide at a later stage that you wish to withdraw from the study, then you will not be asked to give a reason for this. If you withdraw from the study following data collection, it may or may not be possible to remove your contribution to the data. This will be discussed with you.

What will happen if I take part?

If you decide to take part, you will participate in a group discussion (or focus group), in which you will be asked to talk about the reasons why some stroke survivors receive a minimum of 45 minutes of therapy and some do not. This will include discussion about how you decide which stroke survivor to provide therapy to, when resources are limited. It will also include discussion regarding whether or not there are some stroke survivors who are not suitable for this level of input, and what the characteristics of these people are.

The other members of the focus group will be other therapists that you work with, within your team.

What are the benefits of taking part?

There may not be any specific benefits to you talking part in this study. However, you may find it beneficial to discuss your clinical reasoning regarding decision making with your peers.

Are there any risks to taking part?

There is the possibility that discussions touch on difficult decisions you have had to make and bring back unpleasant memories. There will be the opportunity to discuss this on a one to one basis after the group if you would find this beneficial.

How will my confidentiality be maintained?

All participants will be asked to maintain the confidentiality of the other participants in the group, with the agreement that nothing within the group should be discussed after the group has finished. Although participants may refer to each other by first name only during the group, you are asked not to name patients or NHS organisations. All names will be excluded from the transcripts of the groups. A participation number will identify participating individuals in documentation of the research.

What happens if something goes wrong?

If you become distressed during the group, you will be given the opportunity to withdraw from the study. You will also be offered contact details of follow-up services that may be of interest to you.

What will happen to the results of this research study?

On completion of the study, the data collected will be securely stored at the University of Southampton for 10 years, according to University policy. If you have any concerns regarding the study, you should contact:

Research Governance Manager

Research and Innovation Services

University of Southampton

Building 37, Room 4079,

University Road

Highfield

Southampton

SO17 1BJ

Tel: 02380 595058

The findings of this study will be presented in the final research thesis of this Doctoral Study. They may also be published in peer-reviewed journal and presented at professional conference. No participant-identifiable information will be included in any presentation of this research.

Who has reviewed this study in terms of Ethics?

The proposal for this research study has been reviewed and approved by the Ethics committee in the Research Governance office at the University of Southampton.

Who can I contact if I require any further information?

If you require any further information, please contact:

1. Beth Clark

   Doctorate in Clinical Practice Student

   Faculty of Health Sciences (Building 45)
   University of Southampton
   Southampton
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   +44(0)7785 537682

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3. Professor Jill Whitall
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   University of Maryland
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   Baltimore
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J.Truman@soton.ac.uk

Appendix PP Focus group consent form

Title of the Study:

Examining the recommendation for 45 minutes of therapy following stroke

Name of the Researcher: Beth Clark Site Number:

Ethics reference number: 17994 Participant Identification Number:

Please initial the corresponding boxes if you agree with the following statements:

1. I have read and understood the information sheet (date…….version no……..) and have had the opportunity to ask questions about the study ☐
2. I agree to take part in this research project and agree for my data to be used for the purpose of this study ☐
3. I agree to the researcher taping the discussions in the focus group, and making notes. ☐
4. I understand my participation is voluntary and I may withdraw at any time without consequence ☐
5. I agree to maintain the confidentiality of others in the group by not repeating discussions after the group has ended, only using the first names of others in the group, and not mentioning the names of patients or NHS organisations. ☐

Name of Participant (Print Name)	
Signature of participant	

Name of Researcher	Beth Clark
Signature of Researcher	
Date	

If you would be willing to be contacted by the researcher at a future date in order to further participate in this study, please indicate this by providing your email address below. If further participation was requested, full information regarding the nature of this would be provided at the time:

Email Address	

Appendix QQ Email for potential Focus Group participants

My name is Beth Clark, and I am a Doctoral Research Student at the University of Southampton. I am currently undertaking a study exploring the Recommendation for 45 minutes of each relevant therapy, following stroke. In particular, I am interested in how therapists make decisions about the amount of therapy they provide to stroke patients.

I am inviting Occupational Therapists and Physiotherapists who work with stroke patients, both as inpatients and as part of an Early Supported Discharge Service, to participate in a Focus Group. Further details regarding this can be found in the attached Participant Information Sheet. Once I have established which therapists would be interested in participating, I will arrange a mutually agreeable time for the group, which will be held at the Royal Bournemouth Hospital.

If you are interested in participating, or would like further information, please contact me via email (bac3g13@soton.ac.uk) or telephone (07785 537682). If you could please respond by the 8th April, I would be grateful.

Kind Regards

Beth

Appendix RR Coding framework – focus groups

Theme	Sub-themes	Examples of Theme in Focus Groups	Codes
The Stroke Survivor Definition How factors related to the stroke survivor influences the amount of therapy they receive.	1. Effects of the stroke 2. Performance Components 3. Engagement with therapy	**1. Effects of the stroke** (FG1.22-24) I guess that, one of the main ones is the medically unwell, patients…so…but being able to justify that – not just saying at the start of the week that they're medically unwell, but reviewing that on a regular basis but if their blood-pressure is unstable, or their heart rate, or all that kind of stuff… (FG1.25) they're too drowsy (2 - so yeh, alertness levels) to participate (FG1.26) umm and also feeding, kind of, whether their nutrition has been established, ummm, if they've been without nutrition for a few days and they're making decisions about whether to NG or not, ummm, we probably would hold fire on those patients for a while until they've got something established. (FG1.27) Ummm, and obviously the ones that go down more of the palliative route or the doctors aren't so sure….once that palliative decision has been made, then obviously we would stop the 45	**1. Effects of the stroke** BC22]Medically unwell [BC23]Blood pressure unstable [BC24]Heart-rate unstable [BC25]Too drowsy/not alert enough to participate [BC26]If feeding has been established or not [BC27]For palliative care

		(FG1.31) sometimes it is just that they were unwell that day (FG2.10) it's normally somebody's unwell (FG2.21) Acute strokes might just become unwell (FG2.24) Fatigue's quite a big thing for us at home as well, because there's the fatigue for them to participate in a therapy session, but then sometimes you have to put it in the context of what else they've got to do that day to have a meaningful life at home coz you can't just go in for an hour, wipe someone out for the rest of the day and then they just go to bed, it's not really fair, so it's kind of fatigue limiting, but then also planning for the rest of the day (FG2.34) the other thing that limits it as well is co-morbidities and that sort of thing, I think we mentioned that, so you know, patients who might have pre-existing health complaints, so…cardiac issues or umm, respiratory issues, we tend to get quite a few people like that (FG2.115) Similar problems with us are that you might get there and….the patient's not feeling very well (FG1.170-172) (In response to a question related to how you can tell that someone is not tolerating therapy) 3 – I guess they're kind of just disengaging from it sometimes, if they're sort of too fatigued or their attention's not good enough then you know they're just not focusing on doing it enough, as much as they need to.	[BC31]Might not get it if unwell [BC10]Stroke survivor may not receive 45 minutes of therapy because they are unwell [BC21]Patients can become medically unwell, which impacts therapy. [BC24]Fatigue limits therapy [BC34]Receiving 45 minutes of therapy can be limited by co-morbidities. [BC115]Therapy sessions may be cut short as patient not feeling well [BC172] Impaired attention can limit a stroke survivors' ability to tolerate therapy

		(FG2.20) they might not have the attention to process everything that's going on or what you're asking them to do. FG1.176) But, yeah, it depends on the patient, coz some are keen and want to know "what next, when am I seeing you next" (FG1.177) For some it's not even a fatigue thing, it's a motivation thing (3 – Yeah) they just don't, they're not interested, it's hard to get them to engage in, like 10 minutes of therapy sometimes, let alone 45minutes. (FG1.178) we've had some people with low mood who just don't want to engage ummm, and, as long as we fell, like, there's not a mental capacity issue, then, you kind of have to respect that **2. Performance Components** (FG1.143) But often it's the actual level of care needs, you know, that this person is actually still needing nursing care for continence and bed mobility and that is often the objective information that tells the story really, isn't it, what level of dependence is. (FG2.38) they could participate in five sessions of 45 minutes but they wouldn't get the benefit from it, they don't necessarily need it, they could self-manage in between those times so they have a lighter input than 45 minutes, five times-a-week	[BC20]A patient's impaired attention can limit their ability to tolerate therapy. [BC176]Some patients are more motivated for therapy than others [BC177]Patient's motivation can limit them receiving 45 minutes of therapy [BC178] Low mood can be a barrier to delivering the 45 minutes of therapy. **2. Performance Components** [BC143]Patient's level of dependence can indicate their appropriateness for therapy [BC38]Patients not receiving 45 minutes on the basis that they can self-manage

		(FG2.39) it's not because they are falling short of being able to tolerate it or don't have the goals coz I think they're the two parameters aren't they, from the RCP in terms of what we're trying to gain through this, but there still not, they're not meeting that, if that makes sense, so I don't…yeah, I just thought it was quite an interesting thing in terms of our service (FG2.42) So you're asking that question all the time to each of your patients do they need 45 minutes, five times-a-week and then you're making your judgment based on can they self-direct, can they do this, or do they need us physically there for them to be able to do that therapy session (FG1.28) but sometimes it is the case that we are doing the 45minutes while they're in limbo land ummm, to see if that helps to make a decision as to whether they're engaging and that actually helps to improve them or not, just to, sort of, sometimes help with those decisions. (FG1.35) I guess the trickier ones are the ones where you've been maybe rehab-ing for a while and providing the 45minutes daily and then it's making the decision that, actually, they're not progressing in their rehab and they've kind of plateaued out and those are the tricky ones as to when you stop the 45minutes daily input and we do have systems where they are re-prioritized to a different number and they become, like a three-times-a-week person or a once-a-week, kind of, maintenance person but we find that quite difficult sometimes…. (FG1.38) you have to go on the goals and the outcome measures to see if they are….	[BC39]Patients not receiving the 45 minutes, because they can direct their own therapy [BC42]Do not receive 45 minutes of therapy if they can self-direct their therapy [BC28]Whether someone is engaging in therapy or not may help to make a decision regarding need for palliative care [BC35]Changing the amount of input that is given to someone who is 'not progressing' [BC38]Using goals and outcome measures to determine the benefit of therapy

		(FG1. 43) Coz you still have those people who you're like, Oh I want to refer on to a community rehab team, I want them to be going in regularly to see this person, coz I think that's…they're still going to change from here, but they're not going to change, maybe quickly (agreement) It's hard, I find it hard (FG1.105) BC - when you say lower level, you mean….what's a lower level patient? 1 – Sort of your…sitting balance. You know, you might have done maybe half-an-hour with them, but they're absolutely exhausted, so you might get them back to bed and you might (2 – leave it at that) not do anything else with them. (FG1.142) and we've tried to, we've done in-service training looking at outcome measures that we can use that are maybe for those lower level patients, like postural seating assessment scales, so very low level things, so if someone's working towards sitting balance to show that that actually hasn't worked. (FG1.146) you just have to prioritize the rehab patients that are making the most progress (FG2. 71 & 72) **1 -** I think that's really true, though, isn't it, is even for the….it's not for each patient in the time that they're with your service it's not a set…it evolve constantly, doesn't it? Their tolerance to what you're trying to provide and therefore the way in which you need to provide it, which is….then it's about the way you report it, isn't it, and that seems to be where there's a bit of, I don't know **4 –** disparity? **1 –** yeah	[BC43]Speed at which someone is going to progress influencing decisions [BC105]Sitting balance work only = "lower level' patient [BC142]Objectively demonstrating that someone is not improving using Outcome Measures [BC146]Patients who are making the most progress are prioritized for therapy [BC71]What a patient needs evolves [BC72]How therapy is provided changes during a patient journey

		(FG2.250) And you're on a learning curve, you get to know your patients over time. You don't always get it right, initially. (FG1.29) And maybe anyone who was maybe fully dependent before, we would maybe think about whether it's worth our resource to get so involved if someone came from a nursing home where they were well supported – they weren't particularly independent, then we would change our expectations for *that* person (FG2.43) some of our patients we deem not to require the 45 minutes, who are perhaps up and mobile already but they have had a stroke and actually giving them some cardiovascular fitness might benefit them, but our threshold is above that really in terms of what we do offer, we tend not to then put them through a cardiovascular program, potentially we could but um, in order to give them some additional fitness, but we tend to think they're at their baseline and ability to cope to go home so we draw a line there and give them less than the 45 minutes **3. Engagement with therapy** (FG1.32) they declined that day (FG1.135) it's not what the patient actually wants (FG1.137) sometimes they are just really tired and maybe their goals are different to therapy goals, so we're aiming to, I don't know, sit for longer, and they're just happy to stay in bed	[BC250]Takes time to form clinical judgments about individual patients [BC29]If someone was fully dependent before [BC43]Some people might benefit from therapy, but it is not given to them, as they appear to be at 'baseline' and safe for discharge **3. Engagement with therapy** [BC32]Might not get it if patient declined. [BC135]Sometimes patients don't want daily therapy [BC137]Sometimes patients don't want daily therapy

		(FG1.181) sometimes the patient just has other priorities, you know, and sometimes they're just dealing with a lot of horrible stuff that, umm, therapist isn't top priority with, sometimes with end of life patients, you know, they potentially could make some progress from the stroke, but ultimately, they just want to go home and be left alone, so yeah, so consent is something that would change our practice. (FG1.182) Consent…they probably just wouldn't even let you in the door, so (laughter). You kind of take it as consent when they let you in, and kind of engage, and I guess it's more at the stage where you're offering it on the ward that they might say "I'm not interested in that, it's not something that I want to…" or "I don't want people coming into my house" and that's probably more the point that you would get them not engaging in therapy. Normally by the time they know we're coming to see them, they're a bit on board with what we want (FG2.26) They might decide they don't want to have it anymore (FG2.30) You get quite a variety as well, don't you, in terms of those who want the therapy and that's prioritized, and those who want to get on with life and that's prioritized, so that impacts weather they're going to get the 45 minutes, based on their own choices, as well, in terms of when you're offering it (FG2.142) If they can't consent, then we would obviously act in their best interest, that happens all the time, you would provide therapy as a best interest decision	[BC181]Lack of consent can be a barrier to delivering the 45 minutes of therapy. [BC182]If someone has agreed to ESD (in principle), they will likely agree to therapy at home. [BC26]Patients may decide they don't want therapy [BC30]Patient choice may determine whether or not they receive 45 minutes of therapy [BC142]Therapy may be provided in patients best interests (if they lack capacity).

		(FG2.143) if they've got capacity and they can make their own decisions and they don't want therapy or they're not consistently participating then that's their decision and we would just, kind of, support them with whatever they needed, but they might not have therapy if that's not what they want (FG1.33) they've got visitors (FG1.159 & 160) coz that's quite important to the patient, obviously. So it's getting…balancing what's the priority for the patient today, so I wouldn't push it too much. (FG1.179) she's saying she doesn't want to engage with you, so just respect that and…and that's fine, you know, therapy is not her priority at the minute (FG1.191 & 193) it's more open visiting, so quite often they have visitors and….they're just not interested. (FG2.27) maybe they've got to maybe go to sleep for an hour before we come and an hour after and then that's a big chunk of their day and they might want to spend it doing something else kind of thing (FG2.31) You get quite a variety as well, don't you, in terms of those who want the therapy and that's prioritized, and those who want to get on with life and that's prioritized, so that impacts weather they're going to get the 45 minutes, based on their own choices, as well, in terms of when you're offering it	[BC143]Patient might not have therapy if they do not consent (provided they have capacity) [BC33]Might not get it if patient has visitors [BC159]Need to consider what the patient's priority is [BC160]Visitors may limit the ability to deliver 45 minutes of therapy [BC179]Therapy needs to be the priority of the stroke survivor, too [BC191]Having visitors can mean that Stroke Survivors don't want to engage in therapy [BC193]Earlier, visitors did not seem to be a barrier to delivering 45minutes of therapy. Maybe they are, more so, at weekends. [BC27]Patients may decide they don't want therapy because they want to be doing something else. [BC31]A patient's own priorities will influence whether they receive 45 minutes of therapy.

		(FG2.108) You spend half of your 45 minutes in and out the bathroom (FG2.114) they've maybe got an appointment to get to (FG2.179) sometimes it'd dictated for you anyway because they're the ones you can get to (FG2.141) There's probably another group of patient that we'd maybe withdraw from, as well, that's the ones that aren't consistently participating or don't want to participate, but perhaps their family members are saying "yeah, yeah, yeah, they want to do therapy" and then you try, but I think, for us, it's a lot about consistency, if they do it one day but not the other and so on, it doesn't actually go anywhere, so we might discharge them from us in that situation.	[BC108]Therapy sessions can be limited by toileting. [BC114]Therapy sessions may be cut short as patient has made other plans [BC179]Being able to 'get to' patients may influence the amount of therapy they have [BC141]Need consistent participation from patient to continue

Theme	Sub-themes	Examples of Theme in Focus Groups	Codes
The Individual Therapist Definition	1. Patient related 2. System related	**1. Patient related** (FG2.53) we do that with patients that we feel are those that will benefit from joint sessions as opposed to those who would tolerate 45 minutes of	**1. Patient related** [BC53] Doing the 'best thing for the patient'

Individual therapists influence the amount of therapy that stroke survivors receive, predominantly through the decisions they make		both separately, we don't do it as an alternative we do it because that's the best thing for the patient….. (FG2.76 & 78) to be honest, I think we just go with the flow, don't we? Yeah, it's not…like I said, earlier, its not like we have a stop clock it's purely like, well, I've done what I need to do, oh, it's only been 20 minutes, that's what they've needed, or that's only what they've managed to tolerate, or we've come out the gym and you're like, Oh my gosh, we've been in there for 75 minutes, how did that happen, we got a bit carried away. So, the whole concept of 45 minutes it's kind of (5- It's K…. (4)'s fault!) Looking at you, K…..(4) The whole concept of this 45 minutes, where has this magic number come from that patients benefit by having 45 minutes? (FG2.159) **4 –** No! And I suppose that's what…it doesn't really matter, actually…. **3 –** As long as we stay focused on the patient and what's best for them, and what they need… (FG2.211) You're delivering it seven days if they need it irrelevant of whether it says five or seven in the pathway. (FG2.244) It depends on what the goal are for those patients, as well and what you're hoping to achieve. (FG2.240) I think we all come from the same point that the patient is what drives it. Stats sometimes get in the way, but the patient is at the center of it.	[BC76]The amount of therapy a patient gets is based on what they need. [BC78]What the patient needs is more important than a fixed amount. [BC159]Patient need is most important [BC211]Importance of delivering what patients need, not what is outlined in guidance. [BC224]Care needs to be individualized [BC240]Therapy should be patient-focused

		(FG2.249) And that again comes back to that question of, what's best for the patient, and I think that, yeah, conclude that we all go for what we think is best, if they need intensive, but shorter period of time, we'll go for that. If they need to work on endurance, but you might have to slow your pace down a bit, you'll go for that, depending on what they need. (FG1.131) And managing expectations of relatives if you're not seeing them every day, explaining why… (FG1.132) and, course, the thing about the guidelines is it that the public know about them, if they want to, and they maybe have those expectations that they're going to carry on getting those and it's not always the best use of our resources, (FG1.134) It is really, we have had some very difficult care reviews where the family get very upset and are expecting therapy daily and its not appropriate, and it's not what the patient actually wants but its what the family are struggling to come to terms with. (FG1. 140) But then you do get a few families who've read-up and they know everything and they will quiz you on every decision made. (FG2.86, 87 & 88) And we get it quoted by patients, quite frequently they will come and say 'it says that my relative should be receiving this and they're not'…so it feels like we're accountable to some patients who are quite savvy and they have read up	[BC249]Therapy is tailored, dependent on patient need [BC131]Relatives expect therapy daily. [BC132]Public may know about guidelines [BC134]Family expect daily therapy [BC140]Some relatives are aware of guidelines [BC86]Patients/relatives' awareness of guideline [BC87]Increases accountability to patients [BC88]Potentially only accountable to some patients (those who are 'savvy' and have 'read up')

		(FG2.89) I think we should be able to justify why we're not, I think it's a reasonable thing for them to ask and suggest	[BC89]Should be able to justify to patients/relatives why they are not receiving the guideline amount of therapy
		2. System Related	**2. System Related**
		(FG1.37) because of the guideline you feel like you should still be providing the 45minutes of therapy even though you're feeling "oh, I'm not sure I'm making progress, I'm not sure this person is benefiting from this and maybe I should be targeting resource elsewhere", but because of the guideline, you…it doesn't feel right….	[BC37]The need to ensure that resources are used appropriately
		(FG1.39) they're expecting that they have had this daily therapy so far and they are continuing to expect this daily therapy and then you're taking that away and how they deal with that can be really tricky sometimes as well	[BC39]Ensuring family understand about decisions made re: amount of therapy.
		(FG1.133) and they maybe have those expectations that they're going to carry on getting those and it's not always the best use of our resources	[BC133]Have to consider the best use of resources in the provision of therapy
		(FG1.142) and we've tried to, we've done in-service training looking at outcome measures that we can use that are maybe for those lower level patients, like postural seating assessment scales, so very low level things, so if someone's working towards sitting balance to show that that actually hasn't worked.	[BC142]Objectively demonstrating that someone is not improving using Outcome Measures

		(FG1.146) and you just have to prioritize the rehab patients that are making the most progress (FG1.147) you just have to prioritize the rehab patients that are making the most progress and we just have to say that the ones that aren't getting seen that day will just be prioritized the next day and we do have times like that umm, which isn't ideal, but it happens (FG1.180) . But I think we're just so conscious that you have such a small window to access someone's potential and, you know, we definitely communicated that to her (FG2.33) I think as a standard all of the patients are booked in on the basis that we're aiming to do 45 minutes but those patients who can tolerate and would benefit from a functional goal perspective from the 45 minutes…they are earmarked, as well, if that makes sense, so everyone will sort of be, have the opportunity to have those 45 minutes if they're a full referral to the community team for our normal input. (FG2.40 & 41) you wouldn't, you wouldn't want to give them more therapy for the sake of giving them more therapy and actually prioritise them above someone else who will actually gain more from that input and intensity (FG2.89) I think we should be able to justify why we're not, I think it's a reasonable thing for them to ask and suggest	[BC146]Patients who are making the most progress are prioritized for therapy [BC147]Prioritizing patients when there is a lack of resources [BC180]"Small window" of opportunity to access a patient's rehabilitation potential [BC33]Identifying the patients that are MOST appropriate for the guideline amount of therapy [BC40]Not providing people with more therapy for the sake of it [BC41]Needing to manage (or potentially ration?) a resource [BC89]Should be able to justify to patients/relatives why they are not receiving the guideline amount of therapy

		(FG2.98) Yeah, there's sometimes that culture as well, isn't there, that therapy is something that needs to be done to the patient and it's not something that they're responsible for, it's something that we're more responsible for and if they haven't progressed, it's all our fault, but sometimes, it's actually not our fault (FG1.149 & 150) 45 minutes maybe suffers sometimes when we have a massive influx of new patients, because obviously also as part of the SSNAP you have the assessment targets, (FG1.154) Yeah, yeah, so that's when the rehab stuff maybe doesn't happen as much as well, but then again, at that point, you just re-prioritize that patient and make sure they're seen that following day (FG1.156) so they might not finish at 4 (laughter) and in the morning, as well, because it's an hour allocated, sometimes it can turn into a whole morning because of the volume you get, so you just re-shuffle… (FG2.50) I think for us at the moment, because our staffing is pretty diabolical, we're prioritizing our new assessments, because we have to achieve the other things like cognitive assessment and mood assessment within 72 hours, so we're prioritizing those other targets rather than meeting our 45 minute target, so that we're still picking up all of those new people and….it just means that the rehab gets….less (FG2.183) And that's another impacting factor, is what HASU is like, coz if that's just manic and you've got six new patients that day, that changes	[BC98]Differing views on where the responsibility for therapy lies. [BC149]Difficult to deliver 45 minutes of therapy when there is a lot of new patients [BC150]Targets can conflict with each other [BC154]New admissions can limit the ability to deliver 45 minutes of therapy [BC156]New admissions can limit the ability to deliver 45 minutes of therapy [BC50]Might not receive 45 minutes of therapy due to competing targets [BC183]New patient assessments limits ability to provide 45 minutes of therapy

		everything about what happens on the rehab ward, coz we're not a split ward. (FG2.184) And our patients can be outlied and then we still have to provide therapy to the people that are no longer on our ward, so… **4 –** We have no control over the number of patients on our caseload. (FG2.218) We'd probably, well, we'd prioritise the new patient assessments first, over anything else or the discharges and then the rehab sessions after that	[BC184]Size of caseload can determine ability to provide the recommendation [BC218]Stroke rehabilitation sessions are the third priority (after admissions and discharges)

Theme	Sub-themes	Examples of Theme in Focus Groups	Codes
The Stroke MDT Definition The reasons why a stroke survivor might not receive 45 minutes of therapy related to	1. Competing healthcare priorities 2. Other therapists	**1. Competing healthcare priorities** (FG1.151 &152) And then they get taken off for a scan, or the doctor's there, or speech and language therapists are there and it's hard to get to them. (FG1.157) It can effect sometimes the other ones if they're going off for ultrasound or something and you're not necessarily aware of it that day, but actually they're getting whisked off, just as you're about to see them. So you have to, sort of, re-jiggle things. So it potentially can.	**1. Competing healthcare priorities** [BC151]Investigations can limit the ability to deliver 45 minutes of therapy [BC152]Competing professionals can limit the ability to deliver 45 minutes of therapy [BC157] investigations can limit the ability to deliver 45 minutes of therapy

the stroke Multidisciplinary Team (MDT)		(FG1.158) Yeah, there was a lady that was due for lunch group the other day that I went to collect but she'd suddenly been made nil by mouth, so, she was just waiting on an investigation, so, of course, then that scuppered our plans for her that day, so yeah, things like that are unavoidable, you can't really plan for that, can you. I think we tried to see her later on, but, there's nothing you can do about things like that. (FG2.15) And then there's always going to be other things that go on certainly from that ward perspective, you know, somebody might get called for chest x-ray (FG2.23) If they're having all three disciplines, like speech and language, OT, Physio, that's quite a lot for some people in early stroke (FG2.105-107) Yeah, and sessions may not start on time as well, you go to the patient, you've given them prior warning, when you get there, they need their medications, which haven't been given yet, their NGs still attached, **2. Other therapists** (FG1.97) at 1 o'clock we have a meeting, how's everyone getting on, have you got to everyone you need to get to, whereas we maybe used to say "has	[BC158] Investigations can limit the ability to deliver 45 minutes of therapy [BC15]Stroke survivor may not receive 45 minutes of therapy if they have to be taken for investigations [BC23]Amount of therapy input can be dependent on the other therapy that the stroke survivor is also receiving [BC105]Therapy sessions may not start on time due to people needing their medications. [BC106]Limited by sessions not starting on time/patients not being ready for therapy. [BC107]Therapy sessions may not start on time due to people's NG tubes still being attached. **2. Other therapists** [BC97] Therapists are collectively focused on delivering 45minute guideline

		everybody got what they needed, patient-wise, today?" It's now changed to "whose getting, whose *not* getting 45minutes a day?" (FG2.149) in our regular meetings, that's where those decisions are made at the MDT meetings, to decide actually they need this many sessions of Occupational Therapy, you know, you're going to go and see them for those sessions	[BC149] Regular, MDT meetings to discuss the guidelines

Theme	Sub-themes	Examples of Theme in Focus Groups	Codes
The Organisation Definition Identifying how some aspects of the organisation may affect the amount of therapy a stroke survivor receives	1. Service Characteristics 2. Resources 3. Organisational Politics	**1. Service Characteristics** (FG1.44) It's a bit different in that they have their…because you're not maybe providing the same discipline everyday for 45minutes and you're providing just *a* person going in daily for up to 2 weeks (FG1.45) most people don't want more than one visit. Maybe you'll get someone who'll have two but more than that, they don't want at home (FG1.62) Yeh, they just start making plans when they're home (FG1.62-64) If they're quite independent, they want to go out and about and do things, if it's more, like, we're sort of, doing a bit of rehab care kind of thing then yeh, we might be able to fit two or three sessions in, if we're	**1. Service Characteristics** [BC44]Not always the same discipline for 45minutes (in ESD). [BC45]People don't want as much therapy at home (ESD). [BC62]Patients lack time for therapy at home [BC63]Stroke Survivors may want less therapy in order to "get back to normal life"

		doing like their breakfast and shower, then their lunch, then their tea-time visit, then they might be more willing, but yeh, they often quite like to go out and about and do their own thing – get back to normal life.	[BC64]Harder to achieve 45 minutes as part of ESD
		(FG2.56) I think if they are patients who could really tolerate that higher intensity then they might have two 45 minute sessions or two therapies a-day, but that's actually quite unusual and I think from a capacity point-of-view that's quite unusual and that's probably where the staff and the other factors start influencing…	[BC56]In the community, it is unusual for a patient to have more than 45 minutes of therapy-a-day – even if they have more than one therapy involved
		(FG2.57) you maybe might be saying, well we'll do a combined OT/PT session, rather than trying to see whether we can actually do more sessions and divide them up a little bit more.	[BC57] Use of combined OT/PT sessions, even when sometimes might benefit from separate. (in the community)
		(FG1.108) if someone's not so good in the session that you've planned, it does mean then that you haven't got so much flexibility to come back, because, someone else would have to be off your list. Umm, coz having yourself fully booked is kind of the only way you can get to 45minutes with everyone, really. And sometimes it works out that, ya know, one patient may be not well and so you're not seeing them, so you've got a bit of space, but the only way we've managed to meet the target is by being fully booked, so you haven't got so much flexibility, then.	[BC108]Lack of flexibility within the working day may be one reason why someone might not receive 45minutes of therapy - if they 'miss their slot'
		(FG1.110) in acute stroke everything moves so quickly and changes so quickly	[BC110]Fast pace in acute stroke
		(FG1.130) and then the difficulties and logistics of getting back to do smaller chunks more regularly with them in terms of our timetabling	[BC130]Difficult to break down 45 minutes into smaller sessions for those who can't tolerate all in one go

		(FG2.16) And then there's always going to be other things that go on certainly from that ward perspective, you know, somebody might get called for chest x-ray or just the nature of being in an acute hospital, there's always going to be things that you can't….that happen and you can't control that has interrupted your session	[BC16]Interruptions to therapy sessions occur due to the nature of acute hospital work
		(FG2.144) but the 6 weeks is kind of our…you kind of start off with "you're going to have 6 weeks of therapy and when the 6 weeks is up it feels a bit more comfortable to say, "we can't see you anymore"	[BC144]Amount of therapy limited by the nature of service provision
		2. Resources	**2. Resources**
		(FG1.145) Yeah, we do have days where there's maybe sickness or people taking TOIL days for weekends and it all accumulates on one bad day	[BC145]Resources can impact the provision of 45minutes of therapy
		(FG2.14) Staffing levels do sometimes influence how much time we can spend with patients and our staffing levels are variable.	[BC14]Stroke survivor may not receive 45 minutes of therapy due to staffing levels
		(FG2.49) I think for us at the moment, because our staffing is pretty diabolical, we're prioritizing our new assessments,	[BC49]Might not receive 45 minutes of therapy due to issues with staffing.
		(FG2.171) when our staffing levels are low, they don't, really	[BC171]Staffing levels influence the amount of therapy that patients receive.
		FG2.173) (In response to the question; "do you feel that the people who access your service get the right amount of therapy?") I think generally, they	[BC173]Highlighting staffing issues.

		do. Umm, when our staffing levels are low, they don't, really and I think we don't necessarily try to cover it up with, sort of, changing the stats, or by switching roles, or, we highlight that there is a staffing issue. (FG2.184) We have no control over the number of patients on our caseload. (FG1.103) Coz sometimes you feel like, actually, patients would benefit from a bit more little and often, rather than a 45-minute block, but logistically, to try and get that for everyone, it's just a bit of a nightmare. BC – Yeah, so doing 3 lots of…. 2 – fifteen minutes for every patient on your caseload (laughter)…or the ones….would be really….tricky…. (FG1.104) BC – So, say you had that person, who could only, maybe, you know, at the end of 15minutes they're looking grey and wiped out, would that be the end of their therapy for the day? Or….what would happen in a situation like that? 1 – Potentially, you could go back to them, or you might get one of the assistants to do something with them, hopefully. 2 – I think it very much depends on what else if going on in your day…yeah 1 – Yeah, it depends on what your priorities are, but it's normally your cerebella ones, isn't it, that get the fatigue, so, actually they're improving, so you do go back to those, but maybe the lower level ones you might not necessarily….go back to. (FG1.130) I guess, the draw back is that, as we mentioned earlier, with maybe some of the lower level patients just not being able to tolerate the full 45 minutes and then the difficulties and logistics of getting back to do smaller chunks more regularly with them in terms of our timetabling	[BC184]Size of caseload can determine ability to provide the recommendation [BC103]Difficult to achieve a schedule that is not 45 minutes in a block [BC104]Efforts may be made to go back to fatigued patients, but it depends on the patient [BC130]Difficult to break down 45 minutes into smaller sessions for those who can't tolerate all in one go

		(FG2.12) Quite often we break our sessions up, so they may have 20 minutes in the morning and 25 minutes in the afternoon or we see them and then the techs might go back so, ummmm, but again, as K….said, we're lucky that we've got the staffing to be able to do that (FG2.111) We've still got to see all the other patients that are planned in to that time, so it's very difficult… (FG2.245) Our techs sometimes do two visits-a-day, um, qualified would not. It's hard for me to get two visits-a-week, so it wouldn't be a day, but, um, sometimes if they can only, say, tolerate 20 minutes at a time, or half an hour they do, they'd just book two-a-day, wouldn't they? Go back. (FG2.248) I think that, yeah, conclude that we all go for what we think is best, if they need intensive, but shorter period of time, we'll go for that **3. Organisational Politics** **(**FG1.9) because it's more recognized by managers as something that we should be achieving or working towards and they're judging what we're doing, (FG1.13 & 14) we've consistently failed in that area of the audit and so, you know, a manager will start to listen to why you're failing, what are the areas that you're failing on	[BC12]Therapy can be broken up over the day to enable stroke survivors to have more therapy. [BC111]Difficulty being flexible with patient sessions due to planning [BC245]Book in more sessions-a-day if patient's tolerance is low. [BC248]Some people benefit more from shorter, more 'intensive' sessions **3. Organisational Politics** [BC9]Judgment from managers/ managers judge what you are doing [BC13]Non-achievement of guidelines gains management attention [BC14]Not achieving national target perceived as failure.

		FG1.17) I think we've been able to justify the amount of staff that we had. I think there were times when it's been questioned we seem to have a lot of therapists and we have been able to say "Look – have you seen what our targets are? Do you know we have to see every patient for 45minutes?" The only way you can do that is with a certain amount of staff (FG1.94) 2 – there was such a push for, you have to get all of these patients in and 1 – and getting a good score (FG1.96) It did change a lot, didn't it, we used to have therapists have their own timetable and you write down, obviously, what you're doing in the week and, um, I remember that being suddenly scrutinized and instead of having hour blocks on your timetable like 8 til 9, 9 til 10, ya know that had to change, it had to be 45minute blocks and you really felt like you had to have someone in every 45minutes (FG2.51) Sometimes we use it to demonstrate that the staffing levels are lower than are expected, um, so almost…not purposely failing, but not striving to achieve something that's unachievable to cover up gaps in the service	[BC17]Guidelines perceived as a target [BC94]Importance of getting a good SSNAP score [BC96]SSNAP increases accountability/scrutiny [BC51]Using non-achievement of the guideline to highlight issues

Theme	Sub-themes	Examples of Theme in Focus Groups	Codes
The Guideline Definition	1. A Therapy Prescription 2. Is the guideline right? 3. Measuring guideline achievement	**1. A Therapy Prescription** (FG1.36) "I guess the trickier ones are the ones where you've been maybe rehab-ing for a while and providing the 45minutes daily and then it's making the decision that, actually, they're not progressing in their rehab and they've kind of plateaued out and those are the tricky ones as to when you stop the 45minutes daily input and we do have systems where they are re-prioritized to a different number and they become, like a three-times-a-week person or a once-a-week, kind of, maintenance person but we find that quite difficult sometimes, I think, coz, because of the guideline you feel like you should still be providing the 45minutes of therapy" (FG1.97) "at 1 o'clock we have a meeting, how's everyone getting on, have you got to everyone you need to get to, whereas we maybe used to say "has everybody got what they needed, patient-wise, today?" It's now changed to "whose getting, whose *not* getting 45minutes a day?" (FG1.99) Ya know, it's focused us a lot, hasn't it, and it's sort of given you a little motivating target, as a therapist, that: "have all of my patient's had 45 minutes today?" Unless it's not appropriate. You try….you're aiming for that amount aren't you?" (FG1.138) "maybe it's just because when they first come in they're obviously having that daily input because everyone is for 45minutes until you can, kind of, justify otherwise"	**1. A Therapy Prescription** [BC36]The guideline gives a sense of obligation to provide a certain amount of therapy [BC97]The 45 minute guidance has given a target to aim for [BC99] The 45 minute guidance Has given a target to aim for. [BC138]Everyone should have 45 minutes of therapy unless there is a reason not to

		(FG1. 164) "Umm, and maybe some of the slower-stream rehab people, maybe you wouldn't schedule them in *every* day, maybe you would be aiming more for 3 days-a-week just because, actually, their tolerance levels, their medical status, all those sorts of things are just not so good and sometimes 45minutes a day is quite hard for them. But you don't feel you can rule them out of the 45minute category, because you want to give them that chance"	[BC164]Pressure to deliver 45 minutes daily, even if the therapist feels it may not be the right thing for the patient.
		(FG1.169) "if you're not needing to see the slow stream ones every day, you can maybe then provide a higher intensity to the higher level patients and go back and see them again, because…..not that you can't do that now, you just don't have the time because of every other patient that you're trying to see for 45minutes, you're just fully booked, you don't have the opportunity to go back and see those patients that would really benefit from further input…yeah."	[BC169]Potentially the 45 minute guideline disadvantages some people, who would benefit from more than 45minutes of therapy
		(FG2.2) I think it's been really good in providing us with a currency for which to base our decisions upon	[BC2]The 45 minute guideline supports decision making
		(FG2.3) so I think it's a really good starting point, um, to think about, um, how much or how little the patients receive, what they can tolerate, .	[BC3]The 45 minute guideline is a "good starting point" for how much therapy patients receive.
		(FG2.32) I think as a standard all of the patients are booked in on the basis that we're aiming to do 45 minutes but those patients who can tolerate and would benefit from a functional goal perspective from the 45 minutes…they are earmarked, as well, if that makes sense, so everyone will sort of be, have the opportunity to have those 45 minutes if they're a full referral to the community team for our normal input.	[BC32]Patients taken into the service on the basis that 45 minutes of daily therapy can be provided to them

		(FG.81) It's just a currency though, isn't it? It doesn't really matter what it is, whether it's 60 minutes, whether it's 45 minutes, it's somewhere to start….	[BC81]The 45 minute guideline gives services "somewhere to start"
		(FG2.85) it's sort of, because it's written in guidelines it almost suggests that patients won't recover unless appropriately if you don't give them 45 minutes, it's like, do you see what I mean?	[BC85]Perception that patients won't recover unless they're given 45 minutes of therapy.
		(FG1.147) you just have to prioritize the rehab patients that are making the most progress and we just have to say that the ones that aren't getting seen that day will just be prioritized the next day and we do have times like that umm, which isn't ideal, but it happens	[BC147]Prioritizing patients when there is a lack of resources
		(FG2. 174) One thing, I guess, to consider, is if you are low on staff, is it better that less patients are seen, but for 45 minutes and they might only get seen every other day or is it better that they get seen every day, but maybe only for a 20 minute session? I don't know what the best way of, you know, but then….	[BC174]What is the best alternative if unable to meet 45 minutes/day?
		(FG2.176) we probably do, "lets get everyone seen", because you're concerned… **5 –** You feel better about it **6 -** that you, you feel like you want to see everybody, yeah, but you probably don't give them brilliant sessions, really	[BC176]Choose to provide more people with less therapy, daily, when unable to provide the recommendation
		(FG2.177) But we have had times where we've had days where the list is like this (indicates a long list) and there's only a few of us in and you've, for want of a better word, just bashed through the list and given them all…. they've all been seen but they've probably all had 20 minutes and probably not brilliant	[BC177]Making decisions about how much therapy to give when you are unable to provide the recommendation

		sessions, but at least they've had something, rather than, we'd probably do that more maybe, than looking at it and going, those ones, I'm going to park for today and I'll see them tomorrow, and I'm going to give these ones really good sessions, we probably do, "lets get everyone seen", because you're concerned… **5 –** You feel better about it **6 -** that you, you feel like you want to see everybody, yeah, but you probably don't give them brilliant sessions, really (FG2.178) I think about it very differently. So I would rather spend more time with a smaller number of people and then split them over two days. **2. Is the guideline right?** (FG1.30) "I guess that still fits with the actual guidance – it says that for those who have the ability to participate, so of course, if you're drowsey, umm, or you were fully dependent before, then you wouldn't have the ability to participate, so it kind of supports that guideline" (FG1.100) I've only managed to do a short session with this person, so if you could go and see them to, kind of, top it up….Which is obviously beneficial to them as well, but you do feel a bit like you're driven by numbers sometimes (FG1.102) Coz sometimes you feel like, actually, patients would benefit from a bit more little and often, rather than a 45-minute block, but logistically, to try and get that for everyone, it's just a bit of a nightmare.	[BC178]Better to spend more time with fewer patients (difference of opinion) **2. Is the guideline right?** [BC30]The guideline states that 45-minutes of therapy is not right for everyone [BC100]More therapy is better for patients [BC102]Uncertainty that 45 minutes of therapy is the right thing for everyone – therapy schedule may also be important

		(FG1.165) And some patients are the very quick sort of people, who, you know, you can see their not going to be here very long, but they have got some impairments still, they almost need a lot more than 45minutes, so those ones, they need to be doing, they need to be using, they need to be not sitting in bed, but sitting out and so we could easily see them for breakfast group, lunch group, you know, like I was saying at the beginning, an individual session, umm and then you kind of have a random group that they could go to (laughs) because they're just bored, they want to do they want to feel like "I'm staying here, there's got to be some reason for it" ummm, and if it's on, then we'll let them come sometimes, so they, those quick stay ones, they almost need a lot more than 45minutes to justify them staying in for therapy. (FG1.166 & 167) so if you're only seeing them for 45 minutes that day, then that's kind of, not enough, so you could work on that in lunch group, gardening group, exercise group, to really blast them if you feel like they could cope with it and they're up for it. (FG1.168) I guess it's feel that you can just target your resources a bit differently, if you're not needing to see the slow stream ones every day, you can maybe then provide a higher intensity to the higher level patients and go back and see them again, because…..not that you can't do that now, you just don't have the time because of every other patient that you're trying to see for 45minutes, you're just fully booked, you don't have the opportunity to go back and see those patients that would really benefit from further input…yeah.	[BC165]Some people need a lot more than 45 minutes of therapy [BC166]More than 45 minutes of therapy is needed by some patients [BC167]People should have more than 45 minutes if it will benefit them, they can tolerate it and they consent to it. [BC168]Opinion that not all patients need 45 minutes of therapy-a-day

		(FG2.170) (When asked if people get the right amount of therapy) I think generally, they do	[BC170]Generally, patients get the right amount of therapy
		(FG2.186) I don't see a massive negative with it, because it is, exactly what you say, this is what you're aiming for and I would say, if we were going to do something in the community for their goals and it's going to take longer, we factor that in, because that's their goal, that's what they want to do, whether it's getting back in the swimming pool, whatever. If it's not 45 minutes, well we'll timetable that in to take account of that, so we don't just go "I can't do that in 45 minutes, we can't do that activity"	[BC186]Therapy sessions are not limited to 45 minutes.
		(FG1.188) And I know it's due to go up, isn't it, with the new guidelines this year, it's going to seven days, 45, so that would mean upping the bar. And I'm not sure how the patients will feel about that…..	[BC188]Uncertainty surrounding how patients will feel about 45 minutes of therapy 7 days-a week
		(FG1.189 & 190) Honestly, I sometimes go to….well, I often go to people at weekends and they just say, "it's the weekend, what are you….what are *you* doing here. I want a rest"… Especially Sundays	[BC189]Potentially patients don't want therapy at the weekend. [BC190]Potentially patients don't want therapy on Sundays
		(FG1.192) – And it's more open visiting, so quite often they have visitors and….they're just not interested.	[BC192]Potentially patients don't want therapy at the weekend.
		(FG2.201) in the community, I don't necessarily think 7 day is a good thing, because we are about getting people back to their normal lives	[BC201]7 day therapy might not reflect 'real life'
		(FG2.202) They've got no rest	[BC202]7 day therapy means that patients have no rest

		(FG2.203-205) No, no…they want family time and you're trying to get them back to engaging in their real life, so seven days….and having worked in an ESD, with stroke who have attempted, on occasions it does, it didn't work at all. They don't want you, they want you not to be in their home every single day. (FG2.212) Coz it's not that they don't want it at the weekend, they might not want it everyday (FG2.213) **5 -** I guess our patient group might be a bit different, they might be a bit more poorly, they might be less aware or unable to consent, or…… **4 –** not know what day of the week it is **6 –** Yeah, I was going to say, half they time they don't…it doesn't really matter to them whether it's a Monday, Friday, Sunday, that every day's the same for them… (FG2.214 & 215) But some patients do actually need a break and you get to a Friday and you can see the quality of what they are able to achieve just dropping off **6 –** And then actually again, on a Monday, they're pretty good, they've had a nice breather **3. Measuring guideline achievement** (FG1 – 91) Yeah, I remember how patchy that recording was to start with, coz it was just, oh yeah, if you get a chance, just, kind of, input it, and now we've got a dedicated full-time admin person that just does SSNAP input, so it's changed so much	[BC203]Therapy encroaching on 'family time' at weekends. [BC204]Therapy time encroaching on 'real life' [BC205]Patients don't want therapy at home everyday (7 days-a-week) [BC212]No necessarily therapy at the weekend that is an issue, more therapy seven days-a-week. [BC213]Inpatients may be less likely to mind what day-of-the week it is. [BC214]Some patients can' t tolerate therapy 7 days-a-week [BC215]Patients may need a break from therapy. **3. Measuring guideline achievement** [BC91] Introduction of SSNAP increased the recording of the amount of therapy provided.

		(FG1 – 93) I think it's helped highlight it…the need to do the 45minutes…and getting a good score (FG1 – 94) I feel like it's *really* changed the service…coz I was first on the stroke unit, then rotated off for a couple of rotations and then came back and it was so different (FG1 – 97) It did change a lot, didn't it, we used to have therapists have their own timetable and you write down, obviously, what you're doing in the week and, um, I remember that being suddenly scrutinized and instead of having hour blocks on your timetable like 8 til 9, 9 til 10, ya know that had to change, it had to be 45minute blocks and you really felt like you had to have someone in every 45minutes (FG2 – 48) Once they're discharged from kind of their….once they've achieved their, or they've not achieved their goals then they're discharged and that's their SSNAP data done	[BC93] SSNAP has increased awareness of the 45 minute guideline [BC94] SSNAP has had a great effect on therapy services [BC97]SSNAP increased accountability/scrutiny [BC48] SSNAP recording finishes once 'active' therapy is complete

Appendix SS Delphi study participant information sheet

Participant Information Sheet for Delphi Study

Version 5 – 11th October 2019

Study Title:

Examining the recommendation for 45 minutes of therapy following Stroke

Researcher: Beth Clark **Ethics Number: 17994**

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

The National Institute of Health and Care Recommend that stroke services should:

"Offer initially at least 45 minutes of each relevant stroke rehabilitation therapy for a minimum of 5 days per week, to people who have the ability to participate, and where functional goals can be achieved"

Evidence from the Stroke Sentinel National Audit Programme (SSNAP) indicates that this recommendation is not always achieved. The reasons for this are unclear, but could potentially relate to inability to consistently provide this level of input, or that some stroke survivors are not suitable for this level of input. This research will examine and explore the reasons why some stroke survivors do not receive the recommended amount of therapy in the early stages after stroke.

My background is in Occupational Therapy and this study forms part of a research project that is being undertaken for the award of PhD at the University of Southampton.

Why have I been asked to participate?

As an Occupational Therapist or Physiotherapist experienced in Stroke rehabilitation, you make decisions regarding how much therapy you provide to stroke survivors in the early stages following stroke. I would like to investigate the opinions of healthcare professionals regarding the factors that influence such decisions.

What will happen to me if I take part?

If you decide to take part, you will participate in a Delphi Study. This will involve rounds of questionnaires, which include statements about therapy provision to people who have had a stroke, many of which will focus on why a stroke survivor may not receive the recommended minimum 45 minutes of therapy. You will be asked to rate your agreement with these statements, based on your general experience and not specific to any individual person or healthcare organisation/trust.

Following each round of the questionnaire, you will receive feedback, which collates the responses of the previous questionnaire. The rounds of questionnaires will continue until consensus is reached. This is anticipated to take three rounds of questionnaires. The questionnaire will be sent electronically. However, if your preference would be for a postal questionnaire, this can be accommodated.

Ideally, you will participate in each round of the questionnaire, until consensus is reached.

Are there any benefits in my taking part?

There may not be any specific benefits to you talking part in this study. However, you may find you reflect on your clinical decision making as part of this process, which may be beneficial to you.

Are there any risks involved?

Risks to taking part are unlikely. However, there is the possibility that consideration of past decisions you have made may bring back unpleasant memories.

What data will be collected?

In order to participate in the study, you will be required to provide your name and contact details (email address, or postal address if this is your preference). This is in order to consent you to the study and to be able to send you the questionnaires.

Further data collected will be your responses to the Delphi Questionnaires. This will include some very basic questions about you, including your profession (Physiotherapist or Occupational Therapist), your grade (Agenda for Change band or equivalent), your years of experience and the nature of your experience (e.g. inpatient, Early supported discharge). As well as the extent to which you agree with the statements presented in the Delphi, you will be given the opportunity to explain your answer should you wish. Additionally, you will have the opportunity to suggest any further reasons why a stroke survivor may not receive the recommended minimum of 45 minutes of therapy, which you don't feel were represented in the questions asked.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

The identifiable information collected in the course of this research will be stored securely and in accordance with the University of Southampton Data protection policy. Any consent forms that are physically collected will be stored behind 2 locks. Consent forms and contact details will be stored electronically on a password-protected computer, which is kept securely. Any correspondence made via email will be done so from a University of Southampton email account. As the questionnaire is sent via either email or the post, please be aware that there is a possibility of it being intercepted.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part. If you wish to take part, then please contact the researcher, Beth Clark, via email: bac3g13@soton.ac.uk.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. If you wish to withdraw, then please contact the researcher, Beth Clark, via email: bac3g3@soton.ac.uk. If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. The results of the study will be reported in the researcher's PhD thesis and published in peer-reviewed journal. Potentially, results may also be presented at professional conference and details of the study may appear in professional publications.

Where can I get more information?

If you require any further information, please contact: Beth Clark, (bac3g13@soton.ac.uk, 07785 537682).

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers (contact details above) who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you for taking the time to read the information sheet and considering taking part in the research.

Appendix TT Delphi study consent form

Consent Form – Delphi Study

Version 1 – 20th September 2019

Title of the Study:

Examining the recommendation for 45 minutes of therapy following stroke

Name of the Researcher: Beth Clark

Ethics reference number: 17994

Participant Identification Number:

Please initial the corresponding boxes if you agree with the following statements:

1. I have read and understood the information sheet (date 11th October 2019 version 5) and have had the opportunity to ask questions about the study ☐

2. I understand my participation is voluntary and I may withdraw at any time without negative consequence and without having to give reason. In addition, should I not wish to answer any question or questions then I am free to decline ☐

3. I give permission for my anonymised responses to be used during the Delphi process, and to be accessed by members of the research team. I understand that my name will not be linked with the research materials, and I will not be identifiable during the Delphi process or in the reports that result from the research. ☐

4. I agree to take part in this research project ☐

Name of Participant (Print Name)	
Signature of participant	
Name of Researcher	Beth Clark
Signature of Researcher	
Date	

Appendix UU Delphi statement analysis and rewording

This file evidences how Delphi statements were re-worded, on the basis of agreement and comments made in previous rounds. It does not include statements that reached consensus without being reworded.

R1 = Round 1

R2 = Round 2

R3 = Round 3

Binary agreement was also calculated to determine if responses were tending towards agree or disagree

Statements that gained consensus in round 2

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 If a stroke survivor isn't making progress in therapy, they are unlikely to continue to	Disagree - 11.4% Ambiguous - 42.9% Agree - 45.7%	Disagree – 20% Agree – 80%	"It very much depends on the situation and whether this has been the case for a few therapy sessions and what the other MDT	If there is agreement that a stroke survivor is persistently failing to make progress in

receive 45 minutes of therapy daily			therapists and nursing staff observe” “it is dependent how long they have been receiving therapy for type of stroke etc ie if only for one week then I would give more time for patient to progress” “Again dependent on reasons and if a sustained input has not seen any improvements and other approaches have been explored without success”	therapy, they are unlikely to continue to receive 45 minutes of therapy daily

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 In the community, a Stroke survivor may not receive 45 minutes of therapy if they are prioritising getting on with their life	Disagree – 3.2% Ambiguous – 45.2% Agree – 51.6%	Disagree – 6.5% Agree – 93.5%	It depends on patient wishes. Community teams are using this as a convenient get-out with short resources calling it 'self-management'. Hard to say as I have never worked in the community. But in order to be patient centered this sou ds reasonable.	In the community, a Stroke survivor may not receive 45 minutes of therapy if they feel it more important to get on with their life

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 A stroke survivor may not receive 45 minutes of therapy due to new patient assessments being prioritised	Disagree – 5.7% Ambiguous – 37.1% Agree – 57.1%	Disagree – 11.4% Agree – 88.6%	new patients are prioritised but we have separate HASU team to accommodate this need After initial assessment in the community the stroke survivor is likely to go on a waiting list for ongoing therapy This is definitely a case on HASU not so much in ESD or ASU.	In the Hyperacute Stroke Unit, A stroke survivor may not receive 45 minutes of therapy due to new patient assessments being seen as a priority

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - A stroke survivor may not receive 45 minutes of therapy due to patient discharges being seen as a priority	Disagree – 14.3% Ambiguous – 20% Agree – 65.7%	Disagree – 17.1% Agree – 82.9%	This is seen as the number one priority in an acute hospital. Again we have the luxury of knowing these dates and d/c is usually smooth with no extra effort on day of d/c needed from therapists. We are advised not to take a new person onto our caseload until we have completed the discharge admin for the one they are replacing however in practise the discharge admin usually takes 2nd place	In the Hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy due to patient discharges being seen as a priority

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - A stroke survivor may not receive 45 minutes of therapy because of the size of the therapists' caseload	Disagree – 14.3% Ambiguous – 14.3% Agree – 71.4%	Disagree – 14.3% Agree – 85.7%	More of a problem in the acute setting In the acute hospital this was definitely the reason in a rehab unit our caseload size is fixed to the number of beds we have so less of an issue.	In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy because of the size of the therapists' caseload

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - Non-patient contact activities (such as handover, MDT meetings, planning therapy sessions, ordering equipment and documentation) limit my ability to deliver 45 minutes of therapy to stroke survivors	Disagree – 14.3% Ambiguous – 22.9% Agree – 62.9%	Disagree – 17.1% Agree – 82.9%	Patient contact needs to be prioritised in line with the guidelines. Personally disagree - but I do see this as a problem within my team/colleagues.	Within teams I have worked in non-patient contact activities (such as handover, MDT meetings, planning therapy sessions, ordering equipment and paper work) can limit therapists' ability to deliver 45 minutes of therapy to stroke survivors

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan

R1 - If a relative and/or carer are aware of the guidance, then I am more likely to ensure the stroke survivor receives 45 minutes of therapy	Disagree – 74.3% Ambiguous – 22.9% Agree – 2.9%	Disagree – 91.4% Agree – 8.6%	not fully clear what the statement is referring to (slightly disagree) If patients and families were more aware of what they should be getting services would not get away with the under-provision they are currently getting away with. This is not shared with people and is instead kept from them. (slightly agree)	The decisions I make about the amount of therapy I provide to a stroke survivor are not influenced by the stroke survivor, relative/carers' knowledge of the 45 minute guideline

Original Statement	**Agreement – Thirds**	**Agreement – Binary**	**Relevant Comments**	**New Statement/Plan**
R1 - A stroke survivor may not receive 45 minutes of therapy if they need to go for a medical investigation	Disagree – 5.7% Ambiguous – 22.9% Agree – 71.4%	Disagree – 8.6% Agree – 91.4%	Therapy should be available at othere times if medical condition allows (disagree) If the investigation is important we may need to wait for the result. The session will try to be rescheduled if possible (slightly agree) This should not happen however if the patient spends a lot of time in medical investigation ther therapy time gets limited in practice due to limited therapy hour available in a day. (slightly agree)	In the in-patient setting, a stroke survivor may not receive 45 minutes of therapy if they need to go off the ward for a medical investigation and I am unable to reschedule their therapy that day

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - Stroke survivors may not receive 45 minutes of therapy in the acute setting, due to the fast-paced nature of the service	Disagree – 9.7 Ambiguous – 32.3% Agree – 58.15	Disagree – 12.9% Agree – 87.1%	However 'fast-paced' is used as an excuse for failure to meet guidelines the truth is that services are falling short because they are not adequately resourced. Depends on capacity and caseload - expectations are to see new patients and discharges as a priority over rehab in acute setting - TA's help to support this area of rehab we have a dedicated HASU team so patients should receive what they require but at times the caseload may be busy	The fast-paced nature of the hyperacute/acute setting can make delivery of 45 minutes of therapy more challenging

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - Stroke survivors continue to receive therapy for as long as they would benefit from it, within the ESD setting	Disagree – 52% Ambiguous – 24% Agree – 24%	Disagree – 76% Agree – 24%	also important to consider goals and whether they are meeting these Due to lack of staffing resources and high caseloads it is not always possible to provide the patient with the full amount of therapy they require	Due to the time-limited nature of many ESD services, some stroke survivors are discharged from ESD when they would still benefit from 45 minutes of therapy, 5 days per week

			sometimes the the non specialist therapist does not recognise potential and discharge too early	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - Logistically, it is difficult to return to a stroke survivor for a second time in a day, if they are unable to tolerate 45 minutes of therapy in one session	Disagree – 14.3% Ambiguous – 48.6% Agree – 37.1%	Disagree – 28.6% Agree – 71.4%	not always possible but should be tried. Shoorter frequent session must be plabnned carefully to make this possible. In ESD not on the ward In inpatient or ESD? Agree to some degree for ESD but not for inpatients. Logistically ESD services within rural areas are more greatly impacted due to staffing numbers.	In ESD, it is difficult to return to a stroke survivor for a second time in a day, if they are unable to tolerate 45 minutes of therapy in one session

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - If a stroke survivor remains very dependent on care, they are unlikely to continue to	Disagree – 55.9% Ambiguous – 29.4%	Disagree – 70.6% Agree - 29.4%	“Depends on the goal of therapy. Thy might remain dependent on care for certain aspects	If a stroke survivor remains very dependent on care, they won't

receive 45 minutes of therapy daily.	Agree – 14.7%		however there still might be rehabilitation goals for intensive therapy" "It would depend on how long we had been trying for and how much the client was tolerating as mentioned in previous answers." "depends at what stage of their rehab journey they are on (time wise) and what goals we are working towards - if low level goals and are making some small changes I'd give them the same as a patient functioning at a high level." "With higher care needs it is more likely for a patient to be unable to tolerate 45 minute sessions but will still receive as much therapy as they can tolerate. Very dependant on individual cases"	continue to receive 45 minutes of therapy daily

Original Statement	**Agreement – Thirds**	**Agreement – Binary**	**Relevant Comments**	**New Statement/Plan**
R1 - A Stroke survivor may not receive 45 minutes of therapy if they speak little or no English	Disagree – 64.7% Ambiguous – 26.5% Agree – 8.8%	Disagree – 82.4% Agree – 17.6%	it is hard to give quality therapy when they don't speak English especially if trying to complete cognitive rehab	A stroke survivor will not receive 45 minutes of therapy if they lack comprehension of spoken language

			Not ideal but may limit what therapy can be completed As therapists we try and arrange interpreters to assist with therapy and also try and utilise friends and family. However this is not always available and therefore patient may receive less input.	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - A Stroke survivor may not receive 45 minutes of therapy due to social issues (such as lack of social support, addiction or social complexity)	Disagree – 70.6% Ambiguous – 14.7% Agree – 14.7%	Disagree – 76.5% Agree – 23.5%	Any added complexity to someone's care will impede rapid discharge and if length of stay can not be shortened they are low priority. On the wards this should not be an issue however some areas have no ESD so would be unable to see daily for 45 mins Not an issue in acute hospital environment but could be in community settings With individuals with very complex social environments our sessions in ESD can end up trying to ensure safety at home and sorting out these social challenges rather than delivering specific therapy. This can affect the	In an inpatient setting, a Stroke survivor may not receive 45 minutes of therapy due to social issues (such as lack of social support, addiction or social complexity)

			amount of therapy input we are able to deliver. We go out with the intention to deliver therapy but more urgent pressing matters may be raised and helping support with these issues can also be therapeutic and important for the patient to enable them to move forward in their recovery after stroke.	

Statements that gained consensus in round 3

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement
R1 - A therapy session may end if the stroke survivor is not able to maintain appropriate attention to the therapy input	Disagree - 2.9% Ambiguous - 31.4% Agree - 65.7%	Disagree – 8.6% Agree – 91.4%	"Dependent on the reasons for this impaired attention - if other approaches or methods are not successful." (strongly agree) "Part of the OT session will be to improve their attention- starting with shorter sessions as tolerated" (slightly disagree) Many comments allude to the use of strategies	"A therapy session may end if the stroke survivor is not able to maintain attention to the therapy input, despite strategies to assist with maintenance of attention"
R2 - A therapy session may end if the stroke survivor is not able to maintain attention to the	Disagree – 6.9% Ambiguous – 24.1%	Disagree – 6.9% Agree – 93.1%	**"**Therapy may be to increase attention" (disagree)	A therapy session may end if the stroke survivor is not able to

therapy input, despite strategies to assist with maintenance of attention	Agree – 69%		"Need to find other strategies" (slightly agree) "In our unit we would probably take a little and often approach to patients like this or jointly treat with psychology or OT" (slightly agree) "I may first adjust the task to engage the patient" (Slightly agree) "May continue with passive ROM and positioning" (slightly agree)	maintain attention to the therapy input, despite strategies to increase and/or motivate attention

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement
R1 - A Stroke survivor may not receive the recommended amount of therapy if they are not motivated for therapy	Disagree – 8.8% Ambiguous – 55.9% Agree – 35.3%	Disagree – 14.7% Agree – 85.3%	"need to review reasons that they are not motivated and see if any are modifiable ty and ensure approach holistic eg address low mood etc" "I think as inpatient therapists we continue to see these patients and find other ways to motivate	"A Stroke survivor may not receive the recommended amount of therapy if they remain unmotivated, despite efforts to increase or manage motivation."

			them. They may not receive 45 minutes every day but will do so as much as possible. They are less likely to continue with community services however." "If their lack of motivation is resulting in no or much slower than expected progress being made (despite efforts to encourage motivation) we would discharge"	
R2 - A Stroke survivor may not receive 45 minutes of therapy if they remain unmotivated, despite efforts to increase or manage motivation	Disagree – 6.9% Ambiguous – 34.5% Agree – 58.6%	Disagree – 13.8% Agree – 86.2%	**"**As long as mood and cognition have been addressed" (slightly agree) **"**If a patient continues not to engage despite every effort of trying to get an interesting topic then the sessions may be reduced slightly" (slightly agree) **"**a feel this is secondary to a lack of psychology input in the acute setting. As a OT a attempt to advocate for a patients and how mood and emotions can be impacted by the stroke but with no clinical input to support patients early on there is a chance that they disengage." (slightly agree) "If they do not engage a short session may be better than nothing at all." (slightly agree)	In some circumstances a stroke survivor who remains unmotivated despite efforts to increase or manage motivation may not receive 45 minutes of daily therapy

			"it depends on the situation how long post stroke family support etc. hard to answer the question as this is a very patient specific thing and not always a straight yes/no." (slightly disagree) "If they are not engaging despite therapists best efforts then they will have poor carryover and rehab potential. If they are participating a little bit AND changes can be seen then therapy will continue" (slightly agree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement
R1 - A Stroke survivor may not be prioritised for daily therapy if they are not consistently participating in therapy	Disagree – 23.5% Ambiguous – 44.1% Agree – 32.4%	Disagree – 29.4% Agree – 70.6%	It would depend on the reason for inconsistent participation as mentioned in previous answers e.g. cognition vs choice. The reason needs to be further expored and established rather than withdrwaing therapy Depending on the reasons for not participating. If it is cognitive issue then they will continue to attempt to see the pt. However if they have not a particular reason then they will be timetabled less.	"If a stroke survivor is not participating in therapy, despite efforts to encourage and enable participation, then they may not be prioritised for daily therapy"

R2 - If a stroke survivor is not participating in therapy, despite efforts to encourage and enable participation, then they may not be prioritised for daily therapy	Disagree – 3.4% Ambiguous – 34.5% Agree – 62.1%	Disagree – 10.3% Agree – 89.7%	"Therapists should continue to offer and document if and why patients declines - this could count as an interaction" (slightly agree) "It depends how long they have not been engaging for. If this is a new behaviour then they will still be prioritise for a period of time to try and change this. If this is a continuation over a periods of weeks then they may not be prioritise." (slightly disagree) "when staffing is low and pressures for beds is high - yes this does happen but it does not fit well with our morals." (slightly agree) "This is multifactorial and dependent on reason not participating." (disagree) "if not acheieving goals and all avenues have been explored." (slightly agree)	If a stroke survivor consistently does not participate in therapy, despite efforts to encourage and enable participation, then they may not be prioritised for daily therapy

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement
R1 - If a stroke survivor can exercise independently, they are	Disagree – 41.2% Ambiguous – 38.2% Agree – 20.6%	Disagree - 64.7% Agree – 35.3%	"Variable If a patient is independent therapy complete and ready for discharge they would not would not receive 45 minutes daily Patient	"If a stroke survivor can exercise independently, they

unlikely to receive 45 minutes of therapy daily			may be able to complete an independent exercise programme but still require therapy input for more complex tasks - these would still receive 45 minutes" "if they have goals to improve their deficits they will be seen by therapy. We encourage all patients to do exercises independently or with family. Only if they have no deficits will they not be seen"	are won't receive 45 minutes of therapy daily"
R2 - If a stroke survivor can exercise independently, they won't receive 45 minutes of therapy daily	Disagree – 55.2% Ambiguous – 31% Agree – 13.8%	Disagree – 65.5% Agree – 34.5%	"If applicable we may substitute some of their sessions for independent exercises that we prescribe." (slightly agree) "depends on what exercise? A patient maybe able to be set up to do the GRASP programme independently but we wouldn't include this as their therapy - they will then be seen for a OT / PT session." (disagree) "self management is vitally important and out-weighs any therapist led treatment." (agree) "walking wounded: if they have cognitive impairment for example they will receive therapy" (strongly disagree)	"If a stroke survivor is able to undertake ANY independent exercise, then they won't receive 45 minutes of therapy"

			"would depend if still required specific therapy if so coulod have 45 minutes therapy and still do additional exercises independently" (slightly disagree)	

Statements that didn't gain consensus

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - A Stroke survivor may not receive the recommended amount of therapy if they are low in mood.	Disagree – 23.5% Ambiguous – 47.1% Agree – 29.4%	Disagree – 34.3% Agree – 64.7%	"Might require other psychological therapy first before physical participation. Therapy session might need to be modified e.g. short more frequent sessions " "If this affects engagement or they choose to decline the sessions. Efforts would be made to address mood and engage." "If the stroke survivor is not engaging in therapy due to low mood (despite efforts to engage them) then yes"	"If a stroke survivor's low mood is limiting their therapy engagement, despite efforts and intervention to address it, then they may not receive 45 minutes of daily therapy"

R2 - If a stroke survivor's low mood is limiting their therapy engagement, despite efforts and intervention to address it, then they may not receive 45 minutes of daily therapy	Disagree – 10.3% Ambiguous – 31% Agree – 58.6%	Disagree – 27.6% Agree – 72.4%	**"**I would focus on their goals as a motivator to participate" (slightly disagree) "The therapy may change focus ie discussing issues letting the person talk about their feelings and how therapy may help." (slightly disagree) "they may not recieve the 45 miute therapy but I would suggest that this patient needs to leave the acute setting to rehab where they will have access to psychological therapy." (slightly agree) "Again you can put them off completely so something is better than nothing - even if that is not 45 mins - but I would try!" (slightly agree)	A stroke survivor may not receive a full 45 minutes of daily therapy if their low mood limits their engagement, despite amendments to their therapy.
R3 - A stroke survivor may not receive a full 45 minutes of daily therapy if their low mood limits their engagement, despite amendments to their therapy	Disagree – 3.9% Ambiguous – 26.9% Agree – 69.2%	Disagree – 11.5% Agree – 88.5%	They may get a lot of time problem solving but not necessarily therapy (agree) We would try but this is not always possible (slightly agree)	Very close to consensus! This question has been in all three rounds and still not yet reached consensus.

			All attempts will be to find something that they will engage in this may not only be physical tasks. (disagree) If mood is impacting on engagement in therapy we would seek medical advice and ? referral to counselling. (Agree) But would be offered two shorter sessions if capacity allows (Agree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - A Stroke survivor may not receive the recommended amount of therapy if they have visitors	Disagree – 41.2% Ambiguous – 44.1% Agree – 14.7%	Disagree – 50% Agree – 50%	"Only is the patient strongly declines physio and even then we will try and accommodate and see them at another time that day" "There may be occasions when this is true if the stroke survivor does not consent to therapy because of visitors however we would expect therapy to take precedence"	"A stroke survivor who declines therapy in preference to spending time with their visitors may not receive 45 minutes of daily therapy"

			"We encourage visitors to come and see sessions if the patient consents as it makes them more realistic in their expectations. Sometimes patients decline us because of their visitors"	
R2 - A stroke survivor who declines therapy in preference to spending time with their visitors may not receive 45 minutes of daily therapy	Disagree – 13.8% Ambiguous – 31% Agree – 55.2%	Disagree – 17.2% Agree – 82.8%	**"**we do our best to educate both patient and family regarding the importance of therapy and therefore this rarely happens." (slightly disagree) "If it is logistically difficult to offer the therapy at a different time then yes....but if possible this shouldn't be a limiting factor." (slightly agree) "Therapist will try to encourage them and explain why therapy is important but at the end of teh day the patient has to consent to input. The therapist will try and arrange a more convenient time (i.e. avoid visting time) or will involve the visitors in sessions if appropriate" (slightly agree) "attempt to avoid this through timetables and involving relatives in sessions" (slightly agree)	A stroke survivor who declines therapy in preference to spending time with their visitors (despite the importance being explained to them) may not receive 45 minutes of daily therapy

			"try to be flexible but may not be avble to reschedule session if patient decides to see relatives but this would be explained so they could make an informed choice" (slightly agree)	
R3 - A stroke survivor who declines therapy in preference to spending time with their visitors (despite the importance being explained to them) may not receive 45 minutes of daily therapy	Disagree – 3.85% Ambiguous – 23.08% Agree – 73.08%	Disagree – 7.69% Agree – 92.31%	Could ask their visitors to participate in therapy input e.g. encouragement with exercises (slightly agree) We would try to encourage them otherwise and would return if we have time - which we may not (slightly agree) If the patient has capacity then if they decide that visitors are their priority then they may miss their session if another time can not be found (strongly agree) Try to work around it but this may be inevitable (slightly agree)	Close to agreement, but doesn't reach 75%

			rearrange to another time and explain to family (disagree) How can we go against patient choice? (strongly agree) if their therapy time cannot be done later that day yes (agree) We would normally liase with visitors and try to arrange therapy at different times to regular visiting times to aim to avoid this. (slightly agree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - A Stroke survivor may not receive 45 minutes of therapy if they have other priorities (such as an appointment or a wish to do something else at the time they are offered therapy).	Disagree – 8.8% Ambiguous – 26.4% Agree – 61.8%	Disagree – 8.8% Agree – 91.2%	Many times it is patient choice. Or if there is an important medical appointment that may take weeks to reschedule then that takes priority	"A Stroke survivor may not receive 45 minutes of therapy if they express a lack of interest in therapy in preference to other activities (such as a non-medical appointment or a wish to do something else)."

			On the ward this is often the case when patients have medical investigations to attend. If they wish to do something else and do not consent for therapy yes.	Many of the comments talk about consent (and potential lack of consent). Lack of consent is a consensus reason why someone might not receive 45 minutes. Could I legitimately exclude this statement and conclude that it is one of the reasons that someone might not consent?
R2 - A Stroke survivor may not receive 45 minutes of therapy if they express a lack of interest in therapy in preference to other activities (such as a non-medical appointment or a wish to do something else)	Disagree – 20.7% Ambiguous – 31% Agree – 48.3%	Disagree – 27.6% Agree – 72.4%	"Incorporate enjoyable tasks in to treatment" (disagree) "Without consent the patient would not receive therapy" (strongly disagree) - ?did they answer this incorrectly "We will try and include other activities within therapy." (slightly disagree) "We may try and alter our treatment approach but if we run out of approaches I think I would agree" (slightly agree) "comes down to consent and informed decisions which is our role as OT to ensure our patients make decisions on facts - they have the choice." (slightly agree)	A Stroke survivor may not receive 45 minutes of therapy if they prioritise other activities, such as non-medical appointments or simply wish to do something else (despite the importance of therapy being explained to them).

			"If they decline therapy input then they wouldn't receive the 45 mins." (agree) "Think outside the box - can therapy be incorporated into these other activities?" (slightly disagree) "Once efforts are made to explain benefits of therapy" (agree) "There should be patient choice so if they are informed about therapy what it can offer and the benefits then they are perfectly entitled to decline it!" (Agree) "patient centred approach" (slightly agree) "They need to consent to therapy input. The therapist should try and reschedule their session to accommodate the medical test" (slightly agree) "This is where goal setting is massively important as therapy goals and patient goals should be coherent." (disagree)	

			"Although would encourage participation" (agree)	
R3 - A Stroke survivor may not receive 45 minutes of therapy if they prioritise other activities, such as non-medical appointments or simply wish to do something else (despite the importance of therapy being explained to them)	Disagree – 7.7% Ambiguous – 23.1% Agree – 69.2%	Disagree – 7.7% Agree – 92.3%	If they demonstrate mental capacity to make that decision (agree) Again this is if we have time to come back to them (slightly agree) see answer for Q9 (agree) – if they have capacity. if they decline following full information and advice given and they have capacity then they will receive less (slightly agree) the reality is in the community the time and energy it takes for somebody to go out of the house means they wont have the energy for physio. Anyway isn't rehab about encouraging return to normal life surely going out for a non medical appointment and enjoying a normal activity is rehab? (strongly agree)	Very close to consensus! Can't really tell from the comments why people have disagreed

			If consent is not gained then therapists will not be able to see the patient but attempts are made to try to plan therapy to work around meaningful occupations and routines if possible. (agree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R2 - Their own anxiety is a reason why a stroke survivor may not tolerate 45 minutes of therapy (this statement was suggested by a participant in round 1)	Disagree – 10.3% Ambiguous – 44.8% Agree – 44.8%	Disagree – 31% Agree – 69%	Therapy sessions would be adapted to try and improve this (disagree) I would try to break the 45 mins down into chunks they can cope with but this is not always possible. (slightly disagree) Depends on their level of anxiety. Some patients are very anxious about falling and this limits their rehab potential. Generally speaking it shouldn't interfere and the therapist should set goals with the patient so can work on things they want to do (disagree) possibility if this is fatiguing (slightly agree)	If a stroke survivor is anxious and strategies to manage their anxiety are not effective, then they may not receive 45 minutes of therapy.

			You should still be able to work through the anxiety often these patients get more than 45 but with less activity. (slightly disagree) however support would be put in place to manage this (slighty agree) Can impact sessions but usually manageable via strategies (slightly disagree)	
R3 - If a stroke survivor is anxious and strategies to manage their anxiety are not effective, then they may not receive 45 minutes of therapy	Disagree – 3.9% Ambiguous – 61.5% Agree – 34.6%	Disagree – 30.8% Agree – 69.2%	May benefit from breathing exercises (slightly disagree) Again we would really try (slightly agree) Depending on whether the sessions are making the anxiety worse or not. The goal itself would be to reduce anxiety. (slightly disagree) depends if they are still showing improvements with therapy (slightly disagree)	Unable to gain consensus

			as long as all other strategies have faild (agree) If they consent then therapy could be modified to account for the anxiety (slightly agree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R2 - If a stroke survivor has behavioural issues that impact engagement then they may not receive 45 minutes of therapy (this statement was suggested by a participant in round 1)	Disagree – 10.3% Ambiguous – 31% Agree – 58.6%	Disagree – 20.7% Agree – 79.3%	Important to find strategies (slightly disagree) Depending on what the behaviour issues were. this should not impact their therapy. (slightly disagree) Would try to avoid missing therapy but depends on extend and nature of behaviour issue. (slightly disagree) Efforts should be made to overcome such barriers but it may not be possible (slightly agree)	If a stroke survivor has behavioural issues that impact engagement, which cannot effectively be managed, then they may not receive 45 minutes of therapy
R3 - If a stroke survivor has behavioural issues that impact engagement, which cannot effectively be managed, then	Disagree - 0% Ambiguous – 38.5% Agree – 61.5%	Disagree – 3.8% Agree – 96.2%	Do what they can - I believe doing something is better than nothing (slightly agree)	Close to agreement

they may not receive 45 minutes of therapy			It depends but this is possible (slightly agree) If the behaviour issues turn aggressive and it puts people at risk then sessions would change (slightly agree) it needs to be safe for staff (slightly agree) Although hopefully therapy could be modified to take account of the behavioural challenges (agree) only if all other strategies have been tried (slightly agree) We would have a behavioural plan made in consultation with our psychologist to attempt to manage this. (agree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R2 - If a stroke survivor has cognitive impairment (either	Disagree – 24.1% Ambiguous – 41.4%	Disagree – 37.9% Agree – 62.1%	Depend whether they can tolerate a 45 min session. (slightly disagree)	If a stroke survivor has severe cognitive impairment (either new

new or pre-stroke) that that impacts engagement then they may not receive 45 minutes of therapy (this statement was suggested by a participant in round 1)	Agree – 34.5%		We may complete joint sessions rather than isolated profession sessions though. (disagree) comprehensive assessment of cog is required to develop a treatment plan around this for the MDT to follow. (disagree) I would try to think of something to do with them! (slightly disagree) Depends on level of impairment and their carryover/rehab potential. If they are showing improvements then they will be seen (slightly agree) if severely impaired with low rehab potential (slightly agree) Likely will still receive it but in a different format (slightly disagree)	or pre-stroke) which impacts their engagement then they may not receive the full 45 minutes of therapy
R3 - If a stroke survivor has severe cognitive impairment (either new or pre-stroke) which impacts their engagement then	Disagree - 11.5% Ambiguous – 38.5% Agree – 50%	Disagree – 34.6% Agree – 65.4%	Do what they can - I believe doing something is better than nothing (slightly agree) We would really try here (slightly disagree)	Closest to agreement

they may not receive the full 45 minutes of therapy			Strategies should be used to overcome engagement issues and/or therapy may focus on cognitive deficits if new since stroke. (disagree) If they could tolerate a productive 45 min session then they would be offered it. (slightly disagree) if rehab potential is low because of severe impairment following approx. 2 weeks input and not meeting small goals (slightly agree) depends if they are improving and meeting goals. will try to involve family (slightly agree) If cognitive impairment impacting on therapy we would look at adapting therapy input (disagree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan

R2 - If the stroke survivor cannot identify achievable, meaningful goals, then they will not receive 45 minutes of therapy (statement was developed from a goals-related statement in round 1)	Disagree – 65.6% Ambiguous – 10.3% Agree – 24.1%	Disagree – 69% Agree – 31%	If there are deficits that's the patient may not identify and after a physio assessment there could be improvement then they would still receive therapy. (slightly disagree) Part of therapy might focus on ideifying goals (slightly disagree) No-one who 'agreed' wrote any comments.	If the stroke survivor does not independently identify any goals they may not receive 45 minutes of therapy
R3 - If the stroke survivor does not independently identify any goals they will not receive 45 minutes of therapy	Disagree - 73.08% Ambiguous – 15.38% Agree – 11.54%	Disagree – 76.92% Agree – 23.08%	The stroke survivor may not b able to express their goals due to communication impairments or may not have the insight or cognitive ability to independently set goals but can with assistance from the therapist (strongly disagree) Sometimes it is hard at the inpatient stage for patients to identify goals (disagree) therapist will create goals in best interests (strongly disagree) we will try to set goals with them but if not the therapists will set them (disagree)	Very close to consensus disagreement. May have gained a different outcome if made it explicit that they can/can't communicate…have the cognitive ability to participate in goal setting.

			Some patients may be unable to set goals and in this case where they quite clearly have rehab needs we would set these which may be in collaboration with family/carers (disagree) Reasons for not being able to identify needs exploring … other strategies eg. caregivers goals and involvement should be considered (disagree) Therapists can facilitate the goal setting process (disagree) it depends if the patient is able to identify goals eg has no communication or cognitive issues and has nothing s/he wants to work towards why are we trying to rehab them . but other people eg somebody with a severe aphasia may not be able to communicate goals but we would make our best guess and continue working with them (slightly disagree) Patients who have had a severe stroke often can't identify their own goals but require support from therapists to identify but this doesn't affect therapy time spent. (disagree) We would suggest goals if they did not come up with any independently but if our suggestions were rejected	

			as not important to them we would not continue (Slightly agree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R2 - Non-clinical commitments (such as managerial responsibility or the education/supervision of others) impact the ability of therapists to deliver 45 minutes of therapy to their caseload. (this statement was suggested by a participant in round 1)	Disagree – 7.1% Ambiguous – 35.7% Agree – 57.1%	Disagree – 7.1% Agree – 92.9%	Tend to do these after hours if needed. (slightly agree) some times (slightly agree) Often non clinical commitments are not prioritised over patient needs but depends on the situation (slightly agree) The other commitments are part of the role and ensure a well skilled and well running/efficient service it should therefore be taken into consideration when job planning and ensuring appropriate staffing not be blamed for not hitting the 45 minutes. (disagree)	Non-clinical commitments (such as managerial responsibility or the education/supervision of others) sometimes impact the ability of therapists to deliver 45 minutes of therapy to their caseload.
R3 - Non-clinical commitments (such as managerial responsibility or the education/supervision of others)	Disagree - 0% Ambiguous – 30.8% Agree – 69.2%	Disagree – 11.5% Agree – 88.5%	patients are priority but education is also a key part of the job (slightly agree)	Very close to consensus agreement

sometimes impact the ability of therapists to deliver 45 minutes of therapy to their caseload			patients are usually prioritised (slightly agree) very much depends on our staffing. if we are full capacity then no - if we down then supervisions normally are affected rather than therapy. (slightly disagree) Ability to provide adequate education/supervision of others is particularly difficult due to ever reducing staff levels (including therapy assistants) within stroke services and increasing caseloads. In order to provide an appropriate level of supervision/meet managerial responsibilities/support therapy students as per HCPC guidelines and senior management expectation it means less time is available for face-to-face clinical time. (agree)	It's possible that this is dependent on other factors, such as staffing, of what a service prioritises (if they strongly prioritise patients over non-clinical commitments).

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R2 - If I, as the therapist, cannot identify achievable, meaningful goals, then the stroke survivor	Disagree – 42.9% Ambiguous – 39.3% Agree – 17.9%	Disagree – 50% Agree – 50%	They will not be a priority but will receive some physio (agree)	If I am unable to identify any goals for the stroke survivor, they may not receive 45 minutes of therapy.

will not receive 45 minutes of therapy (developed from a statement in round one about goals)			We are not in a position to know what is important to that client. (disagree) patient centred care!! the person has their own goals. (disagree) If there is really nothing left to achieve then therapy input may decrease (slightly agree) This would indicate limited benefit from therapy if there are no goals to achieve (agree) If the patient is not achieving their goals or showing progress they are not benefiting from therapy input and it should be discontinued (slightly agree) if the patient can then we will work towards those (disagree) In collaboration with MDT (slightly agree) Agree with the achievable aspect of this statement. Something may still be meaningful though. (slightly agree)	

R3 - If I am unable to identify any goals for the stroke survivor, they may not receive 45 minutes of therapy	Disagree - 23.1% Ambiguous – 26.9% Agree – 50%	Disagree – 30.8% Agree – 69.2%	This would suggest no benefit to therapy input Depending on the patients point of view (slightly agree) if they have met all of their goals (slightly agree) The client sets the goals unless they cant. In this case if we can not identify any rehab needs then they may be discharged from that therapy. (disagree) Might need to think other ways of providing therapy might not require 45min face to face tHERAPY If I do not know what I am trying to achieve I should not be treating the patient unless they had previous carer support for all ADLs and eatung and tramsfers are at baseline (disagree)	Closest to agreement, but may be unlikely to gain consensus for this statement

			This implies that the patient may not be appropriate for active therapy hence likely not a priority they would more likely receive approx 20 mins of therapy 3-5 x per week for disability management. (agree) If the patient had a goal we would continue with therapy (strongly disagree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R3 - If neither I, as the therapist, nor the stroke survivor can identify any meaningful, achievable goals, then they will not receive 45 minutes of therapy (developed from goal statements in previous rounds)	Disagree - 7.7% Ambiguous – 23.1% Agree – 69.2%	Disagree – 23.1% Agree – 76.9%	Disagree however if the patient is not progressing and is low level and that has not changed then I would agree. (disagree) In this case we needs to be stopping rehab (strongly agree) see above comment (slightly disagree -Above comment: unless they have previous carer support for all ADLs and eating and transfers are at baseline)	(this is the first time this statement was included) Close to agreement

			If the patient has a meaningful goal we believe to be unachievable we would still likely break it down & have a go at achieving a step towards & see how it goes (slightly agree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - A stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session	Disagree – 17.1% Ambiguous – 42.9% Agree – 40%	Disagree – 34.3% Agree – 65.7%	Timetabling as a team can avoid this (slightly disagree) We would endeavour as an MDT not to double book. (disagree) within ESD this is timetabled to ensure this does not happen - the ward should work similarly and all professionals talking to each other (slightly disagree) (it would appear that ESD/Community timetable)	"In the acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session" (ensure you add 'unable to answer based on my experience)
R2 - In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional	Disagree – 10% Ambiguous – 40% Agree – 50%	Disagree – 20% Agree – 80%	"we attempt to timetable patients who are needing all three AHPS to ensure this doesn't happen." (slightly agree)	In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare

at the time of their therapy session			I will try and see them another time if possible (slightly agree) timetabling/planning close communication can overcome this issue (slightly disagree) We can be flexible and either join their session or come back later (slightly disagree) try to revisit later in the day (slightly agree) Depends on professional - sometimes can join session (slightly agree)	professional at the time of their therapy session and I am unable to reschedule
R3 - In the hyperacute/acute setting, a stroke survivor may not receive 45 minutes of therapy if they are seeing another healthcare professional at the time of their therapy session and I am unable to reschedule	Disagree – 0% Ambiguous – 26.32% Agree – 73.68%	Disagree – 0% Agree – 100%	will try and organise another team member (slightly agree) This does happen in practice and is indicative of poor organisation of services for which the patient suffers through no fault of their own. (strongly agree) We attempt to avoid this by timetabling. (agree)	Very close to consensus agreement – and binary agreement = 100%

			typically it would be possible to reschedule and efforts are made to do this. (slightly agree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R2 - Inexperienced or newly qualified staff find it more challenging to deliver the recommended minimum of 45 minutes, 5 days-a-week	Disagree – 18.5% Ambiguous – 37% Agree – 44.5%	Disagree – 29.6% Agree – 70.4%	When I was newly qualified my interventions took longer but were less efficient (slightly disagree) we work a timetabling system that is done by a senior physio. They also have less admin roles / managerial roles on the ward and therefore are mainly clinical (disagree) I feel the opposite here in that we give newer staff more time with clients because they are not as efficient within their sessions yet. (slightly disagree) Most are fine with a bit of training and guidance (slightly disagree) They often have fewer non clinical commitments (disagree)	A stroke survivor may not receive 45 minutes of daily therapy if their therapist is newly qualified and/or inexperienced.

			They are supervised and work closely with more senior staff. They have an induction talk which includes SSNAP and why we do it (disagree) The people who agreed predominantly said it was because newly qualified/inexperienced staff were used to less time with people.	
R3 - A stroke survivor may not receive 45 minutes of daily therapy if their therapist is newly qualified and/or inexperienced	Disagree - 46.2% Ambiguous – 30.8% Agree – 23.1%	Disagree – 61.5% Agree – 38.5%	When I was newly qualified my interactions took longer. We would support any newly qualified staff We try to avoid this where possible and education is given to junior members of staff to understand importance of aiming for 45 mins therapy (slightly disagree) newly qualifieds are supervised closely (disagree)	Overall, closer to disagree than agree Unlikely to gain consensus – might be dependent on the level of support for Band 5's in the organisation. Likely to be a lot of contextual factors, which would need to be unpicked.

			Clear guidance is given to junior therapists and ongoing supervision. Not sure why this would make a difference.	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R2 - In the community (including ESD), lack of effective communication amongst the wider MDT can make delivery of 45 minutes of therapy a challenge (developed from a statement about MDT communication in R1)	Disagree – 18.8% Ambiguous – 43.8% Agree – 37.5%	Disagree – 50% Agree – 50%	Hard to comment as I have limited community experience (slightly disagree) We share an office - ESD and Inpatient staff so we can regularly communicate and plan sessions (slightly disagree) The unpredictability of career times has a real impact and even with trying to accommodate this after there are still clashes. Would be easier if all with in one team. (agree)	In ESD/Community Services lack of effective co-ordination between community services (e.g. carers, GP, District Nurse, any other services involved) may mean stroke survivors do not receive 45 minutes of therapy.
R3 - In ESD/Community Services lack of effective co-ordination between community services (e.g. carers, GP, District Nurse, any other services involved) may	Disagree - 28.6% Ambiguous – 21.4% Agree – 50%	Disagree – 35.7% Agree – 64.3%	There is good communication between services and for the first 5 weeks patients usually receive more than 45 minutes per day (disagree)	Unlikely to gain consensus – this may be different for different services 13

mean stroke survivors do not receive 45 minutes of therapy			As visits may clash client can be to fatigued if too many different visits/appointments occurring. (agree) I have no experience of this being the case (disagree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - The achievement of a good SSNAP score for my organisation influences how therapy is provided to stroke survivors	Disagree – 15.6% Ambiguous – 25% Agree – 59.4%	Disagree – 31.25% Agree – 68.75%	increase in group work and TA time to cover - not necessarily a bad thing but a different way of thinking (agree) Therapy provision is influenced mostly by organisational culture and theraoists knowledge and experience of stroke rehabilitation (strongly disagree) SSNAP is a joke to our team. It has not been designed with community input in mind (disagree)	"The delivery of therapy within my organisation has changed in order to increase the achievement of the 45 minute guideline"

			SSNAP recording are varied across the UK and do not measure quality. Have seen professions achieving high grades on SSNAP but is not reflected in clinical practice (strongly disagree) no influence whatsoever. (disagree)	
R2 - The delivery of therapy within my organisation has changed in order to increase the achievement of the 45 minute guideline	Disagree – 28.6% Ambiguous – 21.4% Agree – 50%	Disagree – 35.7% Agree – 64.3%	Not in the past 5 years or so but prior to that yes (slightly disagree) I'm unsure - I have always worked with the 45 minute guideline (slightly disagree)	Since publication of the guideline, my organisation has changed to improve achievement of 45 minutes therapy
R3 - Since the publication of the guideline, my organisation has changed to improve achievement of 45 minutes therapy	Disagree - 19.2% Ambiguous – 15.4% Agree – 65.4%	Disagree – 30.8% Agree – 69.2%	I have taken part in a Stroke Working Party to update our processes to meet guidelines (Agree) Certainly people are more conscious about how much therapy they provide (strongly agree) Organisations are now all engaged in a free market competitive race to the bottom where contract tenders mean the competition is not based on quality and outcomes but cost. As a	Close to consensus (within 5%) Some comments suggests that guideline achievement is not a priority for organisation. Maybe the priority of guidelines for an organisation depends upon the organisation. People answer based on their experience – therefore, may not reach consensus

			result organisations are increasingly looking to do more with less and this means increasing the number of patients being seen within services with fewer staff to deliver care. Meeting guidelines is not a priority for organisations despite it being so for clinicians- this is in plain language a conflict of interest. (strongly disagree) we don't have more staffing so we can't magic up more sessions. We tend to allocate amount of therapy dependent of assessment findings patients goals patients abilities and come up with a treatment plan that works for stroke survivor and clinician. rather than an arbitrary amount of treatment (slightly disagree) Management is more preoccupied as to the position the service is placed within the statistics reported by SSNAP rather than concerns around patient's receiving the therapy they should be entitled to receive. (disagree) We are not resourced to provide daily therapy in the community so no amount of	13

			reorganisation would enable us to deliver it (disagree)	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R2 - The service I work in is not appropriately funded to provide therapy for at least 45 minutes per day, five days per week (developed based on comments made in round 1)	Disagree – 35.7% Ambiguous – 14.3% Agree – 50%	Disagree – 35.7% Agree – 64.3%	We can do five days but not he seven we have to! (slightly agree) We have empty posts but the posts which are funded should provide enough therapy for patients (disagree) when fully staffed and no staff weakness or leave (its not staffed keeping in mind planed leaves) (agree) If we were at maximum staff 100% of the time then we could probably achieve it but we always have staff on sickness or maternity or vacancies (slightly agree) The majority of stroke services are now inadequately resourced. The market system of competitive contract tenders run by cash-strapped CCGs has led directly to a race to the bottom with each competing organisation	The service I work in is not sufficiently well-funded to provide therapy for at least 45 minutes per day, seven days per week

			offering the service as cheaply as possible and stroke services are fully engaged in it. Stroke is no longer an area where the highest quality of care is received and it is no longer a pleasure or rewarding to work in stroke. (strongly agree) We have seen an increase in patient numbers that is making it harder and harder to deliver the appropriate and required amount of therapy (agree) Speech in particular (slightly agree)	
R3 - The service I work in is not sufficiently well-funded to provide therapy for at least 45 minutes per day, seven days per week	Disagree - 23.1% Ambiguous – 15.4% Agree – 61.5%	Disagree – 34.6% Agree – 65.4%	We have been short staffed of Physiotherapists for 2 years (strongly disagree) when caseload is mid to lower this can be achieved but when high it is not always possible and this is occurring more often. (Agree) weekend cover is reduced staffing. (slightly agree)	Close to consensus (within 15%) Possibly this question is confusing – one of the comments would appear to agree with the statement, although the participant has stated they disagree with the statement. There may just be differences in the way that services are funded

			This underpins every reason for the guideline Therapy not being delivered. It's an ugly truth and one which managers are not facing up to. As a result service quality is perpetually declining patients suffer long-term social and economic costs will rise unmeasured and as is being seen first-hand all around staff are leaving in droves because working in stroke care is no longer anything like the rewarding and desirable specialism it was until the ideological dismantling of the NHS as a system completely ruined its performance as a public service in the last 8 years. (Strongly agree) The hyper acute/acute stroke setting I work in has increased staff numbers at weekends to try and provide an equitable service across 7 days. (Disagree) not for 7 days at present. for 5 days yes (agree) We aim for 5 times a week over 7 days. (agree)	– some may be adequately funded and some may not.

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan

R1 - The presence of the 45 minute guideline influences the amount of therapy I provide to stroke survivors	Disagree – 17.1% Ambiguous – 25.7% Agree – 57.1%	Disagree – 20% Agree – 80%	I am uncertain about the evidence base for this guidance and its relevance to occupational therapy outcomes for the patient so continue to base my decions on amount of therapy on clinical reasoning and patient's goals and decision to engage in therapy. (strongly disagree) We can only provide what we have the staffing to provide (strongly disagree) I will always consider guidelines and research but each client is different. (slightly disagree)	Unsure how I could re-word this. Thought about asking how the introduction of the guideline has influenced, but this will not be applicable for all, as the guideline has been around for nearly 12 years! “I provide 45 minutes of therapy because the guideline says I should”
R2 - I provide 45 minutes of therapy because the guideline says I should	Disagree – 28.6% Ambiguous – 42.9% Agree – 28.6%	Disagree – 35.7% Agree – 64.3%	Struggle to provide 45 mins but try to provide 45 mins because of the guidelines (slightly agree) the guidelines influence the time spent with a patient and how the timetable is laid out. however if more is needed and we have the staffing to provide more then this is what is done (slightly agree) I am aware of the guideline and will try to implement where appropriate but decisions	The existence of the 45 minute guideline increases the amount of therapy I provide to stroke survivors

			about amount of input given are made with each individual in relation to their needs. (disagree) It would be what we aim for but we have to prioritise as we can not provide this service for everyone. I also feel that it is not appropriate for everyone. (slightly agree) It is patient dependent and a continual assessment of need. (disagree) this is our initial approach to therapy but will be reviewed on progress/ medical status (slightly disagree) It is a factor in the decisions I make (slightly agree) However the Stroke Lead Consultant pressures services to achieve this target if not more in order to go up the ranking scale from eg D to A for SSNAP targets for the HealthBoard. (strongly disagree)	

			the guidelines influences but doesn't dictate the amount of therapy provided. (slightly agree) sometimes I do more or less depending on the patient need I don't go into a session thinking I HAVE to do 45 mins (slightly agree) I belive in intensive therapy for people when it is needed and appropriate (strongly disagree) I do not make a conscious effort to time my sessions - I do a treatment session based on what their needs are how much they can tolerate. It is a bit guided if I need to team up with another therapist to see the next patient as we normally plan for 1 hour slots per patient (slightly disagree) The guideline is based on research evidence and has been a good force in driving up therapy standards in stroke care. (agree) And this does seem to be about the amount of physical input that the average patient can tolerate (agree)	

			It is a guide (disagree)	
R3 - The existence of the 45 minute guideline increases the amount of therapy I provide to stroke survivors	Disagree - 15.4% Ambiguous – 34.6% Agree – 50%	Disagree – 38.5% Agree – 61.5%	The evidence is more of a driver for me it certainly gives some structure and sets target (not always though) Some times I provide more sometimes I provide less I think therapy staff would endeavour to see patient's as much as appropriate but guideline encourages accurate recording of this time. Personally I use the guidelines to support my practice and cite them to patients family and management to support my clinical practice. When the guideline was originally published it had a big impact on ensuring teams focussed on the amount of therapy delivered and made us question (and subsequently streamline) non clinical activities. Intensity has become a broader focus for us now and we are more concerned with WHAT happens within therapy	This statement (or similar) has appeared in all 3 rounds of the Delphi. It is essentially aiming to look at the impact that the 45 minute guideline has had on delivery of stroke therapy. Think its unlikely that will reach consensus – likely that people have different views on this. Not a particularly concrete concept.

			than the allocated time.	

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - Providing 45 minutes of therapy seven days a week is not appropriate for the majority of stroke survivors	Disagree – 40% Ambiguous – 48.6% Agree – 11.4%	Disagree – 65.7% Agree – 34.3%	There are a lot of patients who would find this hard - but perhaps less than we think (slightly disagree) It depends on the person (slightly agree) Not all patients cam tolerate it but it would be appropriate for some (slightly agree)	"Most stroke survivors would not want, tolerate or need 45 minutes of therapy, 7 days a week." (The wording of the original statement is difficult, so I think it would be worth re-asking the question for clarification)
R2 - Most stroke survivors would not want, tolerate or need 45 minutes of therapy, 7 days a week	Disagree – 46.4% Ambiguous – 21.4% Agree – 32.1%	Disagree – 50% Agree – 50%	rest is very important and a sense of normality is too and therefore at weekends I do understand when patients decline therapy. (slightly agree) One day off would benefit most people mentally (slightly agree) The moderate /severe stroke pateints are less likely to tolerate such intensity from all 3	Most stroke survivors do not want, tolerate or need 45 minutes of therapy, 7 days a week

			therapies a day and often the therapists carry out one joint session. (strongly agree) most patients are tired and like at least 1 day off a week (agree) some would not tolerate/ want (disagree) Majority of patients would not tolerate any more but there are some patients who can and would want it (slightly agree) If tailored to the individual's goals most people do want to engage in therapy. (strongly disagree) Most want some time off to spend with family/friends when home (agree) This is the community perspective only (agree) Patients usually want more!= (strongly disagree)	
R3 - Most stroke survivors do not want, tolerate or need 45	Disagree - 53.9% Ambiguous – 26.9%	Disagree – 69.2% Agree – 30.8%	don't think we can make general assumptions on such a wide spectrum of complex	Predominantly disagree, but does not reach consensus (and

minutes of therapy, 7 days a week	Agree – 19.2%		impairments. Sometimes it is better to do several shorter sessions than one 45 minute session Some do and some don't Some cannot tolerate this length of therapy but many can In some cases a small number of people do but it is not often we see this. depends on appropriate goals if they can work on them across 7 days then yes - if they cant e.g. too low level then they may not. depends on the set up. eg. in rehab units most do in HASU some might not tolerate and in community thy might not want Many survivors do not want rehabilitation dominating their lives once they are back at home	question has been included in all 3 rounds of delphi) Also, might be a tricky statement – (includes want, tolerate and need – asking multiple questions in one) Might be that some do want/need/tolerate and some don't. Feel it's unlikely that we will reach consensus on this statement. 16

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R2 - It is unrealistic to deliver 45 minutes of therapy, 5 days a week in a community service (post-ESD) (statement developed from comments made in round 1)	Disagree – 27.8% Ambiguous – 16.7% Agree – 55.6%	Disagree – 33.3% Agree – 66.7%	depends on staffing levels surely. (slightly agree) All other comments related to 'agree/strongly agree' . (18 people answered this question (10 selected 'unable to answer'), however, only 10 people have stated that they consider themselves experienced in community rehabilitation)	It is unrealistic to deliver 45 minutes of therapy, 7 days a week in a community service (post-ESD) (include 'unable to answer, based on my experience)
R3 - It is unrealistic to deliver 45 minutes of therapy, 7 days a week in a community service (post-ESD)	Disagree - 31.3% Ambiguous – 18.8% Agree – 50%	Disagree – 43.75% Agree – 56.25%	Dedicated ESD Team timetable sessions (disagree) Not enough resource provision for this level of input (strongly agree) unless there are other forms of providing intensive therapy like groups family/ care giver or peer led (slightly agree) It should be realistic-it is simple: clinical guidelines recommend a level of care services	Not particularly close to consensus. From the comments, it appears that some people may have misunderstood the question and have answered for an ESD service 16 people answered this q, but only 12 have said they have experience in community rehabilitation (post-ESD)

			must be resourced to deliver that level of care. It is time to start being honest about this. (strongly agree) Once home a lot of people especially the milder streokes need time to settle in being at home to figure out their needs and goals. Therapist going in all the time does not give them time to learn self efficacy or give them time to put into practice what we are advising. continued supervision leads to dependence not independence (strongly agree) ESD services are underfunded understaffed lack sufficient resources/equipment to be able to provide this type of service in my geographical area. (agree)	May be different for different services. Therefore, may be unlikely to reach consensus 16

Original Statement	Agreement – Thirds	Agreement – Binary	Relevant Comments	New Statement/Plan
R1 - Stroke survivors who would benefit from more than 45 minutes of therapy-per-day, generally receive it	Disagree – 48.6% Ambiguous – 14.3% Agree – 37.1%	Disagree – 54.3% Agree – 45.7%	Nobody receives it in ESD. Those on the ward receive a diluted version due to use of group therapies regardless of how appropriate this is.	"Stroke survivors who would benefit from more than 45 minutes of therapy-per-day, will receive it"

			Depending on how busy service is at the time this does vary but generally there are not the resources to allow this I appreciate we are likely in a very privileged position to offer this. staffing levels do not support this.	
R3 - Stroke survivors who would benefit from more than 45 minutes of therapy-per-day, will receive it	Disagree - 26.9% Ambiguous – 46.2% Agree – 26.9%	Disagree – 57.7% Agree – 42.3%	See the evidence Staffing/other commitments generally limit this although longer sessions are completed at times where possible If we have the staff to deliver that service If not then they wouldn't. if caseload allows Sometimes but unlikely to be wholly from a qualified therapist and likely to be therapy assistants or groups	I feel we are unlikely to gain consensus regarding this statement. The spread of agreement is fairly evenly split, potentially favouring an ambiguous outcome. It is potentially influenced by resources – some services have the resources to deliver more than 45 minutes, some do not.

			This would only be if capacity allows however this would more commonly exceed 45mins for therapies associated with a therapeutic package of care eg a wash and dress or meal prep may take longer depends on staffing and pressures of hospital. It depends on staffing As a therapy team we would try and provide the amount of therapy appropriate for each patient but this may be impacted by staffing and time available. Time for sessions sometimes are limited due to sharing 45 minutes between other patients across the day. Due to insufficient staffing/resouces the service struggles to provide 45 minutes therapy per day for a 5 day service let alone a 7 day per week service. We do not have the resources. We do vary how much therapy survivors receive tho	

			depending on their commitment & tolerance levels Largely due to capacity.	

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