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University of Southampton

Faculty of Environmental and Life Sciences

School of Health Sciences

Meaningful Outcome Measurement Following Lower Limb Prosthetic Rehabilitation

by

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Thesis for the degree of Doctor of Philosophy

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Abstract

Faculty of Environmental and Life Sciences - School of Health Sciences

Doctor of Philosophy

Meaningful Outcome Measurement Following Lower Limb Prosthetic Rehabilitation

Chantel Ostler

Outcome measurement is crucial to understand the impact of prosthetic rehabilitation. This includes the health and recovery of patients following lower limb amputation and can provide insights to help clinical decision making at the individual level, as well as the service and system levels to inform service improvement and research. Despite its potential value, outcome measurement is not routinely undertaken in prosthetic clinical settings. Little is known about which outcomes should be measured and which measures should be used, particularly considering the perspective of the patient for whom the outcome of prosthetic rehabilitation has the greatest impact.

The aim of this PhD was to understand and contribute to the evidence around meaningful outcome measurement following lower limb prosthetic rehabilitation, and drive changes in clinical practice that foster person-centred approaches to measuring outcome. This aim was addressed across four published papers which comprise this paper-based thesis.

Paper one describes a narrative review which explores the prosthetic outcome measurement literature from a clinical practice perspective. Themes highlight the importance of value in outcome measurement for clinicians, which may be linked to measuring what is meaningful, using feasible outcome measures, as part of outcome measurement practice that informs clinical care. However, understanding outcome domains of importance, especially for prosthetic users is a key issue.

Paper two addresses this issue using a qualitative approach to understand outcome domains of importance following prosthetic rehabilitation from the patient's perspective. Thirty-seven participants recruited from four English prosthetic centres and social media took part in focus groups and interviews. Reflexive thematic analysis was used to generate five themes which describe outcome domains of importance and to develop an initial conceptual model.

Paper three describes a secondary analysis of data collected during the paper two qualitative study and explores the experiences of patients taking part in outcome measurement during prosthetic rehabilitation. Thirty-one participants from the original sample provided data for this analysis which presented four themes describing how outcome measurement made patients feel, concerns about accuracy, questions about who outcome measurement is for, and whether prosthetic services measure what is meaningful. This unique perspective could make outcome measurement practice more meaningful and patient-centred.

The final paper returned to focus on outcome domains of importance and built on paper two's findings. A systematic review and qualitative synthesis using `Best fit' framework analysis was undertaken to explore outcome domains of importance described in the limb loss literature, and further develop the initial conceptual model. Forty studies were included, describing the experience of 539 participants. Analysis led to development of four of the five domains and a second iteration of the conceptual model, named ECLIPSE. Meaningful outcome domains were 1) Being able to participate in important activities and roles, 2) Participating in the way I want to, 3) My prosthesis works for me, 4) If I am in pain, I can manage it, and 5) I am able to accept my new normal.

The ECLIPSE model is a rigorously developed, patient-centred and accessible representation of recovery which could be used to direct prosthetic rehabilitation programmes, as well as inform the evaluation of prosthetic care through the selection of outcome measures. The model sets out which domains should be measured following prosthetic rehabilitation from the patient's perspective, addressing the gap in the literature, and contributing to meaningful outcome measurement practice.

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Research Thesis: Declaration of Authorship

Print name: Chantel Ostler

Title of thesis: Meaningful Outcome Measurement Following Lower Limb Prosthetic Rehabilitation

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:-

Ostler, C., Scott, H., Sedki, I., Kheng, S., Donovan-Hall, M., Dickinson, A., Metcalf, C., (2022) From outcome measurement to improving health outcomes after lower limb amputation—A narrative review exploring outcome measurement from a clinical practice perspective. Prosthetics and Orthotics International 46(4):p e341-e350.

Ostler C, Donovan-Hall M, Dickinson A, Metcalf C. (2023) Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective. Disability and Rehabilitation. 45(23):3937-3950

Ostler C, Donovan-Hall M, Dickinson A, Metcalf C. (2024) Exploring the patient experience and perspectives of taking part in outcome measurement during lower limb prosthetic rehabilitation: a qualitative study, Disability and Rehabilitation.

Ostler C, Donovan-Hall M, Dickinson A, Metcalf C. (Under Review with PLOS one Journal) Development of the ECLIPSE model of meaningful outcome domains following lower limb amputation and prosthetic rehabilitation, through systematic review and best fit framework synthesis

Signature: .... Date: 19/03/24

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Finally thank you to my amazing family. My daughters Kitty and Scarlett who nervously keep asking me if everyone has to do a PhD when they grow up. My wonderful (and new) husband Chris who has obviously put up with my worries and late nights to bed and has developed a side hustle in discussing research papers. Finally, to my ma and pa who have stepped in to look after the kids, cleaned my house, and asked me repeatedly what my PhD is about. Thank you all so much for your support.

Operational definitions and commonly used abbreviations

Outcome domain	An element of health (i.e., pain, physical function, emotional wellbeing, social activity) that is changed by a particular intervention (Clarke *et al.*, 2020).
OM	*Outcome measure*. A standardised instrument used in research and clinical practice to capture and evaluate one or more outcome domains at a single point in time, or evaluate change over time (Robinson and Fatone, 2013).
ROM	*Routine Outcome Measurement*. The systematic use of a standardised OM(s) in clinical practice with every patient as part of a standardised assessment practice guideline (Colquhoun *et al.*, 2010).
Patient Centred	a set of principles that focus on offering personalised, co-ordinated care, in partnership with patients, delivered in a respectful and compassionate way (The health Foundation, 2016).
LLA	*Lower Limb Amputation*. Loss, or removal, of all or part of the lower limb by trauma, illness, or surgery.
TFA	*Transfemoral amputation*. Amputation through the thigh bone, or femur.
TTA	*Transtibial amputation*. Amputation through the shin bone, or tibia.
HD/HAD	*Hip disarticulation amputation*. Amputation through the hip joint.
KD/KDA	*Knee disarticulation amputation.* Amputation through the knee joint.
Symes Amputation	Amputation through the ankle joint.
PPIE	*Patient and public Involvement*. research carried out with or by members of the public rather than ‘to,’ \`about,’ or \`for’ them (Partnership UPISD, 2019)
MDT	*Multidisciplinary team.* Team of clinicians from different professional backgrounds supporting the care and rehabilitation of patients.
BACPAR	*British Association of Chartered Physiotherapists in limb Absence Rehabilitation*. British physiotherapy professional network

BAPO	*British Association of Prosthetists and Orthotists.* Professional body for all UK prosthetists and orthotists.
BSRM	*British Society of Rehabilitation Medicine.* Professional network of British rehabilitation consultants.
ISPO	*International Society of Prosthetics and Orthotics.* Global Professional network of clinicians working in the field of prosthetics and orthotics.
PROM	*Patient Reported Outcome Measure*. Outcome measures which are completed by the patient, often in the form of questionnaires or scales
COMET	*Core outcome measures in effectiveness trials*. An initiative which brings together people interested in the development and application of agreed standardised sets of outcomes.
COS	*Core outcome set*. An agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care (Williamson *et al.*, 2017)
ICHOM	*International Consortium of Health Outcome Measurement*. Organisation developing sets of outcome domains and outcome measures specific to health conditions, for use in clinical practice, to support valued based healthcare (Kelley, 2015).
ICF	*International Classification of Functioning*. A classification system developed by the World Health Organisation (WHO) to provide a universal language to describe the health and functioning of individuals (World Health Organization, 2001)
HIC	*High income country.* Countries with a national income per person of $12,376 or more (The world bank, 2023).
LMIC	*Low- and Middle-Income country.* Countries with a national income per person of between $1,026 and $3,995 (The world bank, 2023).

PhD outputs to date

Publications

- Ostler, C., Scott, H., Sedki, I., Kheng, S., Donovan-Hall, M., Dickinson, A., Metcalf, C., (2022) From outcome measurement to improving health outcomes after lower limb amputation—A narrative review exploring outcome measurement from a clinical practice perspective. *Prosthetics and Orthotics International* 46(4):p e341-e350.
- Ostler C, Donovan-Hall M, Dickinson A, Metcalf C. (2023) Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective. *Disability and Rehabilitation*. 45(23):3937-3950
- Ostler C, Donovan-Hall M, Dickinson A, Metcalf C. (2024) Exploring the patient experience and perspectives of taking part in outcome measurement during lower limb prosthetic rehabilitation: a qualitative study, *Disability and Rehabilitation.*
- Ostler C, Donovan-Hall M, Dickinson A, Metcalf C. (Under Review with PLOS one Journal) Development of the ECLIPSE model of meaningful outcome domains following lower limb amputation and prosthetic rehabilitation, through systematic review and best fit framework synthesis

Platform presentations

- "*The ECLIPSE model - Meaningful outcome domains of lower limb prosthetic rehabilitation*" Chantel Ostler, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf, BACPAR and Vascular Societies Conference 2023, Dublin, Ireland
- "*Exploring the patient experience and perspectives of taking part in outcome measurement during lower limb prosthetic rehabilitation: a qualitative study*" Chantel Ostler, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf, BACPAR and Vascular Societies Conference 2023, Dublin, Ireland
- "*Understanding successful prosthetic use from the patient's perspective*" Chantel Ostler, Centre for Doctoral Training in Prosthetics and Orthotics Summer School 2023, Southampton, UK
- "*Meaningful outcome measurement following lower limb amputation*" Chantel Ostler, Institute for Life Sciences conference 2023, Southampton, UK
- "*Meaningful outcome measurement following lower limb amputation*" Chantel Ostler, Centre for Doctoral Training in Prosthetics and Orthotics Summer School 2022, Southampton, UK

- "*Making outcome measurement work*" Chantel Ostler, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf, ISPO UK Scientific Meeting, 2021
- "*Exploring meaningful outcomes of recovery following lower limb amputation: The patient's perspective*" Chantel Ostler, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf, ISPO Scientific Meeting, 2021
- "*Exploring outcome measurement following lower limb amputation from a clinical practice perspective: a narrative review*" Chantel Ostler, Helen Scott, Dr Imad Sedki, Sisary Kheng, Dr Maggie Donovan-Hall, Dr Alex Dickinson, Dr Cheryl Metcalf. ISPO world congress 2021, Online
- "*Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective*" Chantel Ostler, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf, ISPO world congress 2021, Online
- "*Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective*" Chantel Ostler, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf, BACPAR national conference 2019, Wolverhampton, UK

Poster presentations

- "*Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective*" Chantel Ostler, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf, Institute for Life Science conference 2022, Southampton, UK
- "*Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective*" Chantel Ostler, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf, ISPO world congress 2019, Kobe, Japan
- "*Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective*" Chantel Ostler, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf, ISPO UK Scientific meeting 2018, Southampton, UK

Webinars

- "Everyone's talking about data, but what about the future of data collection in prosthetic rehabilitation?" Chantel Ostler, BAPO Teatime talk series, 2024
- "Making outcome measurement work" Chantel Ostler, Cheryl Metcalf. The Australian Orthotic Prosthetic Association Webinar, 2021
- "Making outcome measurement work" Chantel Ostler, Cheryl Metcalf, ISPO outcome measurement webinar "Outcome Measurement in Prosthetic Rehabilitation: do current methods support evidence-based practice?" 2021.

National representation

- Acted as NHS England representative at the ISPO global Delphi consensus exercise to generate consensus on outcome measurement in prosthetic rehabilitation (COMPASS).

Chapter 1 Introduction to thesis

1.1 Introduction

This thesis comprises the evidence of a novel contribution to the research of meaningful outcome measurement following lower limb amputation. The programme of research addresses gaps in the current evidence base that directly impact the use of outcome measures in clinical practice and takes a novel patient-centred approach to ensure the findings are meaningful to those with limb loss. This chapter introduces topics that are relevant to this area of research and presents the motivation for the project. It will provide contextual information about amputation and the rehabilitation process currently provided in the UK, as well as details about the researcher's background and experience working in prosthetic clinical practice, leading to the work described here. Outcome measurement will be introduced and considered in the context of wider health care data collection and its value to clinical settings. The chapter will conclude by introducing the aims and objectives of the PhD, which has been undertaken using a publication-based approach. The structure and content of the thesis will be set out, presenting four papers, bookended with this Introduction and a Conclusion chapter.

1.2 Lower limb amputation

Amputation is the loss, or removal, of all or part of a limb by trauma, illness, or surgery. Amputation can occur in the upper and/or lower limbs. Due to the differences in functionality between the upper and lower limbs, the impact of limb loss on individuals varies in terms of prosthetic provision, rehabilitation processes and challenges, impact on daily life, and psychosocial considerations (May and Lockard, 2011). Lower limb amputation (LLA) makes up the largest proportion of limb loss within the UK, accounting for around 92% of all amputations (NASDAB, 2007). The relative size of the LLA population and its subsequent demand on healthcare resource, as well as specific recovery needs related to the factors above, has led to a focus on LLA within this PhD.

1.2.1 Causes and levels of lower limb amputation

LLA can be attributed to various aetiologies, such as peripheral arterial disease (PAD), diabetes, infection, trauma, and congenital limb loss. The predominant cause of LLA varies depending on geographical location, with diabetes and peripheral vascular disease cited as the leading causes of LLA in high income settings (Ahmad *et al.*, 2014; Imam *et al.*, 2017; Behrendt *et al.*, 2018), and trauma related causes cited in low- and middle-income countries (Moini *et al.*, 2009; Rouhani and Mohajerzadeh, 2013; Shaw *et al.*, 2018).

In the UK diabetes and PAD are the principle causes of LLA (NASDAB, 2007). PAD is characterised by atherosclerosis of peripheral blood vessels, leading to intermittent claudication, rest pain, tissue loss and subsequent amputation (Swaminathan *et al.*, 2014). Due to its concurrent nature, individuals may also suffer with diabetes. Both type I and type II diabetes can lead to peripheral neuropathy and ulceration, and amputation is often the result of non-healing ulcers. It is estimated that 85-90% of amputations undertaken in the UK are caused by PAD and diabetes (NASDAB, 2007; Davie-Smith, Hebenton and Scott, 2020; Carr *et al.*, 2023). As dysvascularity typically affects older people, the mean age of individuals undergoing LLA is 66 years (Carr *et al.*, 2023). Due to the systemic impacts of both PAD and diabetes, this cohort often have additional co-morbidities such as renal failure, chronic airway limitation, ischaemic heart disease, and global deconditioning (Lim *et al.*, 2006), resulting in complex health and rehabilitation needs, as well as variable outcomes.

Secondary to PAD and diabetes are trauma related amputations which account for 2-8% of amputations (NASDAB, 2007; Carr *et al.*, 2023), and may result from road traffic accidents, combat related injuries or industrial accidents. Other causes include infection (2%) (Carr *et al.*, 2023) related to conditions such as meningococcal septicaemia, sepsis, and failed joint replacement, cancer related causes (2-4%) (NASDAB, 2007; Carr *et al.*, 2023) and congenital limb absence (less than 1%), where all or part of the lower limbs are absent at birth (Carr *et al.*, 2023). This range of aetiologies leads to a diverse limb loss population, spanning a wide age range, with varying rehabilitation needs, goals, and outcomes.

1.2.2 Incidence and prevalence of lower limb amputation

Due to the different causes of amputation described above, understanding the incidence and prevalence of LLA can also be challenging. Epidemiological studies often focus on incidence of amputation related to a specific cause, such as diabetes and PAD, which is most often reported in the UK (Meffen *et al.*, 2021). This body of work describes considerable variation in incidence of PAD and diabetes related amputations. Incidence rates of between 8.2 to 51.1 per 100 000 in the general population and 70 to 291 per 100 000 for the population with diabetes have been reported (Meffen *et al.*, 2021). Much of this variation has been attributed to methodological differences, inconsistent definitions of minor (distal to the ankle) and major (proximal to the ankle) LLAs, and inaccuracies in reporting. These issues have led to calls for improved approaches and standardisation in reporting LLA incidence and trends. As well as the need to understand the prevalence of limb loss which is currently unknown (Meffen *et al.*, 2021).

In the UK, little is known about incidence related to other causes of amputation. NHS England estimate 55-60,000 people are currently living with limb loss, with 5-6,000 new referrals for prosthetic rehabilitation received annually (NHS England, 2023). However, this information still does not fully describe the extent of LLA as not all patients are referred to limb fitting services. Absence of information about the limb loss population in its entirety can make it challenging for policy makers, and prosthetic service providers who manage all amputations irrespective of aetiology, to gauge trends and allocate resources. Despite a lack of understanding about this population, several reports have indicated that the number of amputations undertaken each year is rising (Hughes *et al.*, 2020; Public Health England, 2023), driven by an increasing number of people living with diabetes and peripheral vascular disease (Zghebi *et al.*, 2017).

1.2.3 Levels of lower limb amputation

Across all aetiologies, the extent of limb loss can vary, ranging from partial to complete removal of the lower limb. Amputation can be undertaken at the level of the ankle (Symes), mid lower leg (transtibial), knee joint (knee disarticulation), mid-thigh (transfemoral), hip joint (hip disarticulation) or through the pelvis (hemi-pelvectomy) (Molina and Faulk, 2022).

Due to the loss of additional joints and associated musculature, outcome worsens as the amputation level becomes more proximal (Fajardo-Martos *et al.*, 2018; Kamrad *et al.*, 2020). Higher levels of amputation require greater prosthetic replacement leading to asymmetrical gait, increased energy expenditure , socket discomfort and complex rehabilitation needs (Waters and Mulroy, 1999; Schaarschmidt *et al.*, 2012; Barr and Howe, 2018; Kahle *et al.*, 2020). Preference is given to distal levels of amputation, taking into account the severity of underlying aetiology (Waton *et al.*, 2019). Transtibial, followed by transfemoral amputations are most commonly undertaken within the UK and account for 52-58% and 41-47% respectively (Waton *et al.*, 2019; Carr *et al.*, 2023). Knee disarticulation, Symes (i.e., amputation through the ankle joint), and amputation at the level of the hip and pelvis are less common.

Demographic information about the limb loss population, such as that presented in the previous sections, is crucial to inform the provision of rehabilitation services, as well as understand the limitations of the current evidence base. However, limited data is currently available to describe the characteristics of this population as a whole. The information presented here has been drawn from a variety of sources that all have limitations that impact on their accuracy, such as data collection which focuses on specific aetiologies, or geographical location within the UK. The implications for this are discussed further on in this chapter.

1.2.4 Outcome following lower limb amputation

Due to the variation in patient characteristics described above, outcomes within the limb loss population can be variable (Wu, Chan and Bowring, 2010). However, due to the significant prevalence of diabetic dysvascular amputations, they are often described in the literature as poor. Mortality rates at 12 and 24 months following amputation have been reported as 30% and 40% respectively (Shah *et al.*, 2013). Across data collected in Scotland, it was found that only 40-45% of individuals were rehabilitated with a prosthetic limb following LLA (Davie-Smith, Hebenton and Scott, 2020). For those who undertake rehabilitation with a prosthesis, outcomes have been described as poor with 24-29% of prosthetic users limited to using their limb indoors a year after amputation, and 22% abandoning their prosthesis altogether (Balk et al., 2018). High incidence of phantom pain (Stankevicius et al., 2021) and socket discomfort (Manucharian, 2011) are also reported, alongside depression (Mckechnie and John, 2014), body image anxiety (Holzer et al., 2014) and falls (Steinberg et al., 2019).

Many factors have been described in the literature as influencing the outcome of LLA, including the presence of diabetes, a more proximal level of amputation, older age, poorer pre-morbid mobility and physical fitness, and the presence of co-morbidities (Taylor *et al.*, 2005; Kahle *et al.*, 2016; Davie-Smith *et al.*, 2017; Andersen *et al.*, 2020). These factors illustrate the complexity of the limb loss population, with many patient characteristics influencing outcome across a variety of domains, such as whether an individual is limb fitted or not, how many hours they use their prosthesis, or using a range of different outcome measurement tools (Kahle *et al.*, 2016). An increasing amputation rate, combined with poor outcomes, indicates a need for greater understanding about this population, and their rehabilitation pathway. This understanding is crucial to inform evidence-based care aimed at improving outcomes following LLA.

1.3 Rehabilitation following lower limb amputation

Rehabilitation following LLA is undertaken to address significant losses in mobility, independence, and quality of life (Darter *et al.*, 2018a). Rehabilitation has been defined as “a set of interventions designed to optimise functioning and reduce disability in individuals with health conditions in interaction with their environment” (World Health Organization, 2024). Following LLA, provision of a prosthetic limb is a key part of the rehabilitation process, although not all patients undergoing LLA are referred for limb fitting due to factors described in the previous sections.

Within the UK, prosthetic rehabilitation is undertaken in specialist centres, of which there are 44 throughout the UK and 35 in England (NHS England, 2015) . The rehabilitation pathway is delivered by multidisciplinary teams (MDT) consisting of rehabilitation consultants, physiotherapists, prosthetists, occupational therapists, nurses, and counsellors (British Society of Rehabilitation Medicine, 2018). Rehabilitation can begin before the amputation, preparing the patient for surgery and life with limb loss (Devinuwara, Dworak-Kula and O’Connor, 2018). Following surgery patients may undertake a period of inpatient rehabilitation before continuing as an outpatient at a specialist prosthetic centre (Hebenton *et al.*, 2019). Patients who wish to undergo rehabilitation and have potential to be limb wearers are fitted with a prosthesis and begin gait training and functional activities (Broomhead *et al.*, 2012). Rehabilitation progresses until the patient has achieved their goals and is able to return to their valued activities and roles (British Society of Rehabilitation Medicine, 2018). Following initial rehabilitation individuals continue to interact with specialist centres throughout their life course, seeking changes in prosthetic componentry or ongoing rehabilitation interventions to maintain mobility, independence and mental wellbeing as they age (NHS England, 2015).

Alongside the physical impacts LLA has on mobility and independence, a significant body of evidence has described the psychosocial impact of amputation (Hamill, Carson and Dorahy, 2010; Murray and Forshaw, 2013). Following limb loss patients may experience emotional responses such as sadness, shock and anger, as they face the loss of limb, mobility and independence (Luza *et al.*, 2020). Depressive symptoms are commonly described in the literature and are estimated to affect up to a third of people with LLA (Luza *et al.*, 2020; Castillo *et al.*, 2021). Body image disturbance has also been described where patients experience alterations in their appearance which may cause emotional distress (McDonald *et al.*, 2021). A meta synthesis of qualitative studies exploring the lived experience of limb loss describes how patients are able to cope with amputation through a period of adjustment, characterised by the acceptance of changes which have occurred within the person’s life, and often compared to the bereavement process (Murray and Forshaw, 2013).

Within the rehabilitation pathway, clinical guidance from a variety of professional networks advocate for a patient-centred rehabilitation approach incorporating both psychosocial and physical rehabilitation in order to address complex, individual and multifaceted responses to amputation (College of Occupational Therapists, 2011; Broomhead *et al.*, 2012; British Society of Rehabilitation Medicine, 2018). In practice psychosocial rehabilitation may be offered by specialist practitioners such as psychologists or counsellors (Wegener, Hofkamp and Ehde, 2008), or in less formal ways by other members of the MDT (Desmond *et al.*, 2012). Peer support from individuals with lived experience of LLA and prosthetic use has been documented consistently in the evidence base as an important source of psychological support following LLA (Ostler, Ellis-Hill and Donovan-Hall, 2014; Wadey and Day, 2018; Day, Wadey and Strike, 2019).

Many interventions currently exist which comprise prosthetic rehabilitation, such as gait re-education, strength and conditioning, vocational rehabilitation, falls prevention and counselling. In addition, an extensive catalogue of prosthetic devices (knees, feet and ankles, sockets, liners, adaptors etc.) are available to support recovery following limb loss. However, there is currently little evidence to guide the selection of effective rehabilitation interventions or prosthetic componentry, with only four randomised controlled trials published worldwide in the last 20 years (Healy *et al.*, 2018). This paucity of evidence has led clinical guidance for the provision of prosthetic rehabilitation to be developed based mainly on the consensus opinion of experts in the field (Broomhead *et al.*, 2012). This gap renders evidence-based clinical decision-making particularly challenging for clinicians, contributing to substantial variation in rehabilitation practices and component prescription across the UK, which was highlighted in an NHS England nationwide survey as a major concern for patients (NHS England, 2018).

1.4 My role and background

I am a specialist prosthetic physiotherapist and lead the rehabilitation MDT at the Portsmouth Enablement Centre (PEC), which is the regional specialist prosthetic service, provided by Portsmouth Hospital University Trust (PHU). Having worked clinically, rehabilitating patients following amputation for 20 years, I have experienced the challenges of poor rehabilitation outcomes first hand, witnessing the impact limb loss has on the lives of my patients.

Throughout my career I have attempted to use the evidence base to guide my clinical decision making and identify the most effective interventions and ways of working for my patients. The paucity of evidence in the field has always been a challenge with little research available to guide the selection of effective interventions, prosthetic components, or inform development of rehabilitation pathways (Healy *et al.*, 2018). I have often reflected on the possible causes of this, such as the relatively small and highly specialised prosthetic population, the absence of academic institutions linked to prosthetic rehabilitation centres, or the challenges of blinding patients in clinical trials to prosthetic componentry which might need specific training to optimise use.

Whatever the reason for the gap, the limited evidence to guide decision making has led to a personal desire to better understand the impact clinical interventions have on patients. I initially addressed this by undertaking improvement work, using approaches, such as audit and service evaluation. Examples of this work include designing a triage process for new prosthetic referrals to ensure patients attended for limb fitting at the right point in their recovery, setting up routine outcome measurement within the service to enable evaluation of our care pathway and monitoring of patients over time, as well as taking a demand and capacity approach to reduce waiting times and flow through the rehabilitation pathway. In recent years I developed my research skills by undertaking a research physiotherapist role within an NHS research and development department, setting up and delivering clinical trials across a variety of healthcare settings. This led to an opportunity to act as a research fellow at the University of Southampton, and subsequently undertake a PhD.

Within my clinical role I have consistently taken an evaluative approach to understanding and improving patient care and service delivery and have always been driven by problems faced by patients and clinicians. In several of the examples described above, using data our prosthetic service collects routinely was key to my evaluative approach. Over the years, alongside my colleagues, I have contributed to the routine collection of extensive amounts of healthcare data, including outcome measurement, either through electronic record systems or as part of improvement projects. Despite the extent of this data, my team and I often struggled to realise its potential to direct and improve patient care. Some of the issues we faced were around accessing data and viewing it in an accessible way. Analysing and interpreting data was also challenging, especially regarding outcome measures where it was difficult to know whether we were measuring the right concept, and what changes in scores on specific instruments meant for individual patients. We also struggled to understand the limitations of data and therefore know how much confidence to have in our findings. These questions led me to consider how use of routine healthcare data in clinical settings could be improved.

1.5 Routinely collected healthcare data

Routinely collected health care data are defined as data which are collected for reasons other than research and without a prior research question (Nicholls et al., 2021). This could include clinical information from electronic health records, healthcare administrative data or data collected as part of registries (Nicholls et al., 2021).

Routine healthcare data are increasingly recognised as an important source of information for both clinicians and researchers (Murray et al., 2022). Health care data can be used locally to track patient progress over time, and inform patient consultations and clinical decision-making (Basch, 2017). Aggregated data can be used for service improvement, benchmarking, and to identify and reduce health inequalities (Devlin et al. 2010). A recent review commissioned by the Secretary of State for Health and Social Care highlighted the unrealised potential in NHS healthcare data, to improve quality, safety, and cost effectiveness of care (Goldacre and Morley, 2022). Data are not only useful to direct patient care and service improvement but can also be leveraged for research; the NIHR has highlighted the potential of routinely collected clinical data for research purposes (Sydes, Barbachano and Bowman, 2021).

Aligned with this potential, numerous large-scale initiatives exist which aim to aggregate routinely collected clinical data to inform and improve patient care, such as the National Joint Registry or the National Diabetes Registry. Examples which have been linked to considerable improvements in patient care (Porter *et al.*, 2019; Bak *et al.*, 2021). However, despite the popularity of these initiatives, several authors have questioned their approach, suggesting few registries have realised their full potential and struggle to evidence their impact on patient outcomes (Nelson *et al.*, 2016). Issues have been highlighted such as duplication of data entry, inaccurate data and reporting which lags behind clinical care and is inaccessible for clinicians to interpret and use (Nelson *et al.*, 2016; NHS England, 2017).

In addition to these problems, it has also been suggested that data collected within registries do not reflect what matters to patients (Nelson *et al.*, 2016). A US based data collection initiative, known as the ImproveCareNow network has attempted to address this issue, and their work has led to considerable impact on patient outcomes (Crandall *et al.*, 2012). ImproveCareNow developed a registry for inflammatory bowel disease, but worked in partnership with patients, families, and clinicians to develop and design the project. This led to a focus on collecting data about prolonged steroid-free remissions as their main outcome, which was identified as most important to patients with inflammatory bowel disease. This approach saw rates of steroid free remissions improving from 55% to 78% in participating centres, as care focused on this important outcome (Crandall *et al.*, 2012). Examples such as this have led to a call for data collection initiatives to adopt more patient-centred approaches (Nelson *et al.*, 2016).

1.6 Data collection within UK prosthetic rehabilitation

Despite numerous registries and data collection initiatives for various medical conditions, there is currently no large-scale UK data collection initiative within prosthetic rehabilitation. Demographic information presented in earlier sections of this introduction chapter i.e., details about the proportion of the population with transtibial or transfemoral amputations, or different amputation aetiologies, was identified by piecing together data from a variety of sources. These sources included the National Amputee Statistical data base (NASDAB), Limbless Statistics, the National Vascular Registry (NVR), the Scottish Physiotherapy Amputee Research Group (SPARG) database, as well as a variety of scientific articles. Many of these sources have significant limitations which impact our understanding of the LLA population as a whole. These will be discussed below.

NASDAB is a historical nationwide database which compiled data from all prosthetic centres, reporting prosthetic referral rates, and proportional data regarding levels of amputation, causes, etc. However, the last report was published in 2008. Although useful, this data set is now over 15 years old and only includes information about those referred for prosthetic rehabilitation. Considering the limb fitting rates described above, this may only include 40-50% of the total LLA population. NASDAB was superseded by an unfunded project known as Limbless Statistics (University of Salford, 2013), which used the same data collection model. However, lack of engagement led to fewer centres submitting data and the last published report is dated 2012, with no plans for further data collection. Additionally, neither of these initiatives reported data about patient outcomes.

The NVR collects data about LLAs undertaken within vascular operating centres (Waton *et al.*, 2019). Data is available regarding different levels of amputation, as well as some outcomes, although these do not evaluate prosthetic rehabilitation and focus on in-hospital outcomes such as mortality, revision rates, wound healing, and limb fitting referrals. In addition, it is likely data only represents those who undergo amputation due to vascular aetiology, as the NVR reports less than 1% of amputations are caused by trauma which is not consistent with other data sources (Carr *et al.*, 2023). Data are also only available in the form of annual reports and are therefore not accessible in real time to guide clinical decision making.

Finally, the SPARG database compiles and reports on all amputations occurring in Scotland (Davie-Smith, Hebenton and Scott, 2020; Carr *et al.*, 2023). This initiative offers a more complete data set as it captures amputations related to all aetiologies but is limited to a single country within the UK, i.e., Scotland. While this project generates an extensive amount of data, including outcome information such as numbers limb fitted and functional outcome, the data collection process is burdensome and fails to leverage routinely collected healthcare data. Instead, it relies on additional manual data collection from all physiotherapists working in the field (Carr *et al.*, 2023). Reports also lag years behind data collection making it impossible to use data in real time to guide clinical decision making.

The absence of complete, useful, and accessible information about the LLA population, which includes outcome information, can make understanding rehabilitation needs and potential health inequalities challenging. Routinely collected health care data, such as that collected as part of prosthetic clinical care, could have the potential to provide valuable insights into the limb loss population and underpin clinical decision making. The current absence of a comprehensive data collection initiative offers the field an opportunity to learn from what has been done previously, as well as within other specialities, and explore novel ways to approach routine healthcare data collection. This could include ways to position the patient at the centre of the process and to collect data that is meaningful, accessible, and useful (Nelson *et al.*, 2016). This approach could enable clinical teams to work within data driven care environments where information is available to inform individual patient care as well as direct and inform service improvement work or research. Novel initiatives, developed in a patient-centred way could empower patients and clinicians to engage with data, as well as facilitate access to data by different stakeholders i.e., to promote accessible real-world research and product development (Nelson *et al.*, 2016). Figure 1.1 describes the factors which may contribute to a data driven care environment and could inform the direction of future work. It has been developed from the healthcare data literature, as well as literature included in this PhD as part of the narrative review undertaken as paper one (Ostler et al. 2022). Patient and stakeholder involvement and engagement (PPIE) work, undertaken within this PhD and other related projects has also contributed.

Figure 1.1 Factors that may contribute to a data driven care environment (developed by author)

1.7 Outcome measurement

A key factor of Figure 1.1, included in the pink segment, is meaningful outcome measurement. Including outcome information as part of a data driven care environment is crucial to understand the impact of interventions and to inform clinical decision making. This is evident in the literature (Devlin *et al.*, 2010; Boyce and Browne, 2013; Howell *et al.*, 2015; Wilson *et al.*, 2019; Campbell *et al.*, 2022), and from discussion with clinicians taking part in in wider PPIE work, undertaken by the thesis author and supervisors (Appendix A).

The term outcome measurement can be better understood by breaking it down into the outcome domain being measured and the measurement tool used for the task. An outcome domain can be defined as an element of health (i.e. pain, physical function, emotional wellbeing, social activity) that is changed by a particular intervention (Clarke *et al.*, 2020). A measurement tool can be defined as a standardised instrument used in research and clinical practice to capture and evaluate this change (Robinson and Fatone, 2013).

Measuring health outcomes is especially relevant in today's increasingly evidence-based health services. When facing increasing demands on resources, as well as the expectation of a culture of continual improvement, services need to consistently demonstrate their value and impact (Devlin and Appelby, 2010). However, routinely collecting outcome information has not always been the focus of NHS data collection. Historically, the NHS has evidenced its impact by measuring process data, i.e., waiting times, numbers of referrals or clinical contacts. However, this information only provides insight into the production of `health care' rather than the production of `health'. In addition, a Kings Fund report highlighted that the NHS's attempts to measure `health' often focus on measuring negative impacts (i.e. re-admissions, mortality and hospital acquired infections) (Devlin and Appelby, 2010). Outcome information as part of routine healthcare data collection could provide an understanding of the impact health services and interventions have on the health and wellbeing of patients, and society as a whole.

However, despite the value of outcome measurement, engaging clinicians in the process has been described as challenging (Turner-Stokes, Williams, *et al.*, 2012). Issues such as pressure on time, the burden of paperwork, measures not perceived as helpful for decision making and a lack of measurement 'know-how' are cited (Jette *et al.*, 2009; Jensen-Doss and Hawley, 2010). It is widely acknowledged that outcome measures are not routinely used in clinical practice, despite advocacy and guidance from NHS policy (Department of Health and National Health Service (NHS) England, 2015). Specifically within prosthetic rehabilitation, professional networks such as the British Association of Prosthetists and Orthotists (BAPO) and the British Association of Chartered Physiotherapists in Limb Absence Rehabilitation (BACPAR) have also encouraged use of outcome measures (British Association of Prosthetists and Orthotists, 2015; Scopes *et al.*, 2015).

As a clinician working within an NHS prosthetic service, I have often used outcome measures to evaluate patient progress, or as part of our routine outcome measurement programme to evaluate the prosthetic rehabilitation care pathway. However, I often struggled to use the information effectively and have raised questions about how useful outcome measurement is, such as `which tools should we be using?' or `how do we interpret the scores?' or `what does this change in score mean for patients?' Questions which are currently unanswered in the literature. This knowledge gap raises significant implementation issues for effectively using outcome measures in clinical practice, or as part of initiatives that pool routinely collected healthcare data to improve patient outcomes. This has led me to focus on meaningful outcome measurement within this PhD.

1.8 Ontological and Epistemological position

The world view that shaped this PhD is clearly influenced by my extensive experience of clinical practice within the NHS and the problems I face daily. Clear guidance on best practice is essential in healthcare settings, but it is also recognised that this needs to be interpreted and adapted for individual patient needs within different organisational structures. In light of this, I would consider my worldview is embedded in a critical realist ontology. These lenses or prisms may include individual human factors, in this case the experiences of limb loss or the different aetiologies leading to amputation, as well as external structural, cultural and organisational factors, such as different healthcare settings or social support networks (Archer, 2016; Williams, Rycroft-Malone and Burton, 2017). Critical realism helps to explain how these unobservable factors may interact to produce certain phenomena and lends itself to flexible, creative application outside of methodological boxes (Willis, 2023).

This creative flexible application, which is so relevant in the complex real-life world of health care where both my research questions and their potential solutions are situated, is aligned with my epistemological position, pragmatism (Morgan, 2014). A Pragmatic approach to the generation of knowledge is problem focused in nature and concerned with application, promoting the use of all approaches available to gain a greater understanding of the issue (Cresswell, 2014; Morgan, 2014, 2017). My passion to ensure that research is useful in clinical practice results in a problem focused approach informed by the challenges my patients and colleagues encounter daily, but also driven by the need to ensure the findings from my work can be applied in practice and have impact on patient care.

The flexibility and applied nature of both critical realism and pragmatism lend themselves to the approach taken in this PhD. Methods have been selected at each phase, which are most appropriate to explore the different problems identified from the previous phase. In line with my ontological and epistemological positions, all phases are underpinned by real world problems seen in clinical practice and influenced by the potential translation of research findings into feasible solutions.

1.8.1 Person-centred approach

My world view is also strongly influenced by many years working closely with people who have experienced LLA and the importance of understanding their views, experiences, and priorities to deliver person-centred care. A person-centred approach is defined as a set of principles that focus on offering personalised, co-ordinated care, in partnership with patients, delivered in a respectful and compassionate way (The health Foundation, 2016). At the heart of a person-centred approach is what matters to the individual. This concept has been a key part of my clinical practice but also my research and improvement work. It has led me to consider the importance of what matters to people with limb loss when developing research questions, such as in this PhD, but also when designing, undertaking, and disseminating research. The National Institute for Health and Care Research (NIHR) describe this approach as Public Involvement in research, and define it as research carried out with or by members of the public rather than ‘to,’ ’about,’ or ’for’ them (Partnership UPISD, 2019). Public involvement in research can ensure that research is being carried out to explore issues that are important to patients and the public and undertaken in a way that promotes a positive experience of taking part.

In combination with my ontological and epistemological positions, my person-centred approach has shaped how I have chosen to investigate the topic of meaningful outcome measurement in prosthetic rehabilitation, informing both the research aims and objectives set out in the next section, and the method and study designs used to address them.

1.9 Research aims and objectives

The aim of the PhD is to understand and contribute to the body of evidence around meaningful outcome measurement following lower limb prosthetic rehabilitation, and drive changes in clinical practice that foster person-centred approaches to measuring outcome.

The aim will be addressed by the following three objectives:

Objective 1 - To review the current evidence base investigating outcome measurement in prosthetic clinical practice

Objective 2 - To understand the patient’s perspective of outcome measurement by exploring:

- Meaningful outcome domains of recovery
- Patient experiences of outcome measurement in clinical practice

Objective 3 - To develop a conceptual model describing meaningful recovery following prosthetic rehabilitation and outcome domains of importance to measure in clinical settings

1.10 PhD Structure

This PhD has been undertaken using a paper-based method. A variety of approaches were undertaken to address the research objectives which were carried out across three distinct phases, as set out in Figure 1.2.

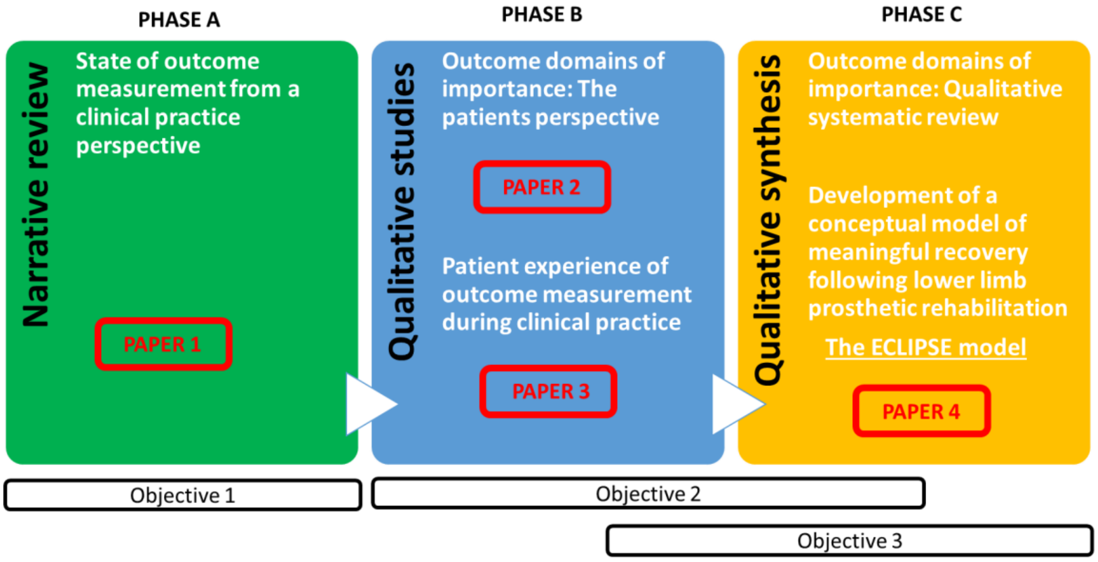

Figure 1.2 PhD structure and alignment with the objectives

Phase A sought to review the current evidence base investigating outcome measurement in prosthetic clinical practice by undertaking a clinically focused narrative review (Objective 1, Paper 1). Phase B aimed to understand the patient's perspective of outcome measurement (Objective 2) through a large qualitative study which is reported in two separate papers (Papers 2 and 3). Paper 2 explored outcome domains of importance from the patient's perspective and led to an initial iteration of a conceptual model describing recovery and outcome domains of importance to measure following prosthetic rehabilitation (Objective 3). The second phase B paper (Paper 3) deepened our understanding of the patient's perspective (Objective 2) by exploring patient experiences of taking part in outcome measurement during clinical care. Phase C concludes the PhD and consists of a qualitative synthesis (Paper 4) which widened understanding of outcome domains of importance from the patient's perspective, as described in the qualitative literature (Objective 2), and further developed the conceptual model leading to the ECLIPSE model which describes m**E**aningful out**C**ome domains of **L**ower l**I**mb **P**ro**S**thetic r**E**habilitation (Objective 3).

1.11 Thesis structure

As this PhD was undertaken using the paper-based approach the thesis has been structured to present the four contributing papers as distinct chapters, bookended by introduction, and discussion and conclusion chapters, as set out below:

Chapter 1 - **Introduction**

Chapter 2 – **Paper 1** - From outcome measurement to improving health outcomes following lower limb amputation – A narrative review exploring outcome measurement from a clinical practice perspective

Chapter 3 - **Paper 2** - Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: The patient's perspective

Chapter 4 – **Paper *3*** - Exploring the patient experience and perspectives of taking part in outcome measurement during lower limb prosthetic rehabilitation: A qualitative study

Chapter 5 – **Paper 4** - Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: A systematic review and best fit framework synthesis to develop the ECLIPSE model.

Chapter 6 – **Discussion and Conclusions**

Each chapter describing a paper will introduce the paper and position it within the overall PhD structure described in Figure 1.2. A summary of the paper in the form of an extended abstract will then be presented. This will include key findings from the research and how the work links to previous papers. Three of the papers have been accepted for publication (Papers 1,2 and 3), and the fourth has been submitted for peer review (Paper 4). Each chapter will provide justification for the choice of peer reviewed journal, details of the publication and any additional outputs from the work. Following this contextual information, the complete manuscript of the paper including references will form the remainder of the chapter.

1.11.1 Writing styles and referencing in this thesis

The writing style of this thesis predominantly follows the traditional convention of writing in the third person. However, at times the thesis does use the first person. This is to provide clinical context from my experience working in prosthetic rehabilitation, as well as to describe the reflexive process as I attempt to acknowledge my subjectivity in relation to the research topic.

As each of the papers are subject to the referencing requirements of different journals, referencing differs throughout the thesis. The introduction sections of chapters two to five will provide information about referencing for the included paper, and the complete reference list for each paper will be presented as part of the full manuscript. References for all text not included in the manuscripts is presented in the Harvard style and included in the reference list at the end of the thesis.

1.12 Summary

This chapter has highlighted the rationale for undertaking this doctoral study which is grounded in the need for a more comprehensive understanding of the limb loss population in order to address poor outcomes reported in the evidence base. Current literature and clinical experience have illustrated that outcome information collected as part of routine healthcare data could be key to understanding and subsequently improving rehabilitation outcomes at the individual, service, and system levels. However, work is required to make the process meaningful, and patient-centred. In an attempt to begin to address these issues, the research aims and objectives of this PhD have been set out along with a summary of the thesis, which has taken a paper-based approach. The next chapter introduces the first of four papers which presents a review of the current evidence base concerning outcome measurement in prosthetic rehabilitation.

Chapter 2 Paper 1 – From outcome measurement to improving health outcomes following lower limb amputation – A narrative review exploring outcome measurement from a clinical practice perspective

2.1 Introduction to paper 1

This chapter introduces the first of four papers which make up this thesis. Paper one is a narrative review which addresses the first objective of the PhD; to review the current evidence base investigating outcome measurement in prosthetic clinical practice. The literature included in the review is considered from a clinical practice perspective, i.e., how the findings could inform or be applied to outcome measurement undertaken in clinical settings. This approach was adopted to understand what work has already been undertaken in the field and identify gaps where future work, including that carried out within this PhD, was needed. This research was conducted as part of phase A, as described in Figure 2.1.

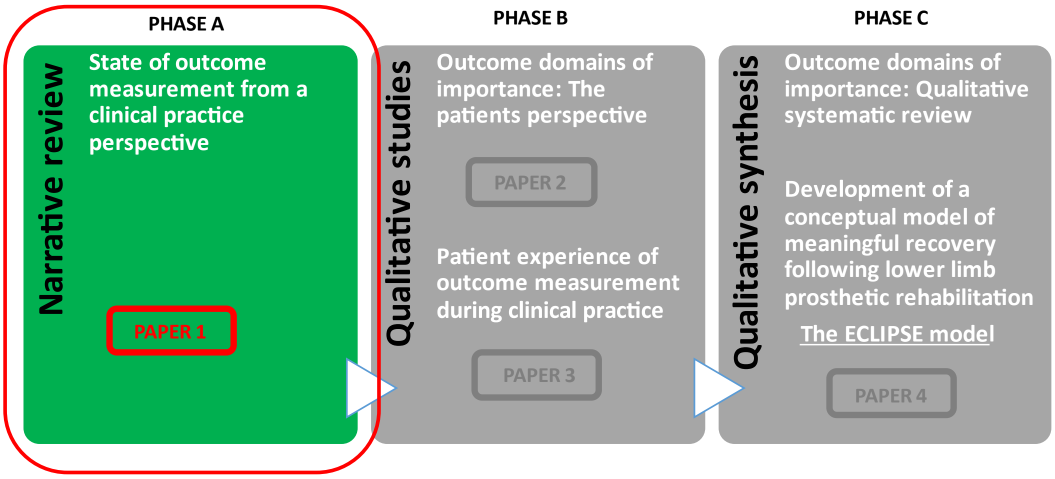

Figure 2.1 Phase A and paper one in the context of the complete thesis

This chapter includes an initial summary of paper one, in the form of an extended abstract, followed by the main manuscript, including all figures and references.

2.1.1 Summary of paper 1

As outlined in chapter one of this thesis, outcome measurement can provide essential information allowing clinical teams to understand the impact of interventions and the performance of services. Despite encouragement from NHS policy (i.e., Department of Health and National Health Service England, 2015; NHS England, 2015, 2016) and professional bodies within prosthetic rehabilitation (i.e.,British Association of Prosthetists and Orthotists, 2015; Scopes *et al.*, 2015), to integrate outcome measures into clinical practice, barriers still exist. There are successful examples of system-level outcome measurement within certain healthcare settings, such as the National Joint Registry (Porter *et al.*, 2019) or the UK Rehabilitation Outcomes Collaborative (Turner-Stokes, Poppleton, *et al.*, 2012). These examples demonstrate the feasibility and benefits of outcome measurement at a larger scale. However, many obstacles remain, preventing the widespread adoption of outcome measurement in clinical practice (Duncan and Murray, 2012).

Previously, no reviews have drawn together the outcome measurement evidence related to prosthetic rehabilitation from a clinical perspective. Therefore, the aim of paper one was to understand what work had already been undertaken in the field of prosthetic rehabilitation related to outcome measurement. The objective was to consider this evidence base as applied in clinical practice, with a view to identifying areas for future work aimed at making outcome measurement in prosthetic rehabilitation a meaningful reality. The focus on clinical practice was particularly relevant due to both the challenges I had faced in implementing outcome measures within my practice, but also the evidence showing that engagement in outcome measurement was a challenge for many allied health professionals (Duncan and Murray, 2012).

2.1.1.1 Method

Scoping searches identified a wide range of studies exploring different aspects of outcome measurement in prosthetic settings. Therefore a narrative approach was chosen to enable a broad exploration, interpretation and critique of the literature, considering all findings as they applied to clinical practice (Greenhalgh, Thorne and Malterud, 2018). In light of the many published criticisms of narrative reviews i.e., the absence of a method that can be peer reviewed, or possible cherry picking of papers by the authors (Dijkers, 2009), a rigorous approach was adopted using processes drawn from systematic reviews. A literature search of four databases was undertaken, following the PRISMA principals appropriate to narrative reviews as set out by Ferrari (Ferrari, 2015). The key words outcome AND (measur* OR tool OR scale OR instrument) were combined with AND (prosthe*OR amput* OR “limb loss”) and searched in titles and abstracts. A total of 1116 papers were identified. Following screening and application of inclusion and exclusion criteria 36 papers were included in the review. As the aim of the review was to explore the current state of knowledge around outcome measurement in prosthetic rehabilitation, no formal critical appraisal tool was used to exclude papers based on their quality.

2.1.1.2 Results

In order to synthesise the findings across the papers, key themes were developed through reading, critiquing and discussing the papers with the research team. Four themes were identified and were posed as questions to address the narrative review aims. The themes were:

> 1) *What outcome domains* should be measured? – Little is currently known about what outcome domains should be measured following prosthetic rehabilitation, especially from the patient’s perspective.
>
> 2) *How* can these outcome domains be measured? – Many outcome measurement tools exist to capture outcome following prosthetic rehabilitation but there is no consensus on which should be used. This may be due to a lack of consensus about which domains to measure as highlighted in theme one. The ability of current measures to detect change when it has happened i.e., responsiveness, which is crucial for use in clinical practice, is currently unclear, impacting the usefulness of measures.
>
> 3) *What are the barriers* to outcome measurement? Barriers to outcome measurement have only been explored from the prosthetist’s viewpoint. Issues such as perceived lack of time, and lack of confidence and knowledge of measurement tools were reported, as well as concerns about the value of information generated through outcome measurement.
>
> 4) *What can be learnt* from examples of routine outcome measurement in prosthetic rehabilitation? Several examples of routine outcome measurement were described in the literature providing interesting insights into the implementation and use of outcome measurement in clinical settings.

2.1.1.3 Conclusions

The review concluded by highlighting that successful outcome measurement appears to be multifaceted and a meaningful approach to measurement in prosthetic rehabilitation should focus on understanding and embedding value at every step in the process. Future work should focus on addressing some of the gaps in the literature such as `what’ outcome domains to measure and `how’ to measure them, which may help establish consensus and enable clinicians to measure what matters most in a consistent way across services. However, the practice of outcome measurement may also need consideration to ensure the process is of value to clinical practice and leads to improved patient care, i.e., outcome data is available for clinicians to use in real time for decision making, support is available to interpret and use aggregated data, and information technology solutions are used to minimise time commitments.

2.1.2 Publication details

Paper one has been published 2022, in Prosthetics and Orthotics international (POI), and is available in its published format in appendix B. POI was selected as it is the scientific journal of the International Society of Prosthetics and Orthotics (ISPO) and the most well-known journal in the clinical community, with ISPO members offered free access. As paper one sets out a unique perspective on outcome measurement that has not been previously described in the prosthetic evidence base, with direct implications for clinical practice, POI was chosen for its reach within clinical settings. An accessible infographic of the paper was produced to aid dissemination of findings to clinicians and non-academic audiences via email and social media (Appendix C). The findings were also presented at a platform presentation at the 2021 ISPO World Congress which was held online.

As the paper reviewed the evidence from a clinical practice perspective and only the PhD candidate is a clinician, several multidisciplinary clinical experts in the field of prosthetics were invited to contribute to the review. Clinical experts included a prosthetist, rehabilitation consultant and physiotherapist, employed in high- and low-income settings. This addition led to interpretation of the findings from a variety of expert perspectives, providing a more comprehensive synthesis and promoting rigour. Greenhalgh et al., (2018) advocate for the role of experts in narrative reviews to judge the selection and interpretation of evidence and offer meaning to the findings which resonates with an audience of fellow experts.

The referencing style of POI is the Vancouver style. Referencing has been presented in this format with an accompanying reference list in the paper one manuscript which comprises the next section.

2.2 Paper 1 manuscript

2.2.1 Title

From outcome measurement to improving health outcomes following lower limb amputation – A narrative review exploring outcome measurement from a clinical practice perspective

2.2.2 Authors

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Dr Cheryl Metcalf - PhD, Principle Enterprise Fellow, University of Southampton, Southampton, UK

2.2.3 Background

Measuring health outcomes is especially relevant in today’s increasingly evidence-based health services. When facing increasing demands on resources, as well as the expectation of a culture of continual improvement, services need to consistently demonstrate their value and impact.[1] Outcome information can provide an understanding of the impact health services and interventions have on the health and wellbeing of patients.

The term outcome measurement can be better understood by breaking it down into the outcome domain being measured and the measurement tool used for the task. An outcome domain can be defined as an element of health (i.e. pain, physical function, emotional wellbeing, social activity) that is changed by a particular intervention.[2] A measurement tool can be defined as a standardised instrument used in research and clinical practice to capture and evaluate this change.[3]

Within clinical practice, outcome measurement in the form of professional reported measures, performance-based measures, or patient/self-reported outcome measures (PROMs),[3] can be used in a number of different ways. On an individual basis, the use of an outcome measure (OM) can be helpful to capture changes in a patient's status following an intervention or when monitoring patients over time.[3] This information can be shared with the patient to review progress throughout rehabilitation, and increase motivation, or can be used by the clinician to highlight areas of concern, direct treatment planning or justify requests for the funding of interventions or devices,[4] i.e. the NHS England Microprocessor knee policy within the UK.[5]

A more co-ordinated approach to outcome measurement along a pathway of care can be described as routine outcome measurement (ROM). ROM is defined as "the systematic use of a standardised OM(s) in clinical practice with every patient as part of a standardised assessment practice guideline".[6] This systematic approach to outcome measurement can provide individual services or departments with a wealth of information on the quality of care and interventions they are delivering.[7] Data can be used to direct and inform improvement work, and evaluate the changes resulting from services or departments developing new ways of working. When co-ordinated ROM is undertaken in a number of services, benchmarking can be undertaken[8] and a system-wide approach adopted, i.e., undertaken across organisations that deliver the same services to a target population. This system-level approach to ROM can be useful in several contexts, especially if widely accessible. It allows comparison of the performance of different health care providers and gives patients valuable information on the best performing organisations, enabling informed decisions on where to receive care.[1] Benchmarking can also help to identify services where outcomes are good and use those as exemplars to raise standards across the NHS, reducing variation in the system. Collating large datasets concerning a specific population, such as lower limb amputation, can also be useful for research purposes to strive to understand, and influence, the factors that may have an impact on clinical outcome.

Outcome measurement is crucial to inform and therefore improve clinical decision-making. If health care services want to ensure they are delivering the most effective care they need information, specifically about the outcome of care, that can both direct the focus of meaningful improvement programmes and evaluate their impact.[9]

The potential for using ROM to evaluate, inform and improve clinical practice at the system level has been realised in several UK clinical settings. Two notable examples are the NHS PROMs programme and the UK Rehabilitation Outcomes Collaborative (UKROC).

The NHS England PROMs programme,[10] collects PROMs data for hip and knee replacements, before and after surgery. Data is collected nationally and allows comparison of surgical centres and informed patient choice of centres with the best outcomes. Crucially this programme is linked to the National Joint Registry (NJR), which collects implant safety data from across the UK on all joint replacement surgery.[11] Combining these datasets allows the value of joint replacement on patients' lives to be assessed, as well as a comparison of the performance of different implant componentry, providing evidence for interventions, service performance, patient safety and component selection.[12]

UKROC applies system-wide ROM in the context of rehabilitation and aims to provide data that can inform the provision of cost-effective neuro-rehabilitation services in the NHS.[13] The collaborative developed a national clinical database combining data on rehabilitation needs, the interventions patients received and importantly their outcomes. Data collected was used to demonstrate that specialist neuro rehabilitation was a highly cost-effective intervention compared to potential lifelong care needs. This evidence led to significant investment in rehabilitation services throughout the NHS, alongside development of evidence-based standards of care that have reduced variation across the system and driven up quality.[14]

However, even within these valuable examples of system wide ROM, engaging clinicians in outcome measurement is a challenge,[15] and it is widely acknowledged that OMs are not routinely used in clinical practice.[4] NHS policy[16], as well as prosthetic rehabilitation professional bodies, such as the British Association of Prosthetists and Orthotists (BAPO) and the British Associations of Chartered Physiotherapists in Amputation Rehabilitation (BACPAR), have issued advocacy and guidance on OMs in clinical services.[17,18] However, use of OMs has yet to become embedded and there is currently no UK outcome data collection initiative capturing the inherent usefulness of this information following amputation.[4] Despite the common view that it is due to ambivalence of clinicians[19], and a resistance to change and innovation amongst service providers,[20] a systematic review by Duncan and Murray exploring barriers and facilitators to OM use amongst allied health professionals (AHPs) suggests this is not the case. Successful implementation needs multifactorial efforts, overcoming barriers such as lack of time, unfeasible OMs, perceived lack of value in measurement and insufficient organisational support.[4]

In order to make ROM a meaningful reality following lower limb amputation, which has the potential to evaluate and direct improvements in the care provided to patients, it is important to understand what is already known about outcome measurement within this context. As described above there are many factors that may need to be identified and considered in this setting. Therefore, a narrative review has been undertaken to enable a broad approach to surveying and critically synthesising the current state of knowledge on outcome measurement within the field of prosthetic rehabilitation and identify problem areas for future work that will have clinical value.

2.2.4 Methods

2.2.4.1 Narrative approach

A narrative approach was chosen for this review to allow for a broader exploration of the outcome measurement literature within the prosthetic rehabilitation evidence base. This broad approach fits well with the narrative review methodology as it does not stipulate formulation of a specific research question, as required for scoping or systematic reviews, which may have resulted in relevant issues being overlooked.[21] For example, a review of systematic reviews in Norway, generated to inform policy making, found that the evidence base included in the systematic reviews was narrow and represented only a small proportion of questions relevant to public policy.[22]

However there has been much criticism of narrative reviews in the past and they have often been described as inferior to systematic reviews.[23] Criticism includes the absence of a method that can be peer reviewed, or the potential introduction of conscious or unconscious bias by the researcher as they select studies to be included without any inclusion or exclusion criteria, or quality assessment.[24] More recently, authors such as Furley and Goldshmeid[25] have challenged this hierarchical stance and suggested that narrative reviews should be seen as complimentary to systematic reviews rather than inferior. They suggest that the lens of the authors - in this case a range of experienced interdisciplinary international clinicians and academics working within the field of prosthetic rehabilitation - can be used to help those viewing outcome measurement through a similar lens, and to understand the implications of the evidence. Perhaps in a similar way to qualitative research, where the researcher is seen as part of the research process and encouraged to be reflexive about their impact, the role and assumptions of the researcher in narrative reviews should also be considered.

Greenhalgh and colleagues[23] also suggest that narrative reviews can be an important start in a field where little is known or summarised about a subject, such as outcome measurement in prosthetic clinical practice. This approach can help contextualise the evidence base and pose unanswered questions for more informed future work.[23] The voice of the clinical narrative thread may have been lost within the constraints of more systematic methodologies[26], therefore, this broad overview may be a useful starting point which sets the scene for more systematic approaches in the future. However, in light of published criticisms, in order for a narrative review to be meaningful a rigorous approach should be adopted, using processes drawn from systematic reviews, such as search methods, selection criteria, data extraction and interpretation.[25,26]

2.2.4.2 Search strategy

A literature search was conducted following the PRISMA principles appropriate to narrative reviews, as set out by Ferrari,[26] and is described here in two steps. Step one describes the initial literature search and the selection of articles from reviewing titles and abstracts. Step two describes the selection of articles following full text review and inclusion of additional papers identified through searching references lists and grey literature sources.

2.2.4.2.1 Step one

The CINAHL, Medline, Science direct and PsychInfo bibliographic databases were searched in July 2020. The key words outcome AND (measur* OR tool OR scale OR instrument) were combined with AND (prosthe* OR amput* OR “limb loss”) and searched in titles and abstracts. An English language filter was used with no specified date range to include all relevant publications. This identified 1116 papers, which following the removal of duplicates was reduced to 777 records. The following selection criteria were used to identify relevant papers, from the 777 records identified, for full text review:

Inclusion criteria:

- papers exploring how to measure outcome following lower limb amputation.
- papers that focused on outcome measurement in prosthetic clinical practice settings.
- papers describing outcome measurement tool development or psychometric property testing for use following lower limb amputation.

Exclusion criteria:

- Studies using outcome measurement for research purposes.

This resulted in 78 papers for full text review.

2.2.4.2.2 Step two

Step one yielded a number of SRs (10) exploring the development and psychometric properties of OMs for use following lower limb amputation. Primary studies of individual OMs were therefore excluded to avoid duplication. The following exclusion criteria were added:

- Primary studies exploring the development of outcome measurement tools.
- Primary studies exploring the psychometric properties of outcome measurement tools.

This resulted in 25 papers. An additional 11 papers were identified through searching of reference lists and grey literature sources. 36 papers were therefore included in the narrative review. See Figure 2.2.

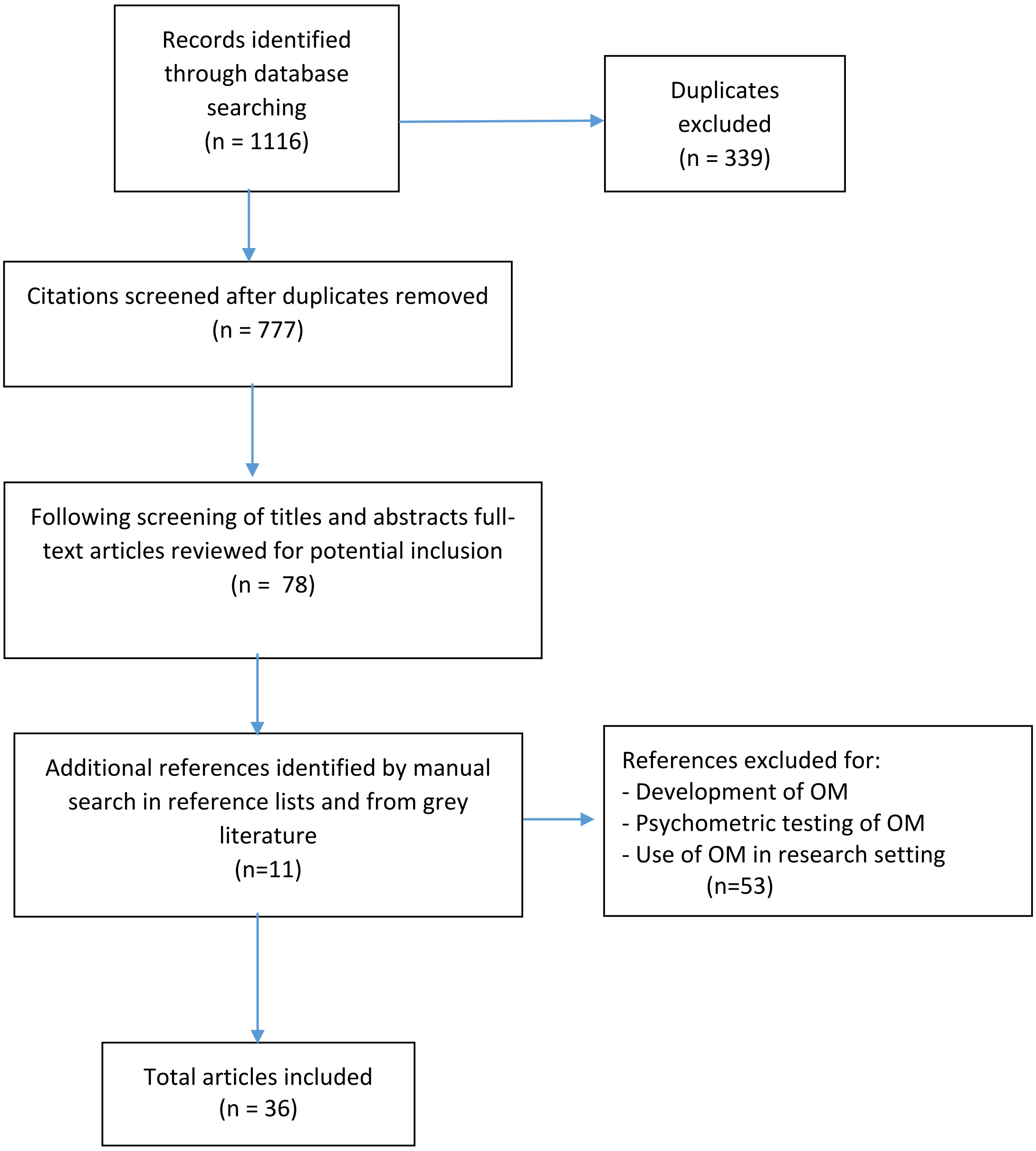

Figure 2.2 Narrative review process flow chart

2.2.4.3 Critical assessment

As the aim of this review was to explore the current state of knowledge, including grey literature, no formal critical appraisal tool was used to exclude any papers based solely on their quality. However, principles of critical appraisal were integrated throughout the review to evaluate and highlight any variability in the quality of the evidence. This approach was taken to ensure all key issues were included at this early scoping stage.

2.2.4.4 Data extraction and theme development

Key themes were developed in order to synthesise findings across the papers. This involved the lead author reading and critiquing the papers, and developing early concepts, which were discussed and refined with the wider team into a clear set of initial themes. These themes were then reviewed and posed as questions to directly address the narrative review aims to 1) survey the state of knowledge on outcome measurement within the field of prosthetic rehabilitation from a clinical practice perspective, and 2) identify areas for future work aimed at making ROM a meaningful reality in clinical settings. The four themes are:

1) *What outcome domains* should be measured?

2) *How* can these outcome domains be measured?

3) *What are the barriers* to using OMs?

4) *What can be learnt* from examples of ROM in prosthetic rehabilitation?

2.2.5 Results

2.2.5.1 Theme 1 - What outcome domains should be measured?

In 2014, a study by Heinemann et al.[27] identified 43 unique measurement instruments designed to capture outcome following lower limb amputation. This wide variety of tools measured an extensive range of outcome domains, such as mobility, falls risk, balance, function, quality of life, socket comfort, psychological adjustment, satisfaction with devices and services. In a number of cases many tools or tests had been developed to capture the same domain, i.e., mobility. Several authors exploring measurement tools have raised the issue that there is no consensus around which tools should be used.[28,29] This plethora of tools and absence of consensus also appears to be evident in current UK Health Policy and professional guidance, where long lists of OMs are suggested for use in the Prosthetic National Service Specification,[30] the NHS Microprocessor Knee Policy,[5] the BACPAR OMs toolbox[18] and the BAPO OM guidance.[17] These resources appear to recommend the use of many different measures, with little consistency, and often include different measures that capture the same outcome domain.

This lack of consensus around measurement tools is a major barrier to system-wide ROM but may in fact be underpinned by another lack of consensus, i.e., what outcome *domains* should be measured. This raises two separate unanswered questions within the field of lower limb prosthetic rehabilitation: *what* outcome domains should be measured and *how,* i.e., with which tools, should they be measured? The studies identified in this review addressing *what* outcome domains should be measured will be discussed in this theme. Studies exploring *how* they should be measured will be reviewed in the theme exploring outcome measurement tools.

Three studies were identified that explored the theme of *what* domains should be measured. A study by Xu et al. approached this question by exploring possible outcome domains that capture the concept of health, as defined using the International Classification of Functioning (ICF).[31] The authors identified a core set of ICF domains which define health as it applies to people following amputation. Currently this work has yielded large numbers of domains which could be measured. However, capturing them all may be impractical in clinical practice and this approach does not give an indication of which of the domains may be most meaningful to measure, especially to prosthetic users themselves, for whom the outcome of prosthetic rehab has the greatest impact.

A more patient-centred approach to outcome measurement in prosthetics was called for in a review by Gallagher and Desmond in 2007 who suggested measuring quality of life may be an important first step in this process.[32] Subsequently two studies have taken this patient-centred approach further by using qualitative methods to explore outcome domains that matter to patients. McDonald and colleagues[33] used focus groups to explore meaningful outcome domains when prescribing prosthetic feet, and Schaffalitzky et al[34,35] explored user, clinician and wider stakeholder views on the outcome of prosthetic prescription via interviews, focus groups and a Delphi consensus process. Both studies focused on the prescription of components rather than holistic rehabilitation post amputation, and McDonald et al. only included six participants. However, they found that qualitative methodologies work well to explore successful prosthetic prescription and highlighted outcome domains that were important to users such as balance and safety, independence and not being in a wheelchair. Interestingly Schaffalitsky et al. also found that clinicians and patients often prioritised different domains, i.e., quality of life, which was prioritised as a domain by clinicians but not by prosthetic users. Users instead appeared to describe *the ways* in which their quality of life could be improved as the important domains. As clinicians are most likely to select what outcome domains are measured,[33] it is possible that services may not be capturing the outcome domains that really matter.[34]

Despite this valuable exploratory work, domain consensus remains elusive in prosthetic rehabilitation and without understanding *what* domains to measure, achieving consensus around *how* to measure them becomes even more challenging. Despite this many of the studies identified in this review focus on how to measure outcome, which will be discussed in the next theme.

2.2.5.2 Theme 2 - How can these outcome domains be measured?

The main focus of the outcome measurement literature identified in this review was the development and psychometric testing of measurement tools themselves. Ten SRs were identified in the literature which collated and critiqued measurement tools for use following lower limb amputation (Table 2.1). The tools identified in the reviews varied in the quality of their methodological development and the different psychometric properties which had been investigated (i.e. the level of measurement, validity, reliability and responsiveness).[36] Seven of the SRs used scoring systems to rate the quality of the instruments they included; however different scoring approaches led to variation in recommended measures.[37-43] This variation, in combination with large numbers of measures, and gaps in the reporting of psychometric properties for many measures, may contribute to a lack of ‘gold standard’ OM or OM consensus. In the most recent SR by Balk et al. the need for a core set of validated OMs is raised to enable comparability across studies and increase their overall value.[37]

Table 2.1 Summary of systematic reviews of OM tools for use following lower limb amputation

Authors	**Outcome domains Included**	**Key findings**
Rommers et al 2001[28]	Mobility	19 different measurement tools were identified that differ in method and measuring range and there is no consensus about measuring mobility in the current literature.
Condie et al 2006[29]	Mobility Function Quality of life	25 measurement tools were identified from 28 different studies. The complexity of studies makes it too difficult for clinicians to use the findings in the literature to inform their choice of outcome measure.
Deathe et al 2009[43]	ICF* domain of Activity	17 instruments were identified but there is a lack of evidence about the responsiveness of all measures included.
Hebert et al. 2009[40]	ICF domain of Body Function and Structure	16 measurement tools were identified but not many comprehensively validated tools exist to measure the domain of body function and structure. For all the tools identified in this review responsiveness to interventions has not been established.
Xu et al. 2011[31]	All domains measured following limb loss	113 outcome measures were identified. 90% of the concepts measured could be linked to ICF categories and these categories could be used to develop an ICF core set for amputation.
Heineman et al 2014[27]	Mobility Function Quality of life	This review replicated Condie et al., 2006 review to update evidence base. Only a few of the included measures present MCID+ values which is vital for tools to be clinically useful and significant work is required to develop both these values and population norms.
Hawkins 2014[38]	Function Quality of life	21 different assessment tools were identified from 40 studies. Only 5 tools were used in more than 3 studies and the heterogeneity of the measures used makes it difficult to compare lower limb outcome studies.
Scopes 2016[42]	Physical Function	37 measures were identified but there is a paucity of high-quality studies exploring the psychometric qualities of outcome measures of physical function. The responsiveness of these measures is generally unknown and limits their use in evaluating the effectiveness of interventions.
Resnick et al. 2017[41]	Participation	34 measures and 94 subscales were identified but most measures had limited evidence around psychometric properties.

Authors	**Outcome domains Included**	**Key findings**
Balk et al 2019[37]	Function Ambulation Quality of life	50 instruments were identified but the numerous instruments available have variable psychometric properties, and there is no evidence as to whether tools designed for use or used prior to prosthetic prescription are predictive of outcome.

*International Classification of Function +Minimal Clinically Important Difference

Among the many outcome measures described in these SRs, two reviews[27,37] included measures that use item banks (Patient Reported Outcomes Measurement Information System (PROMIS) and the Prosthetic Limb Users Survey – Mobility (PLUS-M)[44]), which have interesting implications for clinical practice. An item bank, developed using item response theory,[45] consists of different questions exploring the same outcome domain, which are individually validated and calibrated on a single scale. The items from the bank can then be used as required by individual clinicians or researchers to develop specific short forms, or be administered via Computer Adaptive Testing (CAT).[46] CAT uses algorithms to select items from the bank for individual patients based on their responses to previous questions.[47] This tailored approach is able to achieve the same reliability with fewer questions therefore reducing the measurement burden on patients.[46] Despite the use of different questions with each patient the results are comparable as all items in the bank are drawn from the same scale. Both the PROMIS and the PLUS-M item banks allow comparison of scores to a large development sample allowing clinicians to compare scores with normative data. In the case of the PLUS-M this data is specific to the limb loss population. Normative data for an outcome measure can be useful for clinicians to compare individual patient or service outcome scores, giving meaning to scores as they are viewed in the context of the wider limb loss, or general population. However, few measures for use following amputation have published normative data.[40]

Despite the advantages of this approach, as with all OMs, consideration must be given to the population used to develop the OM or select items for an item bank, especially in limb loss research which can over-sample people with traumatic limb loss[48] and those living in high income countries. This may raise questions about how transferrable OMs are to different populations and subgroups who were not well-represented by the development sample, i.e., older dysvascular patients, or those from different social and cultural backgrounds. This is a global consideration for the OMs described in the SRs. Many of the measures have been developed in English and although some have now been translated and validated in other languages, which is important for use in today's diverse society, and across the world, the challenges of using OMs in different languages is not just about translation. Ensuring the measure is meaningful in different social and cultural settings is often overlooked, i.e., measuring an individual's ability to stand from a chair may not be as meaningful in countries where much time is spent sitting or squatting at floor level.

However, whatever the measure a key concern highlighted in 7 of the 10 SRs was responsiveness, or the ability to detect change when it has occurred[27,29,38–40,42,43] which is a priority when using OMs to evaluate rehabilitation interventions in clinical settings.[49] Many of the SRs described an absence of data regarding the ceiling or flooring effects of OMs[38,43] The presence of a ceiling or flooring effect limits a measures ability to detect change at either end of its scale. In a population where outcomes of rehabilitation can vary substantially between young individuals with a transtibial amputation and more elderly dysvascular persons with a transfemoral amputation, this information is crucial to help understand whether a single measure can be used to capture the outcome of the limb loss population as a whole, or whether different OMs are required for subsets of the population, i.e., high activity patients, in order to generate more meaningful information for clinical practice.

When considering the responsiveness of an OM, two important values exist to help clinicians interpret OM findings, the minimal detectable change (MDC) and the minimal clinically important difference (MCID) values. The MDC is the smallest change that can be detected by the OM which is not due to an error in measurement, i.e. a real change,[50] and the MCID is the smallest change in the score that indicates an important change for the patient, i.e. a meaningful change.[51] Five of the systematic reviews described OMs with these values.[27,37,39,42] MDC (or its equivalent values, i.e., Smallest detectable difference, smallest detectable change and smallest real difference) was established for 20 measures, whereas three reviews identified only two measures with a Minimal Clinically Important Difference (MCID) value.[37,39,42] Although the MDC value can be useful clinically, without MCID values, clinicians and patients do not know if the change they have recorded represents a meaningful change to patients' lives, whether clinical interventions were effective and, importantly, whether the investment in rehabilitation was justified. However, reflecting on the first theme of this narrative review, MCID values may only be truly meaningful if the OM captures an outcome domain which is meaningful to the patient's perception of recovery in the first place.

For clinicians, evaluating and understanding the OMs evidence base presented in these SRs, to help make an informed choice of which OM to use can be challenging. This has been attributed to the technical nature and jargon filled literature describing psychometric properties, as well as considerations over tool development and the appropriate population for use.[29,39] This process may be especially challenging when considering ROM at the service or system level, where OM selection is not guided by an individual patient's problems or needs.

2.2.5.3 Theme 3 - What are the barriers to outcome measurement?

Several studies (4) have explored OMs in prosthetic practice in an attempt to understand what factors may influence their use,[52–55] however, it should be noted that two of them focus on the same group of clinicians.[52,53] The barriers identified in this review focus on the experiences of prosthetists, of whom only 28% - 44% describe themselves as routine users of OMs.[42,52,53,55] Interestingly a thesis study of physiotherapists working in amputation rehabilitation settings found that 100% used OMs regularly, but no information was available exploring the drivers for this level of engagement.[42] Therefore, our understanding of the barriers to outcome measurement in prosthetic rehabilitation is limited to the perceptions of prosthetists, which may not reflect the views of the wider prosthetic rehabilitation multi-disciplinary team.

In all of the studies included in this theme, insufficient time was identified as a key barrier as clinicians struggled to integrate outcome measurement into their usual clinical routines[52,53,55] Although time was identified as a barrier the studies did not objectively produce an actual time for OM administration, suggesting that time may be more of a perceived than an actual barrier. A further impediment to the use of OMs identified in these studies was an often-described lack of confidence and knowledge of the tools themselves. Challenges are commonplace, including choosing a measure that is meaningful, psychometrically sound, and easy to use and interpret within a clinical session. These challenges are reportedly particularly difficult for many clinicians who lack knowledge and understanding in this highly technical field, which is not always covered at undergraduate level.[52,53,55]

An interesting finding from Hafner et al's 2017 study exploring perceptions of outcome measurement amongst 66 US prosthetists showed that a third of participants did not agree that outcome measurement provides useful data.[52] The issue of the value of outcome measurement for clinicians was highlighted again in the same study where prosthetists reported they were more likely to use the Amputee Mobility Predictor (AMP)[56] measure than the quicker-to-administer Timed Up and Go (TUG).[57] The authors discussed that this may be because the AMP was designed to guide the prescription of prosthetic componentry to insurance companies. This is supported by a study from Borrenpohl et al who found that regular OM use increased to 77% when prosthetists were specifically asked about using OMs to support payment claims.[58] These findings demonstrate the impact of perceived value in engaging clinicians in the measurement of outcome.

Solutions to address these barriers were also discussed in the same articles. The need for efficient measures, use of PROMs instead of more time-consuming observed measures, and electronic data collection at the point of care, which is integrated with health records, were all suggested to help overcome time related barriers[52,53] An educational programme focused on improving prosthetist knowledge and skills concerning outcome measurement was tested by Gaunard et al. and was found to improve confidence, which was maintained one year later.[52] However, these findings should be viewed with caution as they did not include a control group and participation in the studies may have been more attractive to those who were particularly interested in learning about outcome measurement.

2.2.5.4 Theme 4 - What can be learnt from examples of ROM in prosthetic rehabilitation?

Despite the many barriers identified in this review, examples of system wide ROM in prosthetic settings were identified, and have been explored in this theme to consider any learning for future work. A single study by Heinemann et al. explored the use of routinely collected PROMs data to inform quality improvement (QI) activities across seven US prosthetic clinics.[59] The authors described the implementation of ROM as challenging with only two of the seven clinics involved actually collecting enough data to undertake QI projects.[54] However, as the study was undertaken as research there was a higher administration burden, which was identified by the authors as the main factor for clinics dropping out.[54] Clinics that were successful in implementing ROM demonstrated high levels of organisation related to the project, integrated data collection with their electronic records and had well defined pathways of care. Clinicians in these centres reported being motivated by the chance to use PROMs to improve the care they provided to patients, however expert external facilitation was described as being crucial to increase QI knowledge within the clinical team, interpret aggregated data and translate ROM findings into improvement work.[54]

Two further examples of ROM identified in this review can be found within national registries, and as with the NJR they attempt to link demographic, surgical information and interventions with outcome data to understand the impact of lower limb amputation on patients, health care providers and society. Although in some case registries can operate separately from clinical settings and may appear inaccessible to clinical practice, they are often dependent on clinical services to collect and input data (i.e., the two examples included). This requires the implementation of data collection processes, including ROM, and therefore these examples have been included in this theme as they may provide interesting insights.

The two registries identified in this review are the Scottish Physiotherapy Amputee Research Group (SPARG) data initiative which collect data on all patients undergoing amputation in Scotland,[60] and SwedeAmp which is the national lower limb amputation registry from Sweden.[61] Both registries attempt to evaluate the whole pathway following lower limb amputation, collecting demographic details, surgical and rehabilitation interventions, prosthetic supply and outcome information, in partnership with local clinicians and services. For SwedeAmp, the authors describe implementation across the country as slow, and after 9 years the registry only captures 62% of amputations,[61] perhaps illustrating the challenges related to multidisciplinary system level data collection. Despite this data were collected on 5762 people following amputation, however the size of the sample described in the presentation of outcome data collected at 12 and 24 months, using the EQ-5D-5L, had notably decreased to n=247 and n=156 respectively. No information was presented to explain this outcome measurement attrition but insights from the project team would be useful to reflect on ROM in these settings.

In contrast, SPARG, which is a small group of 20 clinically based physiotherapists, currently captures 90% of amputations in Scotland and has done for over 20 years.[52] The size and uni-professional nature of the group may account for its success in data capture, alongside the availability of disaggregated data for benchmarking, and ongoing improvement work[62], but also places a limitation on the scope of the data set.

These projects demonstrate that system-wide data collection of outcome information, is possible in this field. Further publications regarding the implementation of these registries, especially regarding ROM implementation and data collection by clinical partners, may have value for the development of similar projects elsewhere. The potential value of the experiences of the SPARG and SwedeAmp creators may also include understanding how the outcome domains were selected and why, how the data are shared with clinical practice and how it informs local and national improvement activities, as well as how data privacy, security and governance were addressed, and finally how the barriers described in this review were overcome.

2.2.6 Discussion

This review has identified many barriers to outcome measurement in prosthetic rehabilitation, however the examples of system wide outcome measurement presented here also give an indication of what may facilitate ROM in prosthetic clinical settings, and suggests that barriers can be overcome but important lessons may need to be learnt to ensure success.

Despite the fact that only the views of prosthetists have been explored regarding outcome measurement in prosthetic clinical practice, their experiences are mirrored by those of other AHPs documented in the wider literature. Insufficient time for both patients and clinicians to complete and score measures in time-pressured clinical consultations, difficulties in selecting a measure and interpreting results, combined with low confidence and limited knowledge of outcome measurement are all commonly reported.[4,20,63–65]

This review identified that establishing value in outcome measurement could be a potential facilitator to addressing barriers to implementation. The issue of value has been raised in previous ROM initiatives. A multi stakeholder consultation on the NHS PROMS programme in 2017 found that many clinicians and managers felt it was not worth continuing with the programme despite 8 years of data collection.[66] The consultation reported that the data collection was not useful to clinical practice, could not be used during clinical consultations and that reports took too long to be published, so findings were out of date.[66] This lack of perceived value was also described in mental health settings where clinicians felt that ROM using the Health of the Nation Outcome Scales (HoNOS) was overly bureaucratic, only concerned with performance management, lacked feedback of results and presented no relative meaning for their role.[67] It seems clear that establishing the value of ROM to clinical stakeholders is key for success.[68–71]

Understanding what outcome domains are important and meaningful to measure, especially from the patient perspective, and how to measure them effectively following lower limb amputation could help make outcome measurement more useful to all stakeholders, and underpin future consensus work. An absence of consensus on outcome measurement[29] is not unique to prosthetic rehabilitation and attempts have been made to address the issue in several areas of health such as rheumatology[72] and women's health,[73] especially when related to research. The reporting of numerous outcomes in clinical trials can make the synthesis and comparison of different studies near impossible.[74] This problem has led to the development of initiatives such as Core Outcome Measurement in Effectiveness Trials (COMET) who seek to develop consensus around what domains to measure through core outcome sets (COS) to be recorded in all clinical trials of a specific condition.[75] They also highlight that this approach can be useful to build consensus around outcome measurement in clinical practice.[74] COMET adopt a multi-stakeholder approach to identifying outcome domains of importance and seek to build consensus that can then be championed by the stakeholders involved. Importantly COMET advocate the inclusion of patients at the centre of this process, ensuring that a COS is measuring domains that matter most to the people affected by the outcome of an intervention.[74] The studies identified in this review by Schaffalitzky et al. and McDonald et al. have made some progress towards understanding the domains that define successful prosthetic prescription from a user's perspective, especially focusing on the need to measure psychosocial outcomes.[33–35] Schaffalitzky et al. also highlight that clinician's and patient's view important outcome domains differently. This difference has been reported in other studies exploring UK orthotists perspectives of clinical outcomes,[76] and in the development of a COS for rheumatoid arthritis,[77] and suggests that when seeking to build consensus around important outcome domains for measurement, that the patient's voice is properly represented, especially in commonly used, but arguably less accessible, consensus building techniques such as Delphi.[74]

A rigorous foundation understanding which outcome domains are most important following prosthetic rehabilitation could lead to a consensus on outcome domains for measurement both clinically and in research, which would then direct the recommendation, or development of, a set of accompanying OMs. This set would need to play its part in overcoming some of the barriers to measurement described here, such as capturing meaningful changes over time, feasibility of use and ease of interpretation in busy clinics, as well as not overburdening patients themselves. This process is unlikely to be simple, as highlighted by the UKROC project when developing a national set for neuro rehabilitation. They describe a tension between identifying measures that have robust psychometric properties that generate data that is useful for quantitative analysis, and measures that are feasible to use in clinical settings, and that clinicians themselves want to use as part of the clinical decision-making process.[15]

Usefully COMET have also defined 'Consensus-based Standards for the selection of Health Measurement Instruments', which is a systematic approach to identifying, selecting and assessing the quality of relevant tools, to capture the important outcome domains agreed upon in a COS[78,79] thus defining a framework for how to measure outcome.

It appears the final piece in the value puzzle may go beyond what to measure and how to measure it and focus on how outcome measurement data can be collected and used, which is described here as outcome measurement practice. This review identified that many prosthetists felt that outcome measurement was not useful[52] which is supported by concerns described in the NHS PROMS programme consultation[66], mental health examples[67] and the wider AHP literature.[65]

All of these examples report that the ability to use OM data as part of usual care to inform treatment planning and monitor the progress of long-term conditions in real time are key.[52,66,67] The use of electronic records systems, as described by Heinemann as a facilitator of success[54], is increasing rapidly throughout health care organisations and presents opportunities to develop IT that supports OM collection. One of the aims of outcome measurement practice could therefore be to integrate results with clinical records and present findings instantly, enabling real time use, as well as for locally owned reporting and upload to national data sets which could be accessed for research.[80] The UKROC programme attributed its consistent high quality data collection to the fact that OM data collated on their electronic system was available 'live' for clinicians. This access combined with careful integration of OMs into all aspects of clinical care, such as managing bed capacity and discharge planning, ensured OMs were useful to clinical teams and promoted delivery of the best care.[15]

Although the use of electronic platforms could allow for less burdensome OM completion, collation, and real time feedback to clinicians, successful clinical uptake is likely to lie in the cost of the system as well as the accessibility of both the electronic version of the measure during data collection with patients, and the mode of presenting information and reporting in an accessible way for interpretation. A qualitative study of UK orthotists perceptions of outcome measurement identified technology as a potential enabler of OM use as long as it was usable, enabled interpretation of reports and met clinical need.[76]

Being able to interpret OM data may be key to outcome measurement practice and could improve acceptance, especially when using aggregated OM data.[3,81] Expert external facilitation was championed by Heinemann et al[54] and has been described as part of other system level OM initiatives.[15] Facilitation would be useful to support clinicians who report low levels of knowledge and confidence in using OMs, as well as working in busy clinical environments where there is often little time for anything other than treating patients.[52,53]

Developing partnerships with academic institutions or QI teams may help clinicians with the interpretation of findings and address educational needs through joint working. Academics often have highly developed data analysis skills and increasingly need to demonstrate the real-world impact of their work, for example in the UK's Research Excellence Framework and Knowledge Exchange Framework. Clinical academic roles, improvement fellowships or partnerships with universities could bridge the expertise gap between clinical practice, academia and QI.[82] This is critically important when attempting to translate outcome data into improvements in care. Outcome data at the service or system level, without the context of the individual patient's problems and goals, does not itself inform what the underlying cause of a poor outcome is, and only indicates where a problem may lie. Further work, as described by Heinemann et al., is then required to investigate causes, implement change and evaluate its effectiveness.[54,62,82] Individuals with this valuable 'knowhow' may be critical to making outcome measurement practice really work in multidisciplinary clinical settings.

2.2.6.1 Limitations

Although a rigorous approach was taken in an attempt to address previous criticisms of narrative reviews,[83] the broad nature of this specific review and the absence of critical appraisal tools, may have led to potential bias in the selection of articles deemed as relevant to the aims of the review. For example, the selection of papers for inclusion within the review and the interpretation of the findings, were based on what the authors felt was relevant to clinical practice. This could result in bias arising from the authors interpretations, and possible 'cherry picking' of papers to address the review aims. However, recent publications by Greenhalgh and colleagues[23] and Furley and Goldschmeid[25] challenge this criticism and suggest no reviews, even systematic ones, are unbiased and that the aim of a narrative review is to interpret the evidence and deepen understanding around a subject, rather than just add to the continued assimilation of numbers.[23] This broad overview, with early scoping objectives, should be seen as a useful starting point which sets the scene for more systematic approaches in the future to explore some of the themes identified here in more detail.

It should also be considered that this review identified OMs in the form of scales, tools or questionnaires and does not include other outcomes that may be in use clinically, or of importance to prosthetic users, such as hours of limb use or limb abandonment.

2.2.7 Conclusion

This narrative review takes a broad look at outcome measurement in prosthetic rehabilitation from a clinical perspective and has suggested that successful implementation is complex and multifaceted. Understanding and embedding value at every step may be key to success.

Measuring the outcome of interventions is important to understand the impact on patients and the performance of services. However, it is more than just selecting an OM. Clinically there is a need to understand the 'why', 'what' and 'how' of outcome measurement. 'Why' measure, i.e., to inform at the individual or system level, 'what' domains to measure, i.e., capturing outcome domains that are meaningful, and 'how' to measure them, i.e., the best tools for the job used in a systematic way that adds value to clinical practice.

Future work needs to engage with patients and stakeholders to develop outcome measurement solutions that consider and overcome the barriers to implementation highlighted in this review. Absence of consensus needs to be addressed around what domains to measure, and how to measure them, whilst ensuring outcome domains are meaningful to patients and measurement tools are accessible to use and interpret. Outcome measurement practice can then be explored in partnership with universities or local quality improvement teams, which focuses on understanding and realising the value of outcome measurement to prosthetic rehabilitation services, to evidence and improve clinical practice.

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Chapter 3 Paper 2 - Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: The patient's perspective

3.1 Introduction to paper 2

This chapter introduces the second of four papers which make up this thesis. Paper two begins to address some of the gaps in the literature identified in paper one. The narrative review (Paper 1) identified that little is known about which outcome domains should be measured following lower limb prosthetic rehabilitation, particularly from the patient's perspective, and suggested measuring what matters most may add value to outcome measurement in clinical settings. This finding led to the development of a large qualitative study, which collected data for papers two and three. This chapter describes the analysis which comprises paper two. Paper two aimed to explore outcome domains of importance from the patient's perspective, addressing the overall aims of the thesis by building our understanding of the patient's perspective of outcome measurement (Objective 2) and beginning to develop a conceptual model of meaningful domains (Objective 3). This research was conducted as part of phase B as described in Figure 3.1.

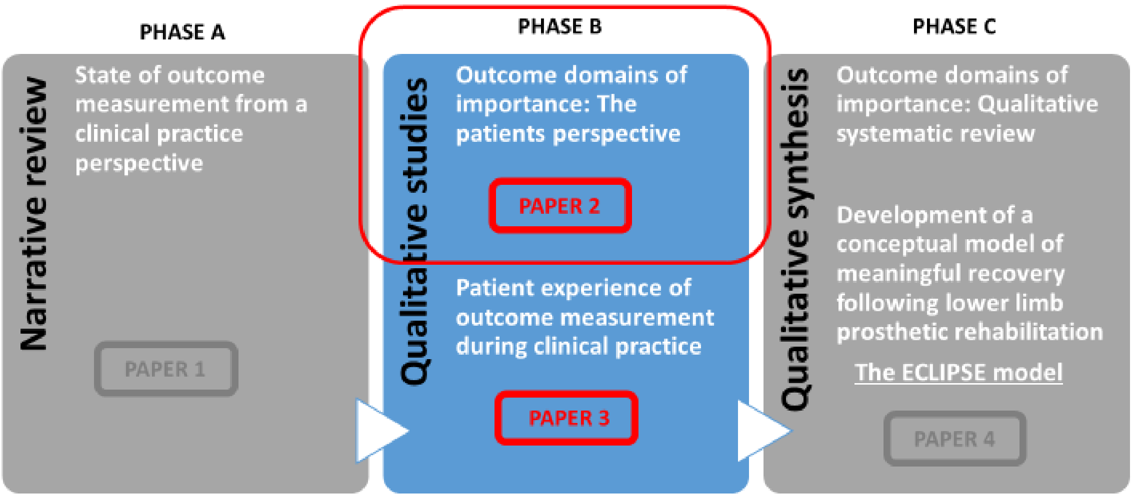

Figure 3.1 Phase B and paper two in the context of the complete thesis.

This chapter includes an initial summary of paper two, in the form of an extended abstract, followed by the main manuscript, including all figures and references

3.1.1 Summary of paper 2

The narrative review described in chapter two (Paper 1) highlighted an absence of consensus regarding what outcome measures to use in prosthetic clinical practice, which could be underpinned by a further lack of consensus of which outcome domains to measure following lower limb prosthetic rehabilitation (Ostler, Scott, *et al.*, 2022). The review also suggested that measuring what matters most may add value to outcome measurement in clinical settings (Ostler, Scott, *et al.*, 2022). Prosthetic users were shown to have a unique insight into important outcome domains (Schaffalitzky *et al.*, 2011)and are conceivably those for whom the outcome of rehabilitation has the greatest impact. Several studies have begun to explore what people who use a prosthetic limb feel are important outcome domains but have focused on the outcome of prosthetic prescription (i.e., different prosthetic feet or knees), rather than the outcome of a multidisciplinary approach to rehabilitation as provided in the UK (Schaffalitzky *et al.*, 2011; McDonald *et al.*, 2019). Therefore, the aim of this study was to explore important outcome domains of recovery from the perspective of people who have undergone prosthetic rehabilitation following lower limb amputation.

3.1.1.1 Method

Due to the exploratory nature of this work and limited previous research on the topic, an experiential qualitative approach was used independent of any defined methodology, such as grounded theory or phenomenology. This open approach, using reflexive thematic analysis (Braun and Clarke, 2021), seeks to capture the complexity and diversity of recovery following lower limb loss, and explore and interpret what domains characterise a successful outcome from the perspective of the person with lower limb loss. The study was informed and designed with a group of public researcher partners who helped ensure the language around outcome measurement, which may be viewed as a `research` or `clinically focused’ concept, was accessible. Thirty-seven participants who underwent lower limb amputation in the last five years were recruited from NHS limb fitting centres and social media. A combination of convenience and purposive sampling were used to ensure a heterogenous sample representative of the UK limb loss population. Data were collected using focus groups and interviews and analysed using reflexive thematic analysis as described by Braun and Clarke (Braun and Clarke, 2006, 2021; Clarke and Braun, 2013). Synthesised member checking (Birt *et al.*, 2016) was undertaken following data analysis to allow participants the opportunity to reflect and feedback on the themes.

3.1.1.2 Results

Five themes were identified that describe outcome domains of importance from the patient's perspective:

1) I am able to participate in my important activities

2) I can participate in my important activities in the *way* I want to, i.e., independently, with ease, without falling over, and with minimal equipment.

3) My prosthesis is comfortable and easy-to-use

4) If I have pain, I am able to manage it

5) I am able to accept my new normal

These five themes, or outcome domains, did not exist in isolation, but appeared to interact with each other, contributing to, or inhibiting the participant's holistic sense of recovery.

3.1.1.3 Conclusions

The findings from this research highlight the need for a multidomain approach to outcome measurement, focused on what is important to people with limb loss and capturing the interrelated nature of domains. Understanding what domains define recovery can help to inform domain consensus, as well as direct the focus of rehabilitation. Domain consensus could guide the selection of measurement tools that evaluate prosthetic interventions in a meaningful way and begin to address some of the wider issues identified in the narrative review (Paper1, Chapter2).

3.1.2 Publication details

Paper two has been published in 2022 in Disability and Rehabilitation, and is available in its published format in appendix D. Disability and Rehabilitation was selected as it has a wider readership than Prosthetic and Orthotics international, extending beyond prosthetics into associated fields of rehabilitation. As the results from paper two could have implications for MDT clinical practice and research, it was decided that this publication would expose the findings to a wider audience. The paper two study documents, such as the recruitment materials, analysis and reflections can be found in appendix E. The findings from this study have also been presented as both platform presentations and poster presentations (Appendix G) at several conferences including the UK BACPAR conference 2019 in Wolverhampton and the ISPO world congress 2021 which was held online.

The referencing style of Disability and Rehabilitation is the Vancouver style. Referencing has been presented in this format, with an accompanying reference list. Paper two is presented in the following section.

3.2 Paper 2 manuscript

3.2.1 Title

Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: The patient's perspective

3.2.2 Authors

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3.2.3 Implications for Rehabilitation

- There is currently no consensus around which outcome domains should be measured following prosthetic rehabilitation
- Outcome domains of importance from a patient's perspective focus on participation in important activities, prosthesis comfort, pain management and acceptance of their new normal.
- Identifying these domains can help direct the focus of rehabilitation as well as inform outcome measurement practice.
- The interrelated nature of these domains suggest the need for a physical and psychosocial multi-domain approach to outcome measurement in prosthetic rehabilitation, with patient priorities at its centre.

3.2.4 Introduction

As the demand for healthcare increases [1] and the cost of delivering services to an aging population spiral [2], outcome measurement has been highlighted as central to understanding the value of healthcare provision [3]. The term 'outcome measurement' can be better understood by breaking it down into the outcome domain being measured and the measurement tool used for the task. An outcome domain can be defined as an element of health (i.e., pain, physical function, emotional wellbeing, social activity) that is changed by a particular intervention [4]. A measurement tool can be defined as a standardised instrument used in research and clinical practice to capture and evaluate the change [5].

Within the field of prosthetic rehabilitation, research focusing on outcome measurement appears to centre around the development and analysis of measurement tools [6–15]. For example, a review carried out by Heinemann and colleagues [16] identified 43 different tools for use following lower limb amputation. The wide range of tools available has led several authors to highlight an absence of consensus in the field regarding the use of measurement tools, i.e., which tools should be used to evaluate different domains [6,7]. A recent narrative review [17] suggests that this may be driven by a lack of understanding and consensus around which outcome domains characterise meaningful recovery following prosthetic rehabilitation.

The absence of consensus regarding both outcome domains and measurement tools is problematic for clinical and research settings. In clinical practice, consensus would enable routine measurement of agreed domains, using standardised tools, across prosthetic service providers nationally and internationally. This information could inform the use of available resources to have the greatest impact on patient's lives [3]. Such an approach could also allow benchmarking to identify services where outcomes measured against agreed domains are good and use those as exemplars to raise standards across healthcare providers, reducing variation in the system.

In research, a consensus about what outcome domains are important and should be measured would enable effective comparison and synthesis of studies that evaluate the same interventions. This could contribute to a less fragmented evidence base and reduce research waste [18]. However, consensus is not a problem unique to prosthetic rehabilitation [19,20] and has led to the development of initiatives such as Core Outcome Measurement in Effectiveness Trials (COMET) [21], and the International Consortium of Health Outcome Measurement (ICHOM) [22]. These organisations take a step back from selecting measurement tools and first seek to develop consensus around what outcome domains to measure, in research (COMET), or clinical settings (ICHOM). Both organisations advocate for a multi-stakeholder approach to developing outcome domain consensus, with patients at the centre of the process, as these are the individuals for whom health and rehabilitation interventions have the most impact. Understanding this perspective not only has the potential to direct meaningful outcome measurement but can also provide insight into what domains are most valued by patients and should be the focus of rehabilitation.

Qualitative approaches are increasingly used to explore meaningful outcome domains from the patient's perspective [18]. Within the field of prosthetic rehabilitation qualitative approaches have been highlighted by Murray and Forshaw as important patient-centred methodologies for informing healthcare for people with limb loss [23]. A recent editorial by Dillon et al. [24] also encouraged qualitative enquiry in the field of prosthetics, championing its use in informing clinical practice and future research.

Several authors have begun to explore what people who use a prosthetic limb feel are important outcome domains using qualitative approaches. A small body of research has explored this phenomenon within the context of the international classification of functioning (ICF) [25–28]. The ICF is a classification system developed by the World Health Organisation (WHO) to provide a universal language to describe the health and functioning of individuals [29]. It describes a dynamic interaction between many different domains, which can be characterised as body impairments, activity limitations, and participation restrictions, as well as contextual factors such as environmental conditions and personal factors [29]. The ICF is often used to categorise functional impairment following amputation [30].

Several studies have used qualitative methods to explore the views of patients and clinicians to develop a core set of concepts from the wider ICF that describe function and disability following lower limb amputation. It has been suggested that these core concepts/domains could be used to inform rehabilitation priorities and direct which outcome domains to measure [25–27].

Although large numbers of the concepts identified by patients (92%) and clinicians (82%) in these studies were matched to ICF domains [25,26], not all the concepts aligned. Both studies highlighted that important concepts, such as `socket comfort and appearance' and `acceptance following amputation', could not be matched and were therefore not included [25,26]. In addition to this, ICF core set development uses a deductive approach that follows core set development guidance [31] including questions designed to illicit responses within the ICF domains [25]. This approach may diminish the voice of the patient by limiting the depth and richness of their personal accounts, which could lead to further important domains specific to prosthetic users being misunderstood or overlooked. Although the ICF provides a useful foundation for understanding functioning and disability, exploring outcome domains of importance exclusively within this universal framework may restrict the depth and understanding of the experience of prosthetic limb users.

Two further studies have used more iterative qualitative designs to take a patient-centred approach to understanding outcome domains of importance, such as balance, safety, independence, and adjustment to amputation [32,33]. McDonald and colleagues [32] used a qualitative focus group approach to explore domains related to physical function, that were important to five individuals with lower limb loss taking part in a trial of two different prosthetic feet. Schaffalitsky et al.[33,34] also explored the benefits of prosthetic prescription from a patient, clinician and wider stakeholder viewpoint. Interestingly clinicians and patients often prioritised different domains. As clinicians are most likely to select what outcome domains are measured [32], it is possible that services may not be capturing what patients think are the domains that really matter.

These studies also focused on the outcome of a single intervention in the post-amputation rehabilitation pathway, i.e., the prescription of prosthetic componentry, and did not consider the outcome of a multidisciplinary approach to rehabilitation with that device, delivered in a holistic way through a variety of interventions i.e. physiotherapy, counselling, occupational therapy etc. Evidence-based guidance from a range of professional bodies involved in prosthetic rehabilitation recommend that recovery following lower limb amputation should be facilitated by a period of multidisciplinary rehabilitation that addresses the physical, psychological and social needs of the patient, far beyond prescribing them with a prosthetic device [35–38].

There is currently limited research which takes an iterative patient-centred approach to understanding outcome domains that are important to prosthetic users following lower limb amputation, particularly from a holistic rehabilitation perspective. Therefore, the aim of this study was to explore important outcome domains of recovery, from the perspective of people who have undergone prosthetic rehabilitation following lower limb amputation.

3.2.5 Materials and Methods

3.2.5.1 Research Design

This research has been developed from a critical realist world view which looks to access the knowable world as seen through different lenses, in this case the perceptions of the most important outcome domains following lower limb amputation, within a community of prosthetic users [39]. Due to the exploratory nature of this work, and limited previous research on the topic, an experiential qualitative approach was used independent of any specific theoretical and epistemological stance, such as grounded theory or phenomenology. This open approach, using reflexive thematic analysis [40], fits well with the critical realist world view, seeking to capture the complexity and diversity of recovery following lower limb loss [39], and will explore and interpret what domains characterise a successful outcome from the perspective of the person with lower limb loss.

3.2.5.1.1 Patient and Public Involvement and Engagement (PPIE)

Patient and public involvement and engagement in research is defined as “research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them”[41,42] and is vital to ensure research is focused on issues the public feel are important and is conducted in a participant centred way. As the notions of ‘outcome’ or ‘domain’ may be viewed as ‘research’ or ‘clinically-focused' concepts, ensuring we were asking about them in a way that people with limb loss found accessible was an important part of our PPIE. We worked closely with a group of public research partners who were established prosthetic limb wearers. The group helped us to think about the language patients may use when talking about outcome domains, as well as practical issues such as where patients would like to find out about the study and how they might like to take part. This crucial PPIE approach allowed us to co-design the study and study materials, such as the interview guide, to ensure a positive participant experience, maximise recruitment and develop accessible language around the concept of outcome domains in partnership with patients.

3.2.5.1.2 Ethical review

The study was given ethical approval by the East Midlands Research Ethics Committee and the National Health Service (NHS) Health Research Authority (Ref: 8/EM/0259).

3.2.5.1.3 Participants

Participants were invited to take part in the study if they were over the age of 18 and had undergone a major lower limb amputation (i.e. an amputation occurring at or proximal to the ankle, due to the extent of the functional impact associated with higher levels of amputation [43]) within the last five years. This was to ensure the clarity with which they were able to recall their rehabilitation experiences. The inclusion criteria also stated that participants must have completed rehabilitation with a prosthetic limb, allowing them to reflect on their own recovery.

A number of recruitment approaches were used to generate a sample with a range of rehabilitation and limb loss experiences relevant to UK practice. Clinical teams (i.e. Physiotherapists, Prosthetists, Rehabilitation Consultants) working in four English NHS prosthetic rehabilitation centres introduced the study to eligible participants as they completed their outpatient rehabilitation, or returned for follow up reviews with their prosthetist or multidisciplinary team. Adverts were also posted on social media platforms and invitation letters were sent to limb loss supporting charitable organisations to share with their members.

Sampling was undertaken using a two-staged process using both convenience and purposive sampling that was informed by a demographic questionnaire. This approach was undertaken to build a sample with a diverse range of characteristics, views, and experiences, which are representative of people who undergo prosthetic rehabilitation. The questionnaire collated self-reported information from participants on a variety of characteristics which may influence outcome following lower limb amputation, such as age, level of amputation, presence of co-morbidities, functional status and social support [44,45]. Convenience sampling was used in stage one, and the characteristics of the sample were monitored throughout. This approach led to fewer older transfemoral participants included in the sample than are described in the UK limb loss population [46–48]. The final six participants in the study were recruited purposively. Stage two purposive sampling involved clinical teams approaching participants with the required characteristics (65 years of age or older, and a transfemoral amputation) which were verified prior to consent using the demographic questionnaire.

3.2.5.1.4 Procedure

As the aim of the study was to explore and understand the views and experiences of participants, focus groups and semi structured interviews were used to collect data as these approaches enable follow up questions and contextualisation of answers [39]. The selection of both of these methods was on the advice of our PPIE group, to enable and promote participation in a way that individuals found most acceptable and comfortable. As we were talking about life after amputation, which is a complex and life changing experience, it was anticipated that the choice of how to be involved would allow people to feel more at ease when sharing their experiences.

Participants self-selected how they would like to take part, and the focus groups and interviews were completed independently of each other and in parallel. This multiple method approach allowed data source triangulation, providing different views of the same phenomenon, gathered using different methods to enhance credibility [49].

Focus groups took place in a quiet room in each of the four recruiting limb centres and lasted no more than an hour and a half. Interviews were undertaken either over the telephone or in a location of the participant’s choosing and lasted up to one hour. Written informed consent was collected from all participants prior to their involvement in the study.

A semi-structured interview guide was co-produced with our PPIE group (Figure 3.2) and was used to collect data during both interviews and focus groups. Data were audio recorded and then transcribed verbatim to capture all verbal utterances. Transcripts were fully anonymised to remove any identifiable information and pseudonyms were used throughout to ensure the confidentiality of participants. Written consent was also obtained for using verbatim quotations.

1. **Introductions and story sharing**
2. **Visual timeline of rehab journey**–

   Imagine we are going to take you back in time to the point where you had finished your rehabilitation (Rehabilitation phase). What had you hoped you would achieve by this point?

   What would you have liked to achieve in order to be happy with the outcome?

   Discuss what 'kind' of walking did you want to be able to do?

   At what point did you think 'I'm OK'

3. **Word cards**

   How would you describe this achievement?

   What words would you use?

   Here are some words used by other people what do you think?

   FREEDOM

   INDEPENDENCE

   COMFORT

   ADJUSTED

   PAIN FREE

   MANAGABLE

   What do you think success is for you?

Figure 3.2 Semi structured interview guide

3.2.5.1.5 Research team and reflexivity

Contextual information about the research team has been presented here to enable readers to assess any influence our background and experience may have had on the research [50]. All of the interviews and two of the four focus groups in the study were undertaken by the first author (CO). CO is a consultant clinical academic physiotherapist at one of the recruiting limb centres. She has over 15 years' experience in prosthetic rehabilitation clinical practice, and 10 years of experience in research. This study is being undertaken as part of CO's Ph.D., but she has undertaken several qualitative research enquiries prior to the study described here. The second author (MDH) is one of CO's Ph.D. supervisors, a health psychologist and associate professor. She has over 20 years of experience undertaking qualitative research with people following limb loss, and complimentary areas of rehabilitation. MDH conducted the other two focus groups as some of the participants were known to CO. Both CO and MDH undertook aspects of the data analysis, described below in Table

3.1. Involvement of a second researcher helped to refine ideas, enhance the reflexive process, and by viewing the phenomenon through a different lens, provide more comprehensive interpretive depth within the findings, therefore enhancing credibility [40].

A reflexive diary was kept by CO throughout and discussed regularly with the rest of the research team (MDH, AD and CM), in order to reflect on the impact of different perspectives and assumptions influencing the study design, data collection and data analysis.

3.2.5.1.6 Data analysis

Data were analysed iteratively using reflexive thematic analysis, described by Braun and Clarke[39,40,51], as it provides a flexible approach which sets out a way of systematically grouping and identifying meaning within the data. NVIVO software (QSR International, Melbourne, Australia) was used to manage the data. Initially interviews and focus groups were analysed separately. Verbatim transcripts were coded in as many ways as needed, allowing lines of text to be coded more than once in order to consider different interpretation and meaning. A second researcher coded a subsection of the transcripts. Similarities and overlap were identified between codes and potential patterns relevant to the research question were created. Visual maps of initial themes from the interview and focus groups analyses were created independently of each other to compare and contrast. The full set of themes from both analyses were then reviewed, refined and integrated, in order to present coherent patterns within the data. Table 3.1 describes the stages of reflexive thematic analysis and who they were undertaken by.

Table 3.1 Description of reflexive thematic analysis process

Phase	Description of process
1. Familiarisation with the data	Audio-recordings of both focus groups and interviews were transcribed verbatim. Transcripts were read and re-read, and initial noticing's recorded in a research journal by CO.
2. Coding	Complete coding of the focus group and interview data sets was performed separately, by CO. With a subsection competed by MDH. Extracts of text were coded in as many ways as needed, including both data derived and research derived codes. Coding decisions were discussed, and a reflective journal was completed by CO throughout the analysis process to reflect on the different researcher lenses, and the researchers own views and assumptions.
3. Generating initial themes	For each analysis the codes and coded data were examined. Similarities and overlap were identified between codes and potential patterns relevant to the research question were created by CO and MDH.
4. Reviewing and developing themes	Separate visual maps of initial themes from the interview and focus groups analyses were created and compared by CO. All transcripts were re-read, and the fit of initial themes reviewed in relation to the full data set and coded data by CO.
5. Refining, defining and naming themes	The full set of themes from both analyses were then reviewed, refined and integrated by CO and MDH. Themes were collapsed or expanded in order to present coherent patterns within the data. The wider research team (AD,CM), reviewed refined themes to ensure they captured important meaning in relation to the research question, and assisted reflection on researcher assumptions. A person-centred approach was taken by CO to name the themes in order to capture the voice of participants.
6. Writing up	Writing the report also acted as part of the process of refining and defining themes. Appropriate examples of extracts from the full data set were selected to represent each theme by CO. Analysis was linked to the research question and literature, and a final report was produced by CO,MDH,AD,CM.

The characteristics of the sample were also analysed using data collected from the demographic questionnaire. Means and percentages were used to describe the full sample. To explore the potential relationship within themes, participant's characteristics were linked to all the quotations within the subthemes. Although this process of synthesis helped contextualise the findings, it was carried out cautiously as the sample was small and this was not the key aim of this qualitative approach.

Data saturation was not sought as reflexive thematic analysis does not presume that the themes emerge from the data but are interpreted during the researcher's analytical process, and on this basis further interpretations are always possible [52]. In addition, experiences following lower limb amputation can be diverse, depending on characteristics such as age or cause of amputation, and it is unlikely any one study design would be able to capture them all [52]. Data collection was completed when close to 40 participants were recruited as this was deemed a pragmatic sample size based on the time and resources available to the research team [53].

Synthesized member checking [54] was undertaken following data analysis to offer participants the opportunity to reflect and feedback on the themes. This process enabled further triangulation of the knowledge gathered around the phenomenon of outcome domains of importance following prosthetic rehabilitation. Member checking allowed participants to assess the trustworthiness of the findings, ensuring they resonated with their experiences so the results may be credible with the wider limb loss population.

An accessible synthesised summary of the results, with space for written feedback, was sent by post to participants with an accompanying return envelope. It was not possible to send all participants a summary. Three participants had not provided an address, one participant had moved, and one participant had died. Seven summaries were returned (19%). All of the returned summaries confirmed the study findings and none of the themes were altered following feedback. Written responses were added to the data set and cross referenced with existing codes, as described in Table 3.1.

3.2.6 Results

3.2.6.1 Sample characteristics

Forty-two participants were approached during the recruitment phase of the study. One participant was ineligible, three participants dropped out due to health reasons and one participant's audio recording malfunctioned. This resulted in 37 participants' views and experiences being included in the study. Eighteen participants took part in interviews (14 via telephone and four face to face) and 19 participants took part in four focus groups comprising of a group of 7, a group of 5, a group of 4 and a group of 3.

The sample characteristics were varied and included participants between 33 and 88 years of age, with a variety of different levels of amputation, including both knee and hip disarticulation. Time since amputation ranged between 6 months and 5 years and the cause of amputation included diabetes, peripheral vascular disease, trauma, cancer and infection. The participants also had varied social situations, employment, self-reported level of independence with activities of daily living, and functional status. Table 3.2 further summarises the sample characteristics.

Table 3.2 Sample characteristics

Characteristic	N=37	
Age	Mean 59 years (Range 33-88 Years)	
Gender	Male	23 (62%)
	Female	14 (38 %)
Level of amputation	Transtibial	20 (54%)
	Knee Disarticulation	4 (11 %)
	Transfemoral	8 (21%)
	Bilateral Transtibial	4 (11%)
	Hip Disarticulation	1 (3%)
Time since amputation	Mean 2.2 years (Range 6 months – 5 years)	
Cause of amputation	Diabetes	10 (27%)
	Trauma	9 (24%)
	Cancer	2 (5%)
	Peripheral Vascular Disease	8 (22%)
	Infection	4 (11%)
	Other	4 (11%)
Number of co-morbidities	None	9 (24%)
	1	9 (24%)
	2	7 (19%)
	3	4 (11%)
	4	2 (6%)
	5	6 (16%)
Social situation	Living alone	8 (22%)
	Living with partner	19 (51%)
	Living with family	10 (27%)
Independence with ADLs	Independent	12 (33%)
	Family supporting	19 (51%)
	Package of Care	6 (16%)
Employment status	Employed	9 (24%)
	Unemployed	10 (27%)
	Retired	15 (41%)
	Volunteer	3 (8%)
Use of walking aids	None/ occasional use	12 (32%)
	Sticks/ Crutches	21 (57%)
	Walking frame	4 (11%)
Community ambulatory	Yes	34 (92%)
	No	3 (8%)
Walking distance	50 metres or less	11 (30%)
	51-500 metres	10 (27%)
	501 metres -1 Kilometre	3 (8%)
	More than 1 Kilometre	11 (30%)
	Unsure	2 (5%)

3.2.6.2 Themes

Five themes, with associated subthemes, were identified, which illustrate what participants felt were the important outcome domains that characterise successful prosthetic rehabilitation. The themes are summarised in Table 3.3 and will be explored below alongside quotes from study participants.

Pseudonyms are used throughout, and quotes have been contextualised with information about the participant's age and level of amputation.

Table 3.3 Summary of study themes and related subthemes

Themes and subthemes
Theme 1. I am able to participate in my important activities *Subthemes:* (1.1) Walking again (1.2) Important activities at home (1.3) Important activities in my community
Theme 2. I can participate in my important activities in the *way* I want to *Subthemes:* (2.1) Doing my activities independently (2.2) Doing my activities easily (2.3) Doing my activities without falling over (2.4) Doing my activities with as little equipment as possible
Theme 3. My prosthesis is comfortable and easy to use
Theme 4. If I have pain, I am able to manage it
Theme 5. I am able to accept my new normal *Subthemes:* (5.1) Chasing normality (5.2) Adjusting to limb loss (5.3) Sense of achievement

3.2.6.2.1 Theme 1 – I am able to participate in my important activities

This theme describes outcome domains of prosthetic rehabilitation related to participation in important activities.

Subtheme 1.1- Walking again

The participants in this study highlighted the importance of being able to walk again following their amputation. This was often the first thing they talked about when describing a successful recovery. The ability to walk was spoken of as a 'wonderful' experience which helped participants regain their sense of wellbeing and was intimately linked with feeling 'normal' again.

> *she said I'd like to try to get you on your feet now. I looked at her as though she was mad. You know and as soon as I got on my feet, I was OK. It was wonderful. I never thought I'd ever walk again.* (David, 74 yrs, TTA)

Being able to walk again was an important outcome; it was also described here as a skill, which when attained enabled people to participate in their important activities. It was this participation that was highly valued. The different activities participants wanted to do were often referred to on a continuum. Activities progressed from indoor household activities discussed mainly by older less mobile participants, to activities within the wider community.

Subtheme 1.2 – Important activities at home

Being able to walk enabled participants to carry out basic but essential household tasks such as personal care or making and carrying their own cup of tea. Doing these important tasks while standing was also described as significant and appeared to be linked to feelings of normality, sense of self and achievement.

> *I was able to achieve what I wanted, I wanted to be able to stand up in my kitchen and cook and things erm like that and walk a little bit and things. Not unaided because I needed to use a stick but to me that was really good.* (Gill, 67Yrs, TTA)

Despite the importance of household tasks, it was clear that being limited to the home environment exclusively would be a frustrating and unsatisfactory experience. Participants described a strong desire to function outside of their homes and within their communities. Even being able to get out of the house and into the garden was identified as something that could ease this frustration, particularly for people who were only able to walk short distances, i.e., less than 50 metres.

> *Well I only just walk up and down really because I have a gardener.*
>
> *I: So just being able to go outside?*
>
> *FP: Yes, Yes Yes, I suppose that is freedom isn't it, because at the moment I'm stuck in the house.* (Rita, 81yrs, TFA)

Subtheme 1.3 – Important activities in my community

Being able to participate in important activities outside the house was described as a vital part of recovery. The activities discussed varied from person to person and reflected the wide range of meaningful things people do in their day to day lives. Some of the activities described included; being able to go shopping, drive a car, go on holiday, and return to work, hobbies, socialising, and sport.

> *my husband and I used to do quite adventurous holidays, so I wanted to get back to that sort of stuff. We'd had to knock that on the head for a couple of years prior to em prior to my amputation.* (Samantha, 54yrs, TTA)
>
> *I know for me I set myself a goal, I left here in October and I said by December I want to be driving so I just got in the car and that was it.* (Lucy, 44yrs, HD)

In order to venture outside of the house, several key skills seemed important for people to attain, in addition to being able to walk. For example, the ability to manage stairs, slopes and uneven ground were viewed as essential skills, which then enabled the important outcome of being participate in important activities. Steps and slope skills enabled participants to sleep upstairs again or visit other people's homes to socialise. Being able to traverse different surfaces was identified as a vital skill to function in the outside world.

> *what are you like on different surfaces um because because that is what pushes you from that technical ability to walking into a functional ability to walk. because it's knowing that if you can walk a mile but you can't walk on any uneven or non-level ground then it doesn't matter how far you can walk really because within that distance you are always going to encounter um some some some sort of uneven ground.* (Darren, 47yrs, KD)

3.2.6.2.2 Theme 2 – I can participate in my important activities in the way I want to

The participants in the study described success as more than whether or not they were able to participate in their important activities, they also talked about `how' they were able to participate.

Subtheme 2.1 - Doing my activities independently

Participants discussed that the degree of independence they achieved following their amputation influenced how successful they felt their recovery was. The impact that independence, and conversely dependence, appeared to have on their wellbeing was significant. Lost independence led participants to talk about losing their dignity and sense of self-worth.

> *I wee in a bottle, I mess in a bucket. My wife has to work full time and comes home at the end of the day and she has to empty my mess out of a bucket. That isn't life. They've just finally given me planning permission and I'm trying to get somebody to come and start the building and all I've been told is next year. So that's going to be another year. Life ain't fun anymore.* (Don, 64ys, TTA)

Without independence, participants were reliant on other people to help with personal care and getting out of the house. They described this reliance as frustrating and debilitating and spoke of feeling like a burden.

> *Yes because then even the simplest thing like going to the supermarket you know its having to say to people oh can you pass me that, can you get me that. You can do things. I mean I'm not having I can get up and get something without having to say to somebody can you do that. and I mean it means if I want to go out in the car I don't have to have the*

> *wheelchair loaded and struggle on and have my wife there with me, I can just go on and jump in the car and go off to where I have to go to.* (Adam, 38yrs, TTA)

Almost all the participants who spoke about the importance of being independent and not having to rely on others lived with a spouse or with their family.

Subtheme 2.2 - Doing my activities easily

As participants described their recovery following amputation, they discussed how their aims shifted over time from being able to do an activity, to doing the activity easily and with less conscious effort. They talked about the importance of mastering tasks to make them less effortful or in need of less planning. Being unable to master a task could result in not doing it at all.

> *I have on occasion walked to the bus stop, got on the bus and gone to a restaurant, got out walked to the restaurant, der der der so I can do that. But I still wouldn't choose to do that if that makes sense. So whilst I can do it, it's still too hard to be a routine thing sort of thing* (Darren, 47yrs, KD)

> *I actually get on with the washing or I get on with things without having to think oh hang on a minute I just have to make sure I've got this there to be able to do then that and then that. It becomes part of you and I think for me that's I think, yes, that's when I thought actually I'm OK here.* (Erica, 39yrs, TTA)

Mastering activities appeared to increase participation, which seemed to be underpinned by feelings of confidence in their own ability and the capacity to adapt to new situations.

> *If you go out you go out sometimes you might go out of your comfort zone but you can soon slot um into being aware of what's required.* (Gill, 67yrs, TTA)

Subtheme 2.3 - Doing my activities without falling over

Falling was a common experience amongst the participants, especially those who described themselves as community ambulators, and was frequently attributed to poor balance with the prosthetic leg. Being able to undertake important activities without falling over was described as a priority, as participants raised concerns over injury or not being able to get up from the floor. This appeared to make them feel vulnerable and increased their reliance on others.

> *You get them with a pushchair and they're coming straight at you. My sticks go like that. And I will put them in the path of anybody that walks in front of me because they don't realise but you have to realise if you go on that floor and you've got a prosthetic leg on it can break any part of your body because you can fall with that, you can break that. You can*

> *break your arm. So then you are in more difficulty than what they think you're in.* (Steve, 83yrs, TTA)

> *My wife is 8 stone. If I fall on the floor she cannot move me. I had to wait for my son, he's a builder, he's got arms like you, and I had to wait for him to come and help me off the floor because I cannot move.* (Don, 64 yrs, TTA)

The consequence of these concerns for participants was a significant fear of falling, especially in community-based situations. Fear of falling appeared to reduce confidence and increased conscious effort when walking. This in turn led to reduced participation in important activities.

> *Well it does make me very wary afterwards for a little while. erm you know you just think oh, em er you just think you know oh I kind of get up and then the next day I'm thinking oh I've got to be very, I'm probably very tentative and looking at everything on the ground* (Elaine, 64yrs, TFA).

Subtheme 2.4 - Completing my activities with as little equipment as possible

Although many participants described using walking aids to improve their balance and confidence, there appeared to be a complex relationship with the equipment that was part of their lives. Being able to cease using equipment, such as wheelchairs, commodes or walking aids, was described by many participants as a successful recovery and indicated a return to normality. Those who lived with their spouse or families often discussed the importance of parting with equipment.

> *So the wife summed it up the other day because I put the wheelchair in the garage because I wasn't using it much, I put it in the garage and covered it up. Oh it's lovely the house, it's getting back to normal. cos the bed was in the living room from January till December and somebody brought it back up for us in December. So that was the bed out of the living room so the living room was back to a living room. So it's changing the house. Yeah the wife said it's lovely. When that wheelchair went in the hall is clear now, I said oh it's lovely to get the house back to normal. It's like getting back to a normal life.* (Jim, 66yrs, TTA)

Despite this goal, if equipment was critical to enabling important activities, participants appeared more able to accept it.

> *So, if I really want to do that then I might have to use the wheelchair to go the long distance to get there but then at least I can walk around whilst I'm there.* (Emma, 41yrs, TTA)

3.2.6.2.3 Theme 3 – My prosthesis is comfortable and easy to use

When considering the role of the prosthetic limb in recovery, socket comfort appeared to be the most important factor and was discussed frequently. A comfortable socket was described as enabling engagement in meaningful activity. Conversely, discomfort meant that people were not able to wear their prosthesis for as long as they needed to. This was often raised by those describing themselves as community ambulators, who reported being able to walk longer distances. In some cases, discomfort or skin breakdown was attributed to preventing limb use. This made participation in important activities very challenging.

> *Socket comfort is pretty, is just so important. So important. Socket comfort because I've had sockets before where I've had them for work and my leg is literally screaming at the end. and then if it rubs, then you've got a blister, then you are back in the wheelchair.* (Ruth, 50yrs, TTA)

Participants also talked about the impact socket comfort had on their adjustment to amputation. Participants described struggling to cope with pain and discomfort from the prosthesis, as well as the frustration of not being able to do important activities. This appeared to make it harder to accept the changes limb loss had brought to their lives.

> *it makes you unhappy because you think OK why is it doing this now and you know every single step you took was...[pause] painful. There was rubbing, there was pinching and if you haven't got that right you don't want to wear it so you think oh God and you get upset and then you get down and reality kicks in again, that I'm an amputee.* (Harry, 33yrs, KD)

Participants highlighted that successful limb use was also about how usable their prosthesis was. They described the challenges of managing the fit of their prosthesis throughout the day as their residual limb volume fluctuated. The burden of having to add socks was described as frustrating and tiring.

> *During the course of the day if I'm doing a lot and I'm heavily sweating I have have to change them so I go about two or three sets of socks so I have to have a lot of socks with me. and em it's just very, that that in itself is very tiring and trying because you can see that and then when my sleeve starts sliding down I have to stop otherwise my leg is going to fall off. and and then it gets really, like I say it gets really uncomfortable. So by the time I'm finished I'm glad to take my leg off and feel much better.* (Adam, 38yrs, TTA)

3.2.6.2.4 Theme 4 – If I have pain, I am able to manage it

The group of participants who shared their views in this study described a range of experiences with pain. Some spoke of phantom pain and others of significant residual limb pain. Some talked about frequent and intense pain, whilst others reported that they had no pain at all. Participants who did experience pain compared the impact to that of socket discomfort, in that it affected their ability to walk again, their participation in important activities and roles, and subsequently their mental health.

> *if I do have this pain then I'm going to have to think about another career, another job, and and I'm going to have to think that this is for life.* (Ruth, 50yrs, TTA)

The ability to manage pain was an important outcome domain for the people in this study. Some participants talked about medication or limb wearing as useful management approaches. Despite these techniques, several participants discussed the need to accept that pain is now part of their lives to some degree, and there was no choice but to learn to manage it.

> *I think pain management because I don't think pain free is the expectation. Well it's an expectation but to achieve that I think at the end of the day you've had your leg chopped off. It's not going to operate like a normal leg would do so I think you learning to cope and deal with the pain is the important bit.* (Jamie, 42yrs, TTA)

3.2.6.2.5 Theme 5 – I am able to accept my new normal

Theme 5 is divided into three subthemes that describe psychosocial outcome domains of importance. Interestingly all these subthemes tended to be discussed by participants who were more than 2 years post amputation, suggesting important domains may evolve over time.

Subtheme 5.1 - Chasing normality

Returning to a sense of normality seemed to be the aim of recovery for participants. This sense of normality appeared to be supported by wearing a prosthesis but was often challenged in situations where the participant's new reality did not align with their life before the amputation, and differences in the 'new normal' were highlighted.

> *When I'm on my leg I feel totally comfortable even though there's pain. But when I em when I take my leg off at night and sleep and then have to scoot on a cushion to the toilet which is only next door I feel uncomfortable and when I'm in a wheelchair I feel uncomfortable because I haven't got my leg on.* (Ruth, 50 yrs, TTA)

Subtheme 5.2 - Adjusting to limb loss

Success within this theme was often described as being able to adjust to, and accept, the new normal. Coming to terms with the changes that amputation had brought to people's lives was described as a process of psychological adjustment that individuals, and often their family members, needed to undertake following limb loss. This process was described as a difficult one, as participants tried to come to terms with the loss of important activities, unmet expectations and changing roles.

> *It's really hard to be honest. Umm ....(sigh) There's a whole array of feelings really, so from feeling a bit silly for even thinking that I'd be able to do that erm to kind of yes but anger, sadness, just kind of getting bit down about it. You know I think I've kind of got to a stage now where there's a degree of acceptance of what I can and can't do.* (Darren, 47yrs, KD)

Being able to adjust to an altered appearance was also highlighted. Participants described trying to adjust to their altered sense of self, as well as how others perceived them, and spoke of using the prosthesis to control their appearance and support their adjustment.

> *actually realistically one leg what do we want to achieve? We want to be able to walk along the street without people pointing and staring and thinking oh look at that poor bastard. That pity effect. You want to be able to walk along quite proud and quite happy with what we're doing and what we achieved without being tapped on the back, oh aren't you doing well………So for me it was very important that I could wear trousers and nobody know I was an amputee.* (Jamie, 42yrs, TTA)

Ultimately, despite the challenge of adjusting to the amputation, success was described as being able to accept and learn to live with the new normal. This seemed to be facilitated by understanding personal limitations and managing them in a satisfactory way, as well as focusing on what could be accomplished.

> *but coming to terms with the things that you actually can't do. I think that's the key to being happy afterwards. I can't walk in the woods and feel the leaves among my feet as I kick them out of the way. I can't cycle and I have had an allotment and I can't use that. But it doesn't matter, I can do other things. (Angus, 88yrs, TTA)*

Subtheme 5.3 - Sense of achievement

Many participants felt very proud of what they had achieved since their amputation, especially when they reflected on how they had progressed over time, and this motivated them to do more. Achievement and motivation were commonly associated with goal setting and many participants identified the setting and achieving of their own goals as an important success following prosthetic rehabilitation.

> *So this year on my 40th birthday we climbed Mount Snowden together as a family so that was my first goal of climbing different mountains. So it's that sort of keeping going isn't it.* (Erica, 39yrs, TTA)

Achieving goals increased people's confidence and helped give their recovery purpose. Many people talked about continuing to set new goals for themselves in the future, this was highlighted as an important part of normal human behaviour.

> *Goals are important throughout our lives, amputee or not.* (Samantha, 54yrs, TT, Member checking summary)

3.2.7 Discussion

The findings from this analysis offer an in-depth patient-centred view into what people who have undergone rehabilitation with a prosthetic limb feel are important outcome domains of recovery. The inductive qualitative approach used here gives voice to the experiences of prosthetic users, allowing them to reflect on what recovery means to them in the context of their own rehabilitation experience and their life with limb loss. To our knowledge no other study has explored this phenomenon with such a large, diverse sample and with a focus solely on the views and experiences of prosthetic users. This group of participants had a mean age of 59, with almost half losing their limb due to diabetic dysvascular reasons. Other causes of amputation, such as trauma, cancer and infection, were also represented and participants with a range of different levels of amputation were included. Our purposive sampling approach sought to ensure this variation so that a wide range of views and experiences could be included. The representation of these characteristics within the sample appears comparable to the UK limb loss population [46–48].

Outcome domains of importance were summarised into five themes that describe a successful recovery following prosthetic rehabilitation from a patient's perspective. The themes highlight the participant's desire to be able undertake their individually valued activities again, in the way they wanted to i.e., easily, independently, without falling over and with minimal equipment. They discussed how important a comfortable easy to use prosthesis is, and that if they have pain, they want to be able to accept and manage it. Finally, they talked about wanting to adjust and accept their new normal following amputation. The domains of pain management, socket comfort, independence, participation in work and social activities, and psychological recovery were also described in a proposed medium term (within 2 years of amputation) core outcome set for use following lower limb amputation due to dysvascular causes [55]. This initiative combined patient and clinician views and focused on outcomes of a single cause of limb loss. Our study corroborates the importance of these domains, as well as highlighting other domains such as falling, and deepens our understanding of their importance solely from the perspective of prosthetic users.

The participants in this study identified being able to walk again as a key aspect of recovery, which contributed to a much-desired sense of normalcy. However, it appeared to be only the beginning of a successful outcome. Walking was often viewed as an essential skill, alongside climbing stairs and descending slopes etc. that enabled the important domain of participation in valued activities. A meta-synthesis of qualitative research exploring the experiences of people following amputation [23] found several papers reporting that it is the involvement in valued activities that is profoundly significant to people following limb loss. When people spoke of ‘how well’ they were getting on this often related to whether or not they were able to undertake these activities.

The concomitant nature of activity and participation described here is clearly depicted within the ICF, which articulates how the ability to perform skills such as walking underpins the person’s ability to participate in their life activities [29]. Although participants articulated the importance of skills such as walking, the outcome domain of importance to participants appeared to be participation in valued activities. Yet many of the outcome measures developed for use following lower limb amputation focus on measuring the underlying domain of mobility. A systematic review by Xu et al. identified outcome domains captured following lower limb amputation in published clinical studies using outcome measures and mapped them against the ICF. Xu et al. found that of the 130 different ICF categories these domains linked to – the most frequently represented concepts, almost a quarter (22%), could be attributed to a single domain, mobility [10]. This suggests that the outcome measures commonly used in prosthetic research and clinical practice, such as the six-minute walk test, the two-minute walk test, the timed up and go, the L-Test and the 10-metre walk test [56–59], as well as several patient-reported measures (PROMs) that seek to assess mobility from the patient’s perspective, such as the PLUS-M and the Locomotor Capabilities Index [57,58], may not be fully capturing domains that are important to patients.

Measuring the domain of mobility as an important outcome domain following prosthetic rehabilitation may assume that the acquisition of mobility skills, such as walking or stair skills etc. indicates that the individual will be able to participate in their valued activities. However, other factors may prevent this important transition, such as the domains identified in this study i.e. socket comfort, fear of falling or difficulty accepting limb loss. Measuring mobility alone may only capture the start of a successful recovery following prosthetic rehabilitation. Capturing true success, as identified by patients themselves, may lie in understanding the extent to which a person can use their regained mobility to participate in important activities.

In addition to informing outcome measurement in clinical settings, these findings suggests that in order for clinical teams to support meaningful recovery during prosthetic rehabilitation, they need to focus on more than just attainment of mobility skills. To enable meaningful participation that is highly valued by patients, the focus of rehabilitation should also involve the contextualisation of mobility skills within different environments and activities.

Our study also highlighted that important outcome domains appear to be about more than whether someone was able to participate in an activity or not, but `how' they were able to do it. Being able to master activities and do them without falling over, or fear of falling over, was described as building confidence and increasing participation. A recent systematic review by Steinberg et al. reported an annual falls rate of 50% in people with a lower limb amputation [60] and falls injuries were reported in 40%-60% of incidents [61], highlighting the frequency of this experience in this population. Balance and safety were also identified as important outcome domains in two qualitative studies exploring meaningful outcomes, from a patient's perspective, following the prescription of prosthetic componentry [32,33]. Both studies reported that greater balance and stability was thought to reduce the risk of falling and this promoted confidence and increased participation in community activities. Several participants also spoke of how this helped them feel more like themselves again [32].

Our findings showed that being able to do activities independently with as little equipment as possible was also key to a successful recovery and appeared to increase our participant's self-worth and feelings of returning to 'normality'. Independence was identified as an important outcome domain in Schaffalitsky et al.'s qualitative study, including both prosthetic users and clinicians [33]. Interestingly clinicians in their study described independence as a functional achievement, whereas prosthetic users appeared to focus on the psychological benefit of independence, highlighting the increased self-efficacy and self-esteem they experienced, as well as the benefit of not having to rely on others. The authors discussed that although the outcome domain identified was the same, the meaning was different between the groups, and this unique perspective illustrates the need to consider both physical and psychosocial outcomes of rehabilitation [33,34].

The concept of how patients are able to participate also provides useful insights to inform the delivery of rehabilitation, which often focuses on achieving a basic level of competence, such as can a patient do a task or not? Independence, mastery, balance and confidence, and the need for less equipment all develop over time and are activity and environment dependent. This may suggest the need for longer-term community-based approaches to rehabilitation focusing on activities of importance within the patient's own environment.

Another outcome domain which was described as an enabler of participation and a factor which dictated 'how' participants were able to engage, was the comfort and usability of the prosthesis. Inadequate socket comfort is the commonest problem reported during visits to prosthetic clinics [62]. Despite this significant clinical burden, and the importance of a comfortable socket to prosthetic users as described in this study, no studies have yet been published exploring the experience of socket comfort from a patient's perspective, and very few outcome measures exist to capture this domain [62,63]. Socket comfort was also one of the concepts that does not fit well within the domains of the ICF [25]. The literature that does exist focuses on assessing satisfaction with the prosthesis, but numerous definitions have been used to operationalise `satisfaction' making comparison between studies challenging [64]. Our study indicates that comfort may be a key element contributing to satisfaction with the prosthesis from a patient perspective. More research is required to understand socket comfort from this viewpoint to inform the design, fitting and use of prosthetic limbs in clinical practice, as well as for measuring the effectiveness of this process.

Linked to the domain of prosthetic comfort was the outcome domain of pain. The pain experiences of participants in this study were highly varied, in terms of both the nature of pain and its prevalence. This variation is also seen in the wider literature [65]. Many studies measure the domain of pain following amputation and focus on capturing pain intensity, frequency and interference [65–68], but only two outcome measures used in these studies capture pain specific to the experience of people following amputation. The Prosthesis Evaluation Questionnaire (PEQ) [69] and the Trinity Amputation and Prosthesis Evaluation Scale (TAPES) [70] both include subscales that measure pain with prosthetic users. The subscales include questions about residual limb pain, phantom pain and back pain, and capture pain intensity, frequency and interference.

However, the outcome domain of importance identified by participants in this study was that they were able to manage their pain. This can be described as pain self-efficacy, which is defined as beliefs about one's ability to control pain [71]. In the wider chronic pain literature self-efficacy has been linked to improved treatment outcomes and participation in important activities [71]. A study by Gupta and Leung found that poor self-efficacy was associated with poorer quality of life in patients with post amputation pain and was linked to increased medication use [72]. This mismatch in how we measure pain following amputation and how patients are experiencing and coping with pain suggests that even within different domains we may not be measuring the aspect of that domain that is meaningful to prosthetic users.

The themes examined so far have predominantly focused on physical recovery. However, 'feeling' normal again was discussed throughout the findings and many of the themes included examples of when problems in 'physical' domains affected the mental health of participants. This clearly demonstrates an interwoven psychosocial recovery. The impact amputation can have on an individual's mental health has been previously documented in the literature with feelings of sadness, shock, anger and despondency described [23], and depression, social discomfort and body image anxiety found to be common experiences [73].

Gallagher and Machlachlan describe physical, psychological and social challenges following amputation [74], which are discussed here in an entwined way by these participants. The psychological recovery following amputation appeared to be impacted by all of the themes described in this study and characterised by the emergence of a new normal following lower limb amputation. This new normal has been described previously in the literature as the forging of new identities within the constraints of prosthetic use [23]. Our findings illustrate that participants valued the ability to adjust to amputation and to be able to accept their limitations regarding participation, as well as appearance. This acceptance was also described in Murray and Foreshaw's qualitative synthesis, where several papers reported that the key task identified by participants was being able to accept their limb loss [23]. Interestingly the themes exploring psychosocial adjustment tended to be discussed by participants who had undergone amputation more than 2 years ago. This may indicate that outcome domains of importance evolve overtime as the reality of limb loss, and the impact and permanence of the associated disability, is more fully experienced. This phenomenon has also been described in research exploring outcome domains of importance to young people with chronic pain, who described 'turning points' in their treatment where outcomes important to them changed [75]. This finding may also affect prosthetic clinical practice as the patient's focus and goals might alter as they progress through rehabilitation and beyond. Perhaps suggesting a need for evolving MDT input and care planning throughout the prosthetic life course to support changing priorities. Further research on how outcome domains of importance to people following amputation change over time would be useful to inform both clinical practice and outcome measurement initiatives, especially considering the lifelong management of this population.

Demographic data was collected as part of this study and was synthesised with the thematic analysis to explore any patterns within the themes. The findings appeared to show that the outcome domains identified were valued by a wide variety of individuals. As a subgroup analysis was not the aim of the current research, future research could explore whether outcome domains of importance vary between different types of patients i.e. transtibial vs transfemoral, or high activity vs lower activity. This would deepen our understanding of what outcome domains to measure and when, as well as inform the focus of rehabilitation for different types of patients.

The apparent interconnected nature of the physical and psychosocial recovery described by these participants also highlights that outcome domains of importance do not exist in isolation for participants. Difficulties experienced by participants in one domain/theme appeared to also impact other themes. This cascade of impact, for example socket comfort limiting participation which then affects mental health, suggests an interdependent relationship between outcome domains of importance. For a prosthetic user, a successful outcome appears to be a holistic one, which combines meaningful recovery in each of these outcome domains. The interconnected nature of these themes/domains is visualised in a conceptual model (Figure 3.3).

Figure 3.3 Model of holistic view of outcomes of importance following lower limb prosthetic rehabilitation

This finding is reflective of frameworks such as the International Classification of Functioning, which describe a holistic, interconnected, biopsychosocial model of disability, functioning and health [76]. The ICF demonstrates how different elements of functioning, such as the themes and subthemes described here, are influenced by each other, as well as environmental and personal factors, to build a picture of the individuals overall health. This interdependency is also seen within the quantitative prosthetic evidence base, where many studies have demonstrated statistical relationships between the outcome domains of importance raised in this paper. For example, the association between pain, activity level, prosthesis satisfaction and psychosocial adjustment [65] or quality of life, mobility and falls mitigation [77].

Within clinical practice, despite recommendations for a holistic patient-centred approach to rehabilitation [36,37], outcome measurement often focuses on capturing outcome domains in isolation. This also appears to be the case in the development of core outcome sets [18]. The findings presented here indicate the need for a physical and psychosocial multi-domain approach to outcome measurement in prosthetic rehabilitation, with patient priorities at its centre, which is able to capture the different impacts of prosthetic rehabilitation on more than just the patient's mobility, but around the whole person.

3.2.7.1 Limitations

The sampling approaches used in this study i.e., self-selection via convenience sampling, followed by practitioner selection of those individuals with purposively identified characteristics, may have led to potential bias. Participants who self-select may be more open and more confident to talk about their experiences [78]. This may be the case for participants who had a more positive experience of recovering from amputation, or who are happier with their outcome. Participants selected by clinicians may also have led to greater inclusion of those who are deemed successful, well-adjusted or more open.

As this study was co-produced with our public research partners, we included both interviews and focus groups, allowing participants to choose how they would like to take part. These data collection methods can produce different data, i.e., in-depth accounts vs group sense making [79] which allowed us to triangulate these methods. We were able to collect large amounts of data through each technique, which provided richness and depth. Nonetheless care needs to be taken that this approach does not imply credibility by assuming that weaknesses in one method will be compensated by the other, rather it suggests a comprehensive process to exploring the phenomenon of interest [80]. Our accessible approach may also have contributed to the excellent engagement we experienced during recruitment and data collection. Being able to choose how to take part may have enabled participants to fit the research into their daily lives and allowed them to choose a forum where they felt most comfortable to be open and share their experiences.

The reflexive process undertaken by CO also highlighted that the perspective of a physiotherapist in clinical practice gave a unique insight into the creation of themes that could be accessible to clinical practice. However, it was acknowledged that this perspective may tend towards a focus on more physical outcome domains. The involvement of MDH (a health psychologist) in the analysis and interpretation of the findings helped strengthen the rigor and credibility of our approach by identifying and understanding this perspective. This process is advocated by Braun and Clarke who suggest that researchers should have insight into, and articulate, their generative roles in research [40]. The wider team of authors were also active in reviewing the analysis and verifying the findings.

The use of an inductive qualitative style using a robust and rigorous approach has provided an in depth understanding of outcome domains of importance following prosthetic rehabilitation for these participants. The findings offer a useful insight but due to the nature of qualitative research, the complexity of this life changing event, and the variability within the limb loss population, they may not reflect outcome domains of importance to all patients following prosthetic rehabilitation. Future research could use quantitative approaches to establish the extent to which the wider population values these domains. This study may also provide a useful foundation for future consensus work aimed at developing core outcome sets for use in research and clinical practice.

3.2.8 Conclusion

Outcome domains of importance following prosthetic rehabilitation appear to extend far beyond a return to walking. They encompass the `what` and `how` of participation, comfort, self-management of pain and acceptance of a post-amputation new normal. Each of these outcome domains are not viewed separately in the experiences of prosthetic limb wearers, and as such their interrelated nature needs to be captured in both clinical practice and the development of future outcome domain consensus initiatives. This will ensure prosthetic services are providing patient-centred rehabilitation and measuring outcome in a holistic way, with a focus on domains that are meaningful to patient recovery.

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Chapter 4 Paper 3 - Exploring the patient experience and perspectives of taking part in outcome measurement during lower limb prosthetic rehabilitation: A qualitative study

4.1 Introduction to paper 3

This chapter introduces the third paper. This paper describes a separate analysis of data collected during the large phase B qualitative study which provided data for both papers two and three. Paper three continues to explore the patient's perspective of outcome measurement in prosthetic clinical practice, addressing objective two of the overall thesis. Understanding this perspective is also an important part of understanding how outcome measurement practice in clinical settings could be developed, which was highlighted as a possible area of future work in the narrative review (Paper 1), where it was suggested as a key element in realising the value of outcome measurement in clinical settings.

Paper three was not originally planned as a separate paper, however unexpected findings collected during the large qualitative study first described in paper two provided novel insights into the patient's perspective of outcome measurement, warranting a paper of their own. This research was conducted as part of phase B, as described in Figure 4.1.

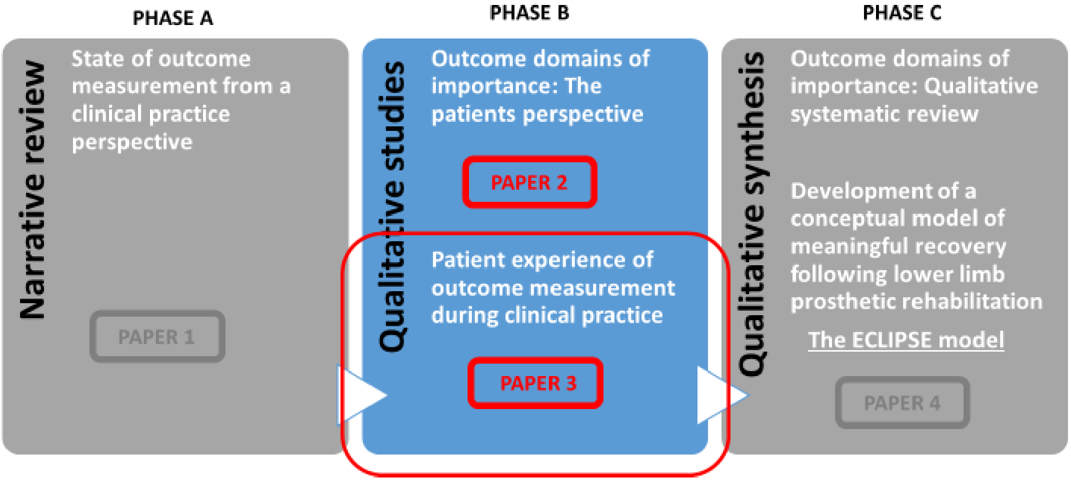

Figure 4.1 Phase B and paper three in the context of the complete thesis

This chapter includes an initial summary of paper three, in the form of an extended abstract, followed by the main manuscript, including all figures and references

4.1.1 Summary of paper

As highlighted in previous chapters, outcome measurement can provide clinicians, services, and funders with useful information to guide clinical decision making and evaluate performance of services. Many different tools are available to capture outcome following prosthetic rehabilitation such as the six minute walk test, the timed up and go, the Trinity Amputation and Prosthesis Evaluation Scale (TAPES) and the Amputee mobility predictor (AMP) (Heinemann *et al.*, 2014). Despite outcome measurement recommendations from professional networks (British Association of Prosthetists and Orthotists, 2015; Scopes *et al.*, 2015) there is currently no UK outcome measure consensus, and self-reported use of outcome measures amongst clinicians is variable (Gaunaurd *et al.*, 2015; Scopes, 2016). The narrative review presented as paper one, exploring the current state of outcome measurement in prosthetic rehabilitation, illustrated the need to understand how outcomes are measured in clinical settings to ensure the practice is a meaningful and useful part of care (Ostler, Scott, *et al.*, 2022). The review (Paper 1) identified issues around outcome measurement practice from the perspective of clinicians, but the perception of patients has yet to be considered. Considering the patient's perspective is essential to ensure a person-centred approach to all aspects of clinical care, including outcome measurement, and to develop our understanding of the value of measuring outcome. Therefore, the aim of this research was to explore experiences of outcome measurement during prosthetic rehabilitation, from the patient's perspective.

4.1.1.1 Method

The findings presented in paper three were developed from data collected as part of the qualitative study described in paper two. The interview schedule developed for the paper two study also included questions asking participants about their experiences of taking part in outcome measurement. Responses to these questions were analysed separately from the rest of the data and presented as paper three.

Thirty-two of the 37 participants involved in the paper two study contributed data to the findings described in paper three. Participants were asked if they had experience taking part in outcome measurement with any member of the MDT during any prosthetic rehabilitation intervention. Those that had were invited to answer questions related to the aims of paper three on completion of the paper two questions. The recruitment methods, procedures and sampling approach are described in paper two. Data were collected using focus groups and interviews and analysed using reflexive thematic analysis as described by Braun and Clarke (Braun and Clarke, 2006, 2021; Clarke and Braun, 2013).

4.1.1.2 Results

Following analysis four themes were identified:

1) How does participating in outcome measurement make me feel?

2) Do the outcome measures used in routine clinical care capture an accurate picture of my recovery?

3) Who is outcome measurement for?

4) Are prosthetic services measuring what is meaningful?

4.1.1.3 Conclusions

These themes suggest outcome measurement is not a neutral activity for patients following lower limb amputation with both positive and negative experiences described. Harnessing the positive impacts of measuring outcome could be used for motivation, to support adjustment and recovery, improve communication and support shared decision-making. However, the potential for patients to respond negatively should not be overlooked. Clinicians may need to consider the impact of outcome measures on psychological wellbeing and offer support during the process, with options to stop if required. More work is required to understand how outcome measurement could be useful to this population, however these initial insights could begin to inform the development of outcome measurement practice and ensure the process is meaningful, and person-centred.

4.1.2 Publication details

Paper three has been published in 2024 in Disability and rehabilitation and is available in its published format in Appendix F. Disability and Rehabilitation was selected as the work described in paper three is closely linked to the study described in paper two, which has been previously published in Disability and Rehabilitation. Paper three study documents, such as the analysis and data tables can be found in Appendix H. This paper has also been presented via a platform presentation at the 2023 BACPAR conference in Dublin.

Chapter 4

The referencing style of Disability and Rehabilitation is the Vancouver style. Referencing has been presented in this format with an accompanying reference list. The paper three manuscript is presented in the following section.

4.2 Paper 3 manuscript

4.2.1 Title

Exploring the patient experience and perspectives of taking part in outcome measurement during lower limb prosthetic rehabilitation: A qualitative study

4.2.2 Authors

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4.2.3 Implications for rehabilitation

- Outcome measurement in prosthetic rehabilitation can provide clinicians, service providers and funders with important information.
- Adopting a patient-centred approach could make the process more meaningful and therefore beneficial for patients themselves.
- Measuring what is important to patients by considering a holistic approach beyond physical domains may make outcome measurement more meaningful.
- Patient-centred approaches may include talking to patients about outcome measurement, using it to support motivation, goal setting and decision-making, as well as exploring outcome ranges to account for, or even capture variability.
- However, the potential for negative responses should not be overlooked, and clinicians should consider the psychosocial impact of outcome measurement on this patient group, especially when using performance-based measures.

4.2.4 Background

Outcome measures are used in clinical practice to capture changes in patient status following an intervention or when monitoring patients over time [1]. This information can be shared with the patient to demonstrate progress throughout rehabilitation, and increase motivation, or can be used by the clinician to direct treatment planning or inform funding requests [2]. Aggregated outcome information can also be used to inform service improvement work and research. Measuring the outcome of health care interventions using outcome measures is especially relevant in today's increasingly evidence-based health services. When facing increasing demands on resources, as well as the expectation of a culture of continual improvement, services need to consistently demonstrate their value and impact [3]. Outcome information can provide an understanding of the effect health services have on the health and wellbeing of patients.

The term 'outcome measure' can be better understood by breaking it down into the outcome domain being measured and the measurement tool used for the task. An outcome domain can be defined as an element of health (i.e., pain, physical function, emotional wellbeing, social activity) that is changed by a particular intervention [4]. A measurement tool can be defined as a standardised instrument used in research and clinical practice to capture and evaluate one or more outcome domains at a single point in time, or evaluate change over time [1]. Measurement tools exist in the form of observed performance measures such as the six-minute walk test [5], or the Timed up and go [6], where a clinician or independent observer rates or measures the individual's ability to complete a predefined activity [1]. Or, patient reported outcome measures (PROMs), which are completed by the patient themselves, often in the form of questionnaires or scales, such as the Trinity Amputation and Prosthesis Evaluation Scale (TAPES) [7] or the Prosthesis Evaluation Questionnaire (PEQ) [8], and reflect the patient's perspective on the outcome domain being assessed [1].

A range of outcome measurement tools have been developed for use following lower limb amputation and prosthetic rehabilitation. Heinemann et al. [9] identified 43 unique measures, and several clinical interest groups have developed recommendations for which outcome measurement tools should be used in clinical practice settings [10–12], such as the six-minute walk test [5], the Timed Up and Go test [6] and the TAPES [7]. The most recent of these is a set of recommended outcome measures from the International Society of Prosthetics and Orthotics [13]. Healthcare policy in the United Kingdom (UK) also recommends the use of outcome measures within the National Health Service (NHS) prosthetic rehabilitation services [14,15].

Despite the availability of many different tools and recommendations, there is currently no UK outcome measurement consensus, and self-reported use of outcome measures amongst clinicians is variable [16–18]. A recent narrative review exploring the current state of outcome measurement in prosthetic rehabilitation called for a focus on how outcome measures are used in clinical settings in order to develop practice that ensures measuring outcome is a meaningful and useful part of clinical care [19]. A few studies have begun to explore the experiences of clinicians using outcome measures in prosthetic rehabilitation, but only focus on the experiences of prosthetists [17,18]. Barriers such as perceived time limitations, poor confidence with, and knowledge of measurement tools which are often not covered in undergraduate education are reported [17,18]. A lack of perceived value in using outcome measures is also described, with prosthetists reporting that tools do not produce useful information [2,17,18]. Experiences of outcome measurement amongst other members of the prosthetic multidisciplinary team are currently unknown.

Within prosthetic rehabilitation the perspectives and experiences of patients taking part in outcome measurement have also yet to be considered. Their experience is particularly relevant in clinical settings where outcome measurement will likely be undertaken as part of clinical care. Patient experience of clinical care is “the process of what receiving care feels like for the patient, their family and carers” and is an important quality indicator and area of focus for healthcare providers [20]. Improved patient experience is linked to organisational reputation, patient outcomes, cost effectiveness of services and staff experience [20]. Understanding how people might experience care can help design healthcare services, processes and interventions that deliver the best outcomes, but also promote positive patient experiences. All aspects of a patient’s care contribute to whether someone has a positive or negative experience, including their experiences of taking part in outcome measurement.

Several systematic reviews have sought to review and summarise the evidence base concerning the experiences of patients taking part in outcome measurement in clinical settings such as primary care, renal care, mental health, musculoskeletal services, and cancer care [21–23]. These reviews focus on people’s experience with PROMs and describe both positive and negative aspects. The benefit of completing PROMs was highlighted as generating information about outcome, which can promote communication and rapport with clinical teams, and improve the quality and focus of care. Concerns focused on how valuable the information collected was, and the accuracy of the questionnaires used to evaluate the impact of health conditions or healthcare interventions [21–23]. Despite the range of conditions included in these reviews, to our knowledge no studies have yet explored the experience of people following lower limb loss and prosthetic rehabilitation, of taking part in outcome measurement. Furthermore, the systematic reviews described here only include studies exploring patient views of using PROMs. Within the field of prosthetic rehabilitation both healthcare policy [14,15] and specialist interest group recommendations [10–12] advocate for a mixed approach to capturing outcome, using both observed performance measures and PROMs.

Due to the ongoing drive to use outcome measures in prosthetic settings [13], and in response to calls for a more meaningful, patient-centred approach to outcome measurement in clinical practice [19], it is vital to consider the perspectives of everyone involved. The findings presented in this article are part of a larger qualitative study which sought to explore outcome domains of importance following lower limb prosthetic rehabilitation from the patient's perspective [24]. Data were collected during the conduct of this larger qualitative study that captured patient experiences of outcome measurement during clinical care. This paper reports the analysis of this data and aims to explore experiences of outcome measurement during prosthetic rehabilitation, from the patients' perspective.

4.2.5 Method

4.2.5.1 Research Design

The findings presented here were collected as part of a larger qualitative study which aimed to explore the patient's perspective of outcome domains of importance following lower limb prosthetic rehabilitation. The interview schedule developed for the larger study also included questions asking participants about their experience of taking part in outcome measurement during prosthetic rehabilitation. Reponses to these questions were analysed separately from the rest of the data. It is these findings that are reported here.

The entire project was developed from a critical realist (CR) world view which differentiates between the 'real' and 'observable' world and suggests the world is built from 'perspectives and experiences'. CR acknowledges there is an objective reality i.e., the 'real' world, but proposes it is never truly observable or knowable as it sits behind, and is therefore viewed through, different lenses or prisms i.e., individual human factors or cultural and organisational factors [25,26]. In this case the lenses of community prosthetic users who have experience of taking part in outcome measurement as part of prosthetic rehabilitation. Due to the exploratory nature of this work and limited previous research on experiences of outcome measurement with this population, a generic approach to qualitative inquiry was used, rather than more defined methodologies, such as grounded theory or phenomenology. This open approach, using reflexive thematic analysis [27], fits well with the critical realist world view, seeking to capture, explore and interpret experiences of outcome measurement following lower limb loss [28].

4.2.5.1.1 Patient and Public Involvement and Engagement (PPIE)

Patient and public involvement and engagement in research is defined as “research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them”[29,30] and is vital to ensure research is focused on issues the public feel are important and is conducted in a participant-centred way. As outcome measurement may be viewed as a ‘research’ or ‘clinically-focused’ concept, we worked closely with a group of public research partners who were established prosthetic limb wearers to ensure we were asking about it in an accessible way. The group consisted of three members, one male with a transfemoral amputation due to trauma, and a male and female with transtibial amputations due to diabetic dysvascularity. CO and MDH met with the group on two occasions and through collective discussions they helped us consider the language used when talking about outcome measures and suggested providing examples of questionnaires and functional tests, during the interviews and focus groups, to stimulate discussion. They also considered practical issues, such as where patients would like to find out about the research and how they might like to take part. They were then able to participate in the study if they wished to. This crucial PPIE approach allowed us to co-design the study and study materials, such as the interview guide, to strive for a positive participant experience, maximise recruitment and develop accessible language around the concept of outcome measurement in partnership with patients.

4.2.5.1.2 Ethical review

The study was given ethical approval by the East Midlands Research Ethics Committee and the NHS Health Research Authority (Ref: 8/EM/0259).

4.2.5.1.3 Participants

The methods for the entire study have been reported in detail in the publication for the first analysis [24] and will be summarised here to provide context for this second set of analysis.

Individuals were invited to participate if they were over the age of 18 and had undergone a major lower limb amputation i.e., proximal to the ankle, within the last five years. Those who had experience of taking part in outcome measurement with any member of the multidisciplinary team (MDT) during prosthetic rehabilitation contributed to the analysis reported here. Prosthetic rehabilitation is defined as initial MDT rehabilitation following limb loss, or any ongoing MDT interventions provided as health or prosthetic needs change. People with experience of both observed and PROMs were included, as this mixed approach to capturing outcome is reflective of current recommendations for outcome measurement practice in prosthetic rehabilitation [10–13].

Participants were recruited from four English NHS prosthetic rehabilitation centres who used outcome measures as part of routine care. Adverts were also posted on social media platforms and invitation letters were sent to limb loss supporting charitable organisations to share with their members.

A two-staged process, using both convenience and purposive sampling, was utilised to recruit a diverse sample with a range of characteristics, views, and experiences, which are representative of people who undergo prosthetic rehabilitation in the UK. A demographic questionnaire was used to collate information from participants on a variety of characteristics, such as age, level and cause of amputation, and presence of co-morbidities [31,32]. This information allowed the research team to monitor the sample characteristics during the convenience sampling stage, and then employ purposive sampling later in the recruitment process to ensure harder to reach groups (i.e., older, transfemoral participants) were represented.

4.2.5.1.4 Procedure

Focus groups and semi structured interviews were used to collect data as these approaches enable follow up questions and contextualisation of answers [28]. The selection of both of these methods was on the advice of our PPIE group, to enable and promote participation in a way that individuals found most acceptable and comfortable. Participants self-selected how they would like to take part, i.e., focus group or interview, and the focus groups and interviews were completed independently of each other and in parallel. This allowed data source triangulation, providing different views of the same phenomenon, gathered using different methods to enhance credibility [33].

Focus groups took place in a quiet room in each of the four recruiting limb centres. Interviews were undertaken either over the telephone or in a location of the participants choosing. Questions addressing the aim of the larger study i.e., what participants felt were meaningful outcome domains following prosthetic rehabilitation were asked first. If the participant had experience of outcome measurement as part of prosthetic rehabilitation, they were then asked additional questions addressing the aims of this analysis. The interviews and focus groups for the entire study lasted no more than an hour, and an hour and a half respectively, with contributions to this analysis lasting between 15 and 30 minutes. Written informed consent was collected from all participants prior to their involvement in the study.

A semi-structured interview guide was co-produced with our PPIE group and was used to collect data during interviews and focus groups. Table 4.1 describe the questions related to this analysis. A selection of outcome measures from UK health policy [14,15] and professional guidance [10–12] were described by researchers, or in the case of PROMS were available as examples to help stimulate discussion. These included the six/two-minute walk tests, timed up and go, Activities Balance Confidence Scale UK. TAPES, PEQ, Locomotor capabilities index 5 and the Re-integration into Normal Living Index. During telephone interviews all outcome measures were verbally described to participants by the researcher.

Table 4.1 Semi structured Interview guide questions

1. Can you tell me about your experiences completing questionnaires or any tests of your ability to do different things?
2. These are some examples of the ways your clinician may have measured how you were getting on. • Locomotor capabilities index 5 • Activities Balance Confidence Scale UK • Timed up and go • 6 minute and 2 minute walk tests • Socket comfort score • Prosthesis Evaluation questionnaire • Reintegration into normal living index
3. Do you have any thoughts about these or any other tests you took part in?
4. What do the tests or questionnaires mean to you?
5. Could they be improved and if so how?

Data were audio recorded and then transcribed verbatim to capture all verbal utterances. Transcription was undertaken by a professional transcriber contracted to the University of Southampton. Audio recordings were anonymised to remove any identifiable information, and pseudonyms are used throughout the results section to ensure the confidentiality of participants. Written consent was also obtained for using verbatim quotations.

4.2.5.1.5 Research team and reflexivity

Contextual information about the research team has been presented in Table 4.2 to enable readers to assess any influence our background and experience may have had on the research [34]. As CO is a practicing physiotherapist in one of the recruiting rehabilitation services. Because of this several of the participants were aware of her role but had never been treated by her, any participants who had a previous clinical relationship with CO were interviewed by MDH. All of the interviews and two of the four focus groups in the study were undertaken by the first author (CO). MDH conducted the other two focus groups as some of the participants were known to CO. Both CO and MDH undertook aspects of the data analysis, described below. Involvement of a second researcher helped to refine ideas, enhance the reflexive process, and by viewing the phenomenon through a different lens, provide more comprehensive interpretive depth within the findings, therefore enhancing credibility [27].

A reflexive diary was kept by CO throughout and discussed regularly with the rest of the research team (MDH, AD and CM), in order to reflect on the impact of different perspectives and assumptions influencing the study design, data collection and data analysis.

Table 4.2 **Summary of research team background and experience**

Researcher	Background
CO	Is a consultant clinical academic physiotherapist at one of the recruiting limb centres. She has over 15 years' experience in prosthetic rehabilitation clinical practice, and 10 years of experience in research. This study is being undertaken as part of CO's Ph.D., but she has undertaken several qualitative research enquiries prior to the study described here.
MDH	Is one of CO's Ph.D. supervisors, a health psychologist and associate professor. She has over 20 years of experience undertaking qualitative research with people following limb loss, and complimentary areas of rehabilitation
AD	Is one of CO's Ph.D. supervisors, a mechanical engineer and associate professor. He has over 15 years of experience undertaking biomechanics research, the last 8 of which relate to limb loss and prosthetics.
CM	Is one of CO's Ph.D supervisors, she is a professor and head of school of Healthcare Enterprise and Innovation. She has a diverse background spanning computer science, biomechanics and health sciences with much of her work within the amputation rehabilitation and mobility sector.

4.2.5.1.6 Data analysis

Data were analysed iteratively, using reflexive thematic analysis as described by Braun and Clarke [27,28,35], to identify inductive themes from the transcripts which gave understanding to the participants' experience of taking part in outcome measurement. Thematic analysis was used as it provides a flexible approach which sets out a way of systematically grouping and identifying meaning within the data. NVIVO software (QSR International, Melbourne, Australia) was used to manage the data.

Initially interview and focus group data were analysed separately. Audio-recordings of both focus groups and interviews were transcribed verbatim. Transcripts were read and re-read, and initial noticing's recorded in a research journal by CO. Verbatim transcripts were coded in as many ways as needed by CO, with MDH coding a subsection of the transcripts. For each analysis the codes and coded data were examined. Similarities and overlap were identified between codes and potential patterns relevant to the research question were created by CO and MDH. Separate tables of initial themes, codes and quotations from the interview and focus groups analyses were created and compared by CO. All transcripts were re-read and the fit of initial themes reviewed in relation to the full data set and coded data by CO.

The full set of themes from both analyses were then reviewed, refined and integrated by CO and MDH. Themes were collapsed or expanded in order to present coherent patterns within the data. The wider research team (AD, CM) reviewed refined themes to ensure they captured important meaning in relation to the research question, and assisted reflection on researcher assumptions. A person-centred approach was taken by CO to name the themes in order to capture the voice of participants. Appropriate examples of extracts from the full data set were selected to represent each theme by CO, and a final report was produced by CO, MDH, AD, and CM.

Data saturation was not sought for this study as reflexive thematic analysis does not presume that the themes emerge from the data but are interpreted during the researcher's analytical process, and on this basis further interpretations are always possible [36]. In addition, experiences following lower limb amputation can be diverse, depending on the rehabilitation setting, and individual characteristics such as age or cause of amputation, and it is unlikely any one study design would be able to capture them all [36]. Data collection was completed when close to 40 participants were recruited for the larger qualitative study as this was deemed a pragmatic sample size based on the time and resources available to the research team [37]. All participants taking part in the larger study were asked whether they had experience of outcome measurement during prosthetic rehabilitation, only those who said yes answered questions for this analysis.

4.2.6 Results

Thirty two out of the 37 participants who took part in the larger study reported they had experience with outcome measurement in clinical care and therefore contributed information to this analysis. Of the 32, 13 took part in interviews (nine via telephone and four face to face) and 19 participants took part in four focus groups comprising of seven, five, four and three. The sample characteristics were varied and included participants between 33 and 88 years of age, with a variety of amputation levels (Table 4.3). Over half of the participants had undergone a transtibial amputation (TTA) (53%). Participants with other levels of amputation, including transfemoral (TFA) (22%), bilateral (9%) and both knee (KDA) (13%) and hip disarticulation (HDA) (3%), were also represented. Time since amputation ranged between 6 months and four and a half years and the main causes of amputation were diabetes (28%), peripheral vascular disease (22%), and trauma (22%). Participants losing their limb/s due to infection (13%) and cancer (6%) were also included.

Table 4.3 Sample characteristics

Characteristic	N=32	
Age	Mean 59 years (Range 33-88 Years)	
Gender	Male	20 (62.5%)
	Female	12 (37.5%)
Level of amputation	Transtibial	17 (53%)
	Knee Disarticulation	4 (13%)
	Transfemoral	7 (22%)
	Bilateral Transtibial	3 (9%)
	Hip Disarticulation	1 (3%)
Time since amputation	Mean 2.1 years (Range 6 months – 4.5 years)	
Cause of amputation	Diabetes	9 (28%)
	Trauma	7 (22%)
	Cancer	2 (6%)
	Peripheral Vascular Disease	7 (22%)
	Infection	4 (13%)
	Other	3 (9%)
Number of co-morbidities	None	8 (25%)
	1	8 (25%)
	2	7 (22%)
	3	4 (12.5%)
	4	1 (3%)
	5	4 (12.5%)
Recruiting location	Centre 1	15
	Centre 2	7
	Centre 3	2
	Centre 4	8

4.2.6.1 Themes

The findings from this study have been grouped together into four themes, which describe these participants experience of taking part in outcome measurement in routine prosthetic care:

1. How does participating in outcome measurement make me feel?

2. Do the outcome measures used in routine clinical care capture an accurate picture of my recovery?
3. Who is outcome measurement for?
4. Are prosthetic services measuring what is meaningful?

Theme development is visualised in the coding tree in Figure 4.2. Each of the themes will be discussed in turn and illustrated using quotations from the study participants. Pseudonyms are used throughout, and quotes have been contextualised with information about the participant's age and level of amputation.

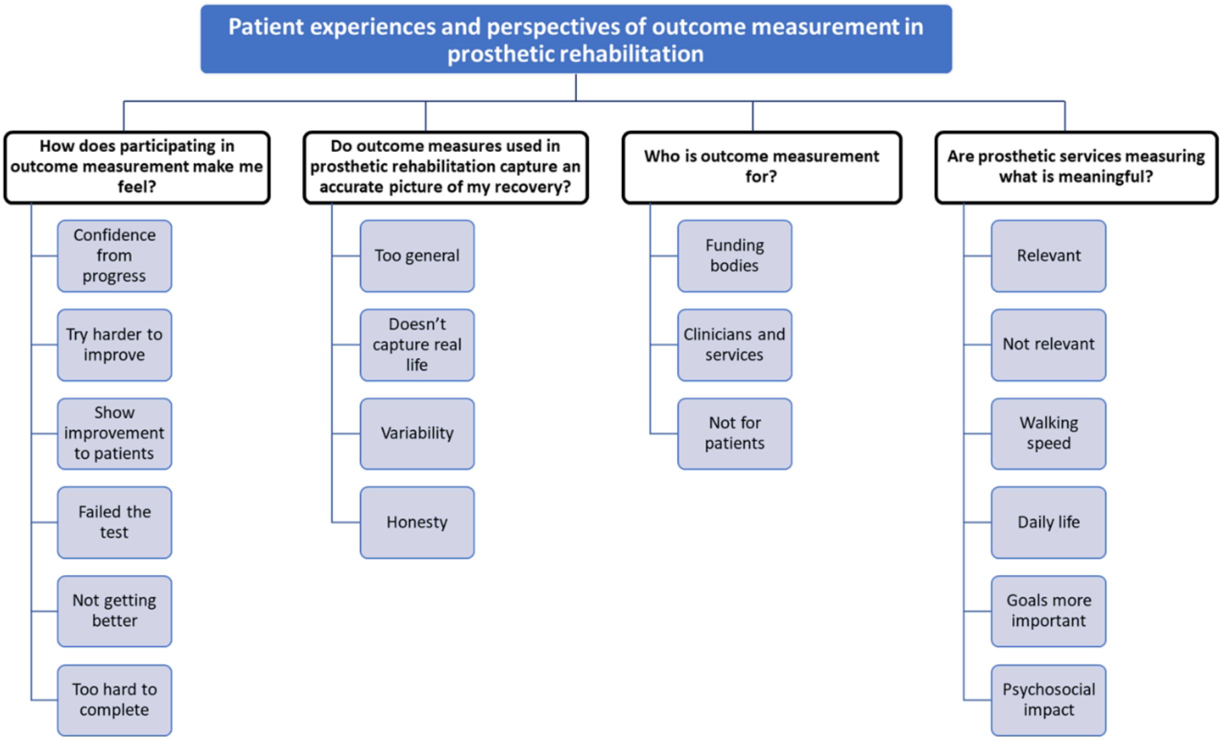

Figure 4.2 Coding tree describing development of study themes

4.2.6.1.1 Theme 1: How does participating in outcome measurement make me feel?

The participants in this study spoke about their experience of taking part in outcome measurement during their rehabilitation, and the impact it had on them. Many participants reflected on completing performance-based measures or filling out PROMs as a positive experience, discussing how assessing outcome helped them to realise how far they had progressed, allowing them to see the improvements they had made.

> *I think they were very useful because it made me realise how much I'd improved. Which is easily forgotten you know. It was very affirming of the of the progress I'd made.* (Karen, 61 yrs, TFA)

This affirmation appeared to give them confidence and a sense of satisfaction with their recovery.

> *I just filled them in. I just thought to myself right I've done all that, ticked everything and I'm happy with the situation.* (Chris, 55yrs, TTA)

Others reported that taking part in outcome measurement was motivating and encouraged them to work harder in order to try and beat previous scores.

> *Male participant 2: Yes. A goal. This is when I was here and how long it took me to walk around the thing and back again and how long before I could go in a certain distance.*
>
> *Male participant 1: Try and improve each time I think* (Alex, 45yrs, TTA and Angus, 88yrs, TTA)

> *Come on I'm going to be better. I'm going to be better*. (Erica, 39yrs, TTA)

Participants also discussed that motivation could be harnessed by both clinicians and patients throughout the rehabilitation process to promote and consolidate achievements, as well as identify areas where greater input is required.

> *you've started to walk so they might be feeling a bit more happier or you could do something at the beginning, middle and then end to see how that patient has progressed from the beginning and at the end they could be feeling more happy about themselves than what they were at the beginning. So they can see then they've achieved ……… because there's an an amazing vibe so at the middle of their rehabilitation, see the percentage, see if it's changed and at the end see if it's got better. If it has great, if it hasn't what can be done.* (Harry, 33 yrs, KDA)

However, despite many positive comments about the experience and impact of outcome measurement, several participants perceived the process in a negative way. People who felt they had not increased scores captured on some performance-based measures, or those who's scores had deteriorated, described a very different experience. One participant described feeling disappointed he had not improved despite working hard to get better.

> *Competitiveness that you want to try and get yourself better than what you did last time and that. If you get the same sort of time or lower you are really quite disappointed.* (Alex, 45yrs, TTA)

One participant in particular described performance-based outcome measurement as a test, which she felt she had failed.

> *Participant: The day I failed the test I had to say I felt like a failure because having achieved it once before but then having broken my leg I was just so frustrated..... because I can't do anything.*
>
> *Interviewer: So how did that make you feel when the score showed that you'd gone backwards?*
>
> *Participant: (sigh) Very frustrated...... Incapable.* (Gill, 67 yrs, TTA)

She went on to describe the impact of this perceived failure on how she felt about her rehabilitation potential and that it led to her being discharged from physiotherapy.

> *Participant: I didn't expect to be discharged..... so quickly but then I suppose if things aren't happening (sigh) it's a waste of a physios time to do things.*
>
> *Interviewer: How did that make you feel?*
>
> *Participant: Almost that I er I was a dead loss if you know what I'm trying to say because it was pointless working with me.* (Gill, 67 yrs, TTA)

One participant felt negative experiences may have been linked to the questions included in PROMs or the tasks included in performance-based measures. She highlighted that some tasks could be too hard for some patients, especially those with co-morbidities, which are highly prevalent in this population, and this could disadvantage some people.

> *So I think I think if we make outcome measures too difficult em then then it can be quite derogatory for patients and certainly some of these people who have em got all sorts of other issues going on. They've had an amputation, they've got other comorbidities, they might have back problems because of the issues they've had with their leg over the years.* (Sam, 54yrs, TTA)

4.2.6.1.2 Theme 2: Do the outcome measures used in routine clinical care capture an accurate picture of my recovery?

As well as discussing the impact of being involved in outcome measurement on the experience of rehabilitation, participants also talked about whether outcome measurement can capture a real and honest picture of their recovery. One participant described the conflict of attempting to quantify the uniquely personal experience of recovery, using PROM questionnaires.

> *To sum it up the problem with these forms and all the others that says ability and mobility and everything else is that these forms are black and white, life is grey.* (Simon, 36 yrs, TTA)

Participants highlighted that day-to-day life as a prosthetic user can be highly variable, in terms of the different types and amount of activity they are able to do each day, and in some cases this can vary from hour to hour. They suggested that measuring outcome at a single point in time, such as during a clinic visit, may not capture a true reflection of the complexity of their recovery.

> *I think it depends how you feel on the day like these guys have said. One minute he's in pain and the next minute you're not in pain. So it depends when you are asked these questions as to what the answer is going to be………. you're never going to get an accurate outcome really because you might get the worst-case scenario where you are in pain or you might get the best-case scenario whereas actually I feel on top of the world today.(*Alison, 51yrs, KDA)

It was suggested by one participant that this 'variability' is an important part of recovery following amputation and needs to be captured to comprehensively reflect the nature of recovering from amputation.

> *But it's like that's on my best day, that's on my worst day. On a normal day it's around about this. I think that would be a better way of measuring it because you'd get an understanding of not every day is the same…………The people who get this information might not appreciate and understand that. So maybe wording them ever so slightly, it's difficult because you want to get as broad amount of information as possible without overkilling it but giving someone that range, worst, average, best, what can you achieve on those days because it's going to be different for everybody.* (Jamie, 42yrs, TTA)

Alongside the daily variation in outcome described by these participants there were also other concerns about whether outcome measures can truthfully capture progress through rehabilitation. Some participants felt that the clinical environment where performance-based outcome measurement takes place, with its large open spaces and smooth flat flooring, does not reflect the 'real world' in which life with a prosthesis actually happens.

> *See I think the thing about the tests is hospitals have magic floors so actually whether you can go really fast down the corridor doesn't really matter because what's out there is bumpy roads and pavements*. (Erica, 39yrs, TTA)

Another concern was whether the responses, captured using PROMs are influenced by worries from patients about their benefit entitlements. Participants highlighted a conflict between demonstrating improvement through outcome measures and the consequences the results may have on financial support, suggesting this could influence self-reporting.

> *I can guarantee probably 80% of people answering these sort of questions are going 'If I put that down they might take my PIP [personal independence payment] away'. You know, nervous as hell going what if someone gets hold of that, that's my PIP gone…….If you say how far can you walk someone in their head is going well I'm going to lose my PIP so it's going to be zero.* (Jamie, 42yrs TTA)

4.2.6.1.3 Theme 3: Who is outcome measurement for?

The participants in this study raised the question of 'why outcomes are measured' and 'who the information is collected for'. It appeared participants viewed outcome measurement as a process not intended for their use, but about informing others, such as service providers or researchers.

> *So I think I've always just assumed it's more measurement for you guys (indicating researcher) than it is for me* (Erica, 39yrs, TTA)

One participant perceived that outcome measurement was also used to justify funding from bodies, such as the Veterans Prosthetic Panel.

> *Yes the only problem with, it's great as a person to measure achieving goals but unfortunately like the Veterans Board want you to measure this sort of thing, don't they, running around the chair. So it's not what you want to achieve with the leg so if you do that with us then you've got to get these Boards on board as well haven't you.* (Alison, 51yrs, KDA)

These examples provided by the participants demonstrate that they don't feel outcome measurement generates information they would use, rather it is completed to provide services or funders with information. One participant also questioned whether 'what' was being measured was important to patients, or whether it just evaluated the work done in limb centres.

> *Male Participant: The questions were important, very important. They were the right questions.*
>
> *Female Participant: I think they are in the context of the work that goes on here but it's so much more than that.* (Chris, 55yrs, TTA and Tina, 58yrs, Bilateral TTA)

4.2.6.1.4 Theme 4: Are prosthetic services measuring what is meaningful?

Many participants felt that the type of information captured during their experience of outcome measurement was important and often assessed their ability to do the different activities they want to do, as well as considering the impact of different environmental contexts on outcome.

> *So they were asking how long do I wear my leg inside em the house, do I wear my leg outside. So they were covering a lot of areas, so they were covering indoors, outdoors, stairs, stuff that normal ....people who aren't amputees take for granted. So all the stuff that I've had to learn how to do again, how to manage, em how to actually em walk backwards and stuff like that. So, they em yes, they were they've done, I felt that it was really comprehensive what they did.* (Adam, 38yrs TTA)
>
> *They were all things you needed to be able to do........ So it's not like going to school and they teach you all of this stuff about Shakespeare and goodness knows and you don't need it ever again in your life you know. It's all stuff that is relevant.(* Gill, 67 yrs, TTA)

However, other individuals discussed feeling frustrated that the activities measured were not relevant to their lives or were too hard for them to do.

> *Well I've mean on this; I mean we've got no stairs.* (Mike, 74yrs, TTA)

> *Interviewer: Are you looking at the balance one there that says about standing on a chair and things like that?*
>
> *Male Participant: Yes, I couldn't do that. I mean with my balance I would be straight on the floor.* (David, 74yrs TTA)

Walking speed was highlighted as a domain that was commonly measured, using performance-based tests such as the 6 Minute Walk Test or the Timed Up and Go, but was suggested by many as not being a priority in their day to day lives.

> *I think they put way too much emphasis on speed because it doesn't matter whether you walk really slowly with or without a stick or whether you walk fast with or without a stick. It's what is comfortable for you, it's what is manageable for you and especially over a longer distance and you might not have been a fast walker beforehand. It doesn't matter if you can walk between now and the shops within two minutes or whether you do it in ten minutes, it's an achievement if you've done it. But I think they do put a lot of emphasis on how fast.* (Emma, 41yrs, TTA)

Despite these useful reflections on the relevance of the domains measured in the experience of these participants, it was also suggested that some important elements of recovery are not always included. Participants suggested that the outcome measures they had experienced tended to focus on the technical aspects of recovery, such as walking and balance, and did not necessarily capture a more holistic view of their lifestyle.

> *Lifestyle is what you can and can't.... do. I mean the balance thing, yes, that's very important but there's nothing sort of about lifestyle. It's all one thing, one subject. There needs to be a bigger picture to the questions* (Harry, 33yrs, KDA)

Many participants also felt that understanding whether people had achieved their goals was an important aspect to capture. Goal achievement was described as more important to participants than the results of measurement tools.

> *I certainly agree that that questionnaires that are subjective are very useful, but I also think em that that setting little goals and seeing if people achieve them. em so For example, walking up and down the stairs em initially was really difficult for me and by the end of it I was walking up and down the stairs holding on to one bannister instead of two.* (Sam, 54yrs, TTA)

> *I think that for me, I do remember what I said for those 'what would you have liked to have done in the next six weeks' and I do remember those goals. So I think for me those questions were more important I guess than this (indicating outcome questionnaire)* (Erica, 39yrs, TTA)

A notable domain that some participants described as overlooked during their experience of outcome measurement, was the psychosocial impact of recovering from amputation with a prosthesis.

> *think possibly er er to some of the people that are more severely injured er erm it possibly could go more into assessing er erm the mental wellbeing side of it, the psychology of it basically*

> *rather than just the physiology if you know what I mean. It was rather physically prioritised shall we say as to can you do this, can you do that? Erm there was probably a little less emphasis on the psychological side.* (Bruce, 64yrs, TTA)

4.2.7 Discussion

The findings from this analysis offer an insight into the experience of taking part in outcome measurement in clinical practice as part of lower limb prosthetic rehabilitation and include contributions from a large and diverse sample whose characteristics reflect those of the UK limb loss population [38–40]. To our knowledge, no other study has explored this aspect of prosthetic rehabilitation with people with limb loss, especially considering their experience of both performance-based outcome measures and PROMs. Although considerable qualitative literature has been published in other healthcare settings exploring the patient's perspective of using PROMs, there is a paucity of evidence available exploring the experiences of patients taking part in performance-based outcome measurement, which is highlighted in a critical review of performance-based outcome measures in occupational therapy [41]. This lack of exploration brings into question how patient-centred and meaningful performance-based outcome measures are [41]. Although we did not ask patients to distinguish between different types of outcome measurement within this study, it is hoped that this paper may provide insights that could begin to address this gap in the literature. However, future research is required to fully understand patient experiences of using performance-based outcome measures during prosthetic rehabilitation, and wider rehabilitation settings.

The first theme presented in this study highlights the impact outcome measurement can have on patients and describes how participation in the process affected them. Most participants described their experience of outcome measurement using PROMs and performance-based measures in a positive way, discussing how seeing their improvement validated their recovery and highlighted progress that was hard to see or remember. Positive experiences were also described in several systematic reviews exploring patient experiences with PROMs, where patients described outcome measurement leading to a sense of empowerment through self-reflection [22], or helping to reinforce positive changes when symptoms were on track or progress had been made [23]. Our participants also talked about how outcome measurement could be motivational and was useful for goal setting. Using outcome measurement to facilitate goal setting has been described in a study using PROMS in pain management services. Both clinicians and patients found using outcome information in this way useful, resulting in more individualised care plans [41–43].

Despite many positive experiences, some participants in this analysis also described negative responses to outcome measurement, particularly related to experiences of taking part in performance-based measurement. When scores didn't improve, some participants described feeling like they had failed a test or were not progressing. Mixed responses to outcome measurement have been reported in research using the Multiple Sclerosis Symptom and Impact Diary (MSSID), where participants reported both positive impacts of seeing symptoms improve, and feelings of depression if symptoms worsened [43]. A systematic review by Soldstad et al. [42] highlighted the negative impact of outcome measurement for people with mental health conditions and suggested that in this population it could be completed with clinicians for emotional support, as well as practical help. Greenhalgh [43] highlighted the need to explain the possible positive and negative impacts of outcome measurement to patients and ensure processes are in place to allow patients to cease participation if they need to. The varied emotional responses described in our analysis may suggest that patient-centred approaches to outcome measurement in prosthetic rehabilitation need to be individualised and supportive, especially in light of the well-documented struggles with psychosocial adjustment in this population [44]. Future approaches to outcome measurement should consider the individual patient's coping strategies and adjustment process, and could include support and options to opt out, where required.

A further concern highlighted by participants in this study, and described in the second theme, was whether outcome measurement captures an accurate picture of recovery. For Performance-based measures, accuracy concerns focused on the testing environment, as flat hospital/clinic floors were not thought to represent the wider environment that patients with limb loss need to navigate. For PROMs, participants questioned how honestly measures would be completed, especially when people were concerned about how outcome information may affect the financial support they were receiving via the UK benefits system. Participants talked about not being able to show the best of what they can do during outcome measurement over fears that their benefits may be reduced.

This tension has been described previously in the limb loss and wider disability literature [45,46]. Wadey and Day [46] reported prosthetic user's need to present 'their worst day' during the benefits application process in order to receive the ongoing financial help needed. These concerns seem to be underpinned by a natural variation in outcome experienced by people recovering from lower limb amputation with a prosthetic limb, which was highlighted by our participants. This variation, described in other studies with limb wearers as 'good and bad' days [47], was identified as an accuracy concern, as the response or performance captured during outcome measurement may be affected by the type of day a person was having. This has been reported previously with musculoskeletal patients in primary care worrying about what type of day they were having when completing PROMs, and whether it would give their clinicians a ‘representative picture’[22]. Measuring outcome at a single point in time does not acknowledge the variation in ability that people may experience as part of recovery, as well as during lifelong prosthetic use [47]. The findings from this analysis may indicate that patient-centred approaches to outcome measurement lie in capturing this ‘natural’ variability, which may reflect the true nature of recovery as an outcome range. Thus, offering a more complete and meaningful picture.

The third theme described in this study focused on patients’ perception of who outcome measurement is undertaken for, highlighting that some participants perceived it as a process that does not generate information that is useful for them. They describe a lack of ownership or involvement in the wider outcome measurement process, which in their view appears to focus on providing information for clinical teams and funders. This view of measuring outcome has also been reported in the mental health literature, with routine outcome measurement in psychological services described by patients as a bureaucratic exercise only for the benefit of service providers [42], or only used for research applications rather than patient-centred reasons [22].

Interestingly, this contrasts with the positive experiences described in the first theme which reflect the many ways outcome measurement could be of value to patients. This suggests a possible gap in how outcome measures are routinely used in clinical practice, i.e., whether results are discussed with patients, or how they are used to inform and direct prosthetic rehabilitation. Systematic reviews evaluating patient experience with PROMs report that patients identify value in outcome measurement when the information generated is actually used as part of their care, i.e., to improve communication between patients and clinicians, facilitate clinical assessment, for diagnosis and monitoring of problems, and to support shared decision making [22,23]. Shared decision making has recently been advocated for in the limb loss population with the publication of clinical decision-making tools for partial foot verses transtibial amputation [48].

Despite numerous recommendations from prosthetic rehabilitation specialist interest groups about which outcome measurement tools to use [10–13], very little information is available about how they should be used in clinical practice, i.e., how outcome data can be integrated with patient care and what patient-centred approaches look like. Further work is required in the field of prosthetic rehabilitation to understand how outcome measurement could be used by both patients and clinicians to add value to clinical care, as well as to understand the impact it may have on prosthetic rehabilitation outcomes and lifelong prosthetic management.

The final consideration raised by these participants was whether outcome measurement in clinical settings is capturing what is meaningful to patients. Participants discussed that some of the PROMs they had used were too hard for them to complete, or included elements that were not relevant to their lives or their recovery. Many studies have reported similar frustrations from patients using PROMs, who had difficulty answering questions which were not relevant, were unclear or not specific enough [49–52]. In terms of the outcome domains being measured, some participants in this study felt the measures they experienced did capture the concepts which were important to their recovery. Whereas others felt measurement was too focused on physical recovery and did not evaluate important domains such as lifestyle or psychological response to limb loss, perhaps suggesting the need for a more holistic approach. Previous outcome measurement research has indicated that a holistic approach made patients feel that clinicians cared about them as a whole person rather than just their medical condition [23], and that outcome domains of importance following lower limb prosthetic rehabilitation extend far beyond physical capabilities, such as walking, and may need a holistic multi-domain approach [24].

The contrasting views described here regarding what was measured in the experience of different participants may be due to variability in which outcome measures are used across UK prosthetic rehabilitation settings, or variation in use by different professionals within the MDT. Within prosthetic rehabilitation there is currently a lack of consensus over which outcome measures to use following lower limb prosthetic rehabilitation [53,54]. A recent narrative review of outcome measurement in prosthetic clinical practice suggested this may be due to a lack of understanding, and subsequently consensus, about which outcome domains are most important to measure, especially according to prosthetic users themselves [19]. However due to the significant variation in the extent of recovery experienced following lower limb amputation [55], which can range from using a prosthetic limb for transfers only to returning to high impact sporting activities, it may be hard to find or develop measures which are appropriate for all patients. This may indicate the need for individualised outcome measurement tools which allow patients to identify the activities most important to them, or to select and weight issues that are of most importance, especially in situations where what is of most concern may vary [22], as may be the case following prosthetic rehabilitation.

4.2.7.1 Limitations

This analysis was part of a larger qualitative study which first asked questions about what the participants felt were outcome domains of importance following lower limb prosthetic rehabilitation. Limitations to the full study design are described further in the first analysis publication [24]. Regarding this analysis, it should be considered that prior discussions about outcome domains of importance may have influenced answers to questions about the participants experience of taking part in outcome measurement. For example, this may have influenced the theme of `are prosthetic services measuring what is meaningful.

When talking to the participants about their experiences of outcome measurement, we did not ask them to differentiate between their experiences with PROMs or performance-based measures. It is therefore possible that the findings may have been different if the study focused on one measurement type or the other. However, this mix of approaches reflects current UK practice. Future work could explore the differences in patient experience with different types of measure, especially performance-based measures considering the dearth of studies exploring perspectives of this approach across all healthcare settings.

During the interviews and focus groups we used several examples of outcome measures, as suggested by our PPIE group, to help stimulate discussion around the outcome measurement process. It is possible that the examples we used could have influenced the findings as participants may have focused on these examples rather than others measures with which they may have had experience. However, the measures we included were recommended for use in UK practice service specifications and policy [14,15], as well as professional guidance [10–13]. We also included participants from four different UK prosthetic centres, which may have all exposed participants to a variety of different tools used within the recommendations, or others that were not included.

It should also be considered that nine of the participants chose to take part over the telephone, which meant they would not have seen the outcome measure examples. In these cases, the researcher verbally described the measures to the participants, however this may have affected the recall of their experiences, their engagement in the discussion and the depth of their responses.

The findings from this study offer a useful insight into experiences of outcome measurement from the perspective of lower limb prosthetic users. As this is the first study to consider the patient's experience of this aspect of prosthetic rehabilitation, these findings could initiate a conversation about patient-centred approaches to outcome measurement in clinical settings that may not have been considered before. However, future research is needed to broaden our understanding of this phenomenon, for example understanding the experience of outcome measurement with different health care professionals, or when used in different ways i.e., to evaluate the impact of a specific intervention, or when used routinely to monitor progress over time. Furthermore, this study only included participants within five years of amputation due to inclusion criteria set for the larger study, and therefore may not represent the views of more established patients. Future research with these groups could provide additional insights. Alongside in-depth qualitative approaches, as used here, quantitative approaches may be useful to establish the extent to which the experiences of outcome measurement described in this analysis, are shared by the wider population.

4.2.8 Conclusion

Taking part in outcome measurement may provide clinicians, service providers and funders with useful information. However, adopting a patient-centred approach could make the process more meaningful and therefore beneficial for patients themselves. Harnessing the positive impacts of measuring outcome, reported in this study, could be used for motivation, to support adjustment and recovery, improve communication and support shared decision-making. As well as a patient-centred approach it appears a holistic approach may help to capture outcome information that is meaningful to patients. Considering the variable nature of outcome following prosthetic rehabilitation may also help capture the range of recovery experienced following limb loss more accurately. Despite this initial insight into clinical outcome measurement from the patients' perspective, further work is required to understand how it could be useful to this population.

In addition, the potential for negative responses to outcome measurement should not be overlooked. Clinicians may need to consider their patient's psychological wellbeing when using outcome measures, perhaps more so with performance-based measures. Patients may need support to undertake the process and should have options to stop if required. Further research is needed to provide greater understanding of the patients experience with different types of outcome measurement.

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Chapter 5 Paper 4 - Development of the ECLIPSE model of meaningful outcome domains following lower limb amputation and prosthetic rehabilitation, through systematic review and best fit framework synthesis.

5.1 Introduction to paper 4

This chapter introduces the last of four papers which make up this thesis. Paper four builds on the research described in paper two by further exploring outcome domains of importance following prosthetic rehabilitation and developing the early conceptual model. Paper two used an experiential qualitative approach to inform the development of an initial model of meaningful outcome domains following lower limb prosthetic rehabilitation. Paper four built on this by exploring the phenomenon as described in the qualitative evidence base and used these findings to produce a rigorously developed second iteration of the conceptual model. Paper four addresses the aims of the PhD by seeking to further understand the patient perspective of outcome measurement (Objective 2) and develop a conceptual model describing meaningful recovery following prosthetic rehabilitation and outcome domains of importance to measure in clinical settings (Objective 3). This work was undertaken as part of phase C, as described in Figure 5.1

The model has been named the **ECLIPSE** model; m**E**aningful out**C**ome domains of **L**ower l**I**mb **P**ro**S**thetic r**E**habilitation. Using an acronym to shorten the title of the model and generate a single word for its name was undertaken to help raise awareness of the research within the field and make the model memorable and accessible for use in clinical settings. Many acronyms are used in healthcare settings, often without meaning, to shorten complex terms and enable clinical discussion, such as the PPAM aid (Pneumatic Post Amputation Mobility aid). However, care will need to be taken when sharing findings with patient populations. Appropriate lay explanations should be developed and included to enable patients to engage with and use the model.

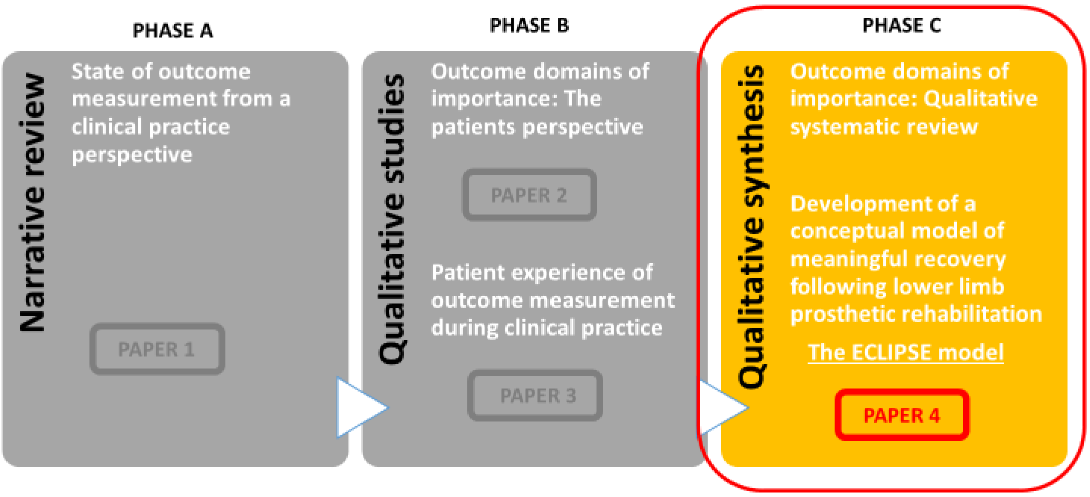

Figure 5.1 Phase C and paper four in the context of the complete thesis

This chapter includes an initial summary of paper four, in the form of an extended abstract, followed by the main manuscript, including all figures and references

5.1.1 Summary of paper

As highlighted in the previous papers that make up this thesis, little is known in prosthetic rehabilitation about which outcome domains characterise a meaningful recovery and should therefore be measured. The narrative review presented as paper one suggested this has contributed to an absence of consensus around which outcome measures to use in clinical settings (Ostler, Scott, *et al.*, 2022). The review also proposed than an absence of consensus could underpin reports of clinicians struggling to identify value in outcome measurement (Ostler, Scott, *et al.*, 2022). To address this gap, previous qualitative work undertaken in paper two of this PhD began to develop a conceptual model of outcome domains meaningful to patients (Ostler, Donovan-Hall, *et al.*, 2022). However, it only included the views of 37 people, all of whom were living in England. Paper four sought to build on this work and deepen our understanding of this phenomenon. In order to do this a qualitative synthesis was chosen to make use of the growing body of qualitative research exploring lower limb loss. This step allowed a diverse range of experiences described in a variety of studies undertaken with different patient groups, in different settings, to be considered and incorporated. Therefore, paper four comprises a qualitative synthesis which aims to explore views and experiences of outcome domains of importance to patients as captured in the limb loss literature and use these experiences to further develop the conceptual model.

5.1.1.1 Method

A systematic search strategy was conducted to comprehensively identify all available studies which could contribute to the synthesis. The bibliographic data bases CINAHL, Psychinfo and Web of Science were searched from 2011 to early 2023 in order to focus on current rehabilitation services and advances in prosthetic technology. Studies with a qualitative design focusing on views and experiences of lower limb prosthetic users were eligible for inclusion. Title and abstracts, followed by full texts, were screened by independent reviewers. Quality was assessed using the CASP (Critical Appraisal Skills Programme) tool, but no papers were excluded based on quality to ensure all possible outcomes of importance were considered. 'Best Fit' framework synthesis was used to synthesis the evidence and develop the conceptual model. This approach is based on framework synthesis but uses a pre-existing conceptual model, i.e., the model developed in paper two, to inform the development of an `a priori' framework (Carroll *et al.*, 2013). Evidence from the included studies is coded against the themes from the 'a priori' framework and data which does not easily fit within the framework is analysed separately using thematic analysis. This dual approach allows new concepts to arise inductively from the data, and the conceptual model to be reviewed, developed, altered, or enhanced in light of both analyses (Carroll, Booth and Cooper, 2011).

5.1.1.2 Results

Searches identified 2709 records, which following removal of duplicates and screening of titles and abstracts, produced 101 potentially relevant articles. Following full text review, 40 studies from 15 countries, describing the experiences of 539 participants were included. Data from the studies supported the pre-existing conceptual model but led to expansion and re-specification of four of the five domains (1,2,3 and 5) through renaming and addition of subthemes.

The newly named ECLIPSE model describes meaningful outcome domains as:

1) Being able to participate in my important activities and roles
   - Walking again
   - Undertaking activities in my home
   - Undertaking activities in my community
   - Fulfilling my roles.
2) Being able to participate in the way I want to
   - Independently
   - Easily and well
   - Without falling over

  - With as little equipment as possible.

3) My prosthesis works for me
   - It is comfortable
   - Easy to use
   - Enables me to participate.

4) If I am in pain, I am able to manage it

5) I am able to accept my new normal
   - Feeling a sense of normality
   - Adapting and accepting my limitations
   - Accepting my appearance
   - Sense of achievement
   - Lifelong health and wellbeing

The views from only a small number of participants from low- and middle-income countries were included in the synthesis, therefore it is unclear if the ECLIPSE model describes outcome domains of importance in these settings.

5.1.1.3 Conclusions

This synthesis provides a rigorous foundation for understanding outcome domains of importance following lower limb prosthetic rehabilitation. Our focus on the patient's perspective ensures that the ECLIPSE model describes a meaningful recovery in the lives of those with limb loss, especially in high income settings. The ECLIPSE model is an accessible representation of recovery and could be used by clinicians to shape and direct the focus of rehabilitation programmes and inform goal setting, as well as direct the evaluation of impact through the selection of appropriate outcome measures. The interconnected nature of outcome domains of importance also highlights the need for a holistic approach to outcome measurement, capturing success in all aspects of the patient's life.

5.1.2 Publication details

This paper has been published in the PLOS One scientific journal in July 2024 and is available in its published format in appendix I. This journal was selected as it is open access and has a cross disciplinary readership. As this paper describes the final model, we felt it was important to target a wide readership that could benefit both from the findings and the methods used to develop the model. It was also considered that a different perspective on the peer review process could further strengthen the paper. The findings from paper four were also presented via a platform presentation at the 2023 BACPAR conference in Dublin.

The referencing style of PLOS one is the Vancouver style. Referencing has been presented in this format with an accompanying reference list in the paper four manuscript. The manuscript is presented in the following section.

5.2 Paper 4 manuscript

5.2.1 Title:

Development of the ECLIPSE model of meaningful outcome domains following lower limb amputation and prosthetic rehabilitation, through systematic review and best fit framework synthesis.

5.2.2 Authors:

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5.2.3 Background

Outcome measurement is increasingly important in clinical practice, assisting clinicians to understand the impact of their interventions and the effectiveness of the services they provide [1]. The term outcome measurement can be better understood by breaking it down into i) the outcome domain being measured and ii) the measurement tool. An outcome domain can be defined as an element of health (i.e., pain, physical function, emotional wellbeing) that is changed by a particular intervention [2]. A measurement tool can be defined as a standardised instrument used in research and clinical practice to capture and evaluate change [3].

Despite its potential value, outcome measurement is still not routinely used in clinical practice [4]. Within prosthetic rehabilitation several clinical interest groups, such as the British Association of Physiotherapists in Limb Absence Rehabilitation (BACPAR) and the International Society of Prosthetics and Orthotics (ISPO), have attempted to increase health care professional engagement by publishing recommended outcome measures for use in clinical settings [5-8]. However, numerous outcome measures are included in the recommendations, with different measures proposed by different professional groups. The recommendations also include many outcome measures capturing the same outcome domain (i.e., mobility via measures such as the Six Minute Walk test, Timed Up and Go, or the Amputee Mobility Predictor). A recent narrative review highlighted the absence of outcome measure consensus in the field of prosthetic rehabilitation and suggested it may be driven by a lack of understanding around which outcome domains characterise a meaningful recovery following prosthetic rehabilitation, and should therefore be measured [9].

Gaining consensus regarding outcome domains of importance is crucial to allow effective comparison of research findings and clinical data. Consensus is advocated for by organisations such as Core Outcome Measurement in Effectiveness Trials (COMET) [10], and the International Consortium of Health Outcome Measurement (ICHOM) [11], who recommend domain consensus in research and clinical settings, respectively. Both groups promote a multistakeholder approach, including patients, to ensure domains are relevant to those for whom health and rehabilitation interventions have the most impact. However, a recent review of patient participation in core outcome set development questioned how patient-centred the process is [12]. The review found health care professionals tended to dominate prioritisation exercises, and few studies employed qualitative methods that may give patients more opportunity to contribute in a meaningful way [12].

Within prosthetic rehabilitation several authors have begun to explore which outcome domains are important to people who use a prosthetic limb, using qualitative approaches. McDonald et al. and Shaffalitsky et al. [13,14] both explored outcome domains of importance following the prescription of a prosthesis, focusing on the impact of componentry rather than the wider, holistic impacts of prosthetic rehabilitation recommended by professional groups [5,15]. These authors identified domains of importance such as balance, independence and adjustment, and interestingly highlighted *differences* in what patients and clinicians thought was most important [14]. Another small body of work attempted to develop an International Classification of Functioning (ICF) core set which could be used to inform which outcome domains to measure [16-19]. However, the authors identified several important concepts which could not be matched to the ICF and were therefore not included, such as socket comfort and feelings of acceptance following amputation. Moreover, the deductive approach recommended for ICF core set development may have diminished the voice of the patient.

This current study follows on from our large English qualitative study [20], which began to address the knowledge gap regarding outcome domains of importance following prosthetic rehabilitation. The study included a heterogenous sample of 37 lower limb prosthetic users and identified five key outcome domains of importance from the patient's perspective, which were presented as a conceptual model to inform both outcome measure selection and rehabilitation priorities (Figure 5.2). The study included a wide range of views and experiences but was limited by only involving individuals from England. Both convenience and purposive sampling were used to generate a diverse study population, however participants were identified by clinicians which may have led to a bias towards patients who had a positive experience of rehabilitation, or a more successful outcome.

Figure 5.2 The Author's previously developed conceptual model of outcome domains of importance following lower limb prosthetic rehabilitation.

Due to the limitations of a single qualitative study, further research is required to understand outcome domains of importance following prosthetic rehabilitation and continue developing the conceptual model considering the views and experiences of a larger population in different settings. Therefore, the aim of this article is twofold. Firstly, the study aims to use a systematic approach to search and synthesise published qualitative research, to explore outcome domains of importance following rehabilitation from the prosthetic user's perspective, as captured in the current evidence base. Second, the study extends the authors' empirical qualitative research described above [20] that underpinned the first stage of the conceptual model development, to generate a second iteration of the model informed by the wider experiences described in the limb loss literature.

5.2.4 Materials and methods

5.2.4.1 Research design

A systematic review of the literature and ‘Best fit’ framework synthesis were undertaken to address the research aims. A comprehensive systematic approach was adopted to identify relevant publications, ensuring findings are based on a foundation of rigor and resonate with the prosthetic community which has been described as having a culture of quantitative enquiry [21]. `Best fit’ framework synthesis was used to analyse data and further develop the authors conceptual model of meaningful outcome domains in light of experiences described in the qualitative evidence base.

This approach was underpinned by a critical realist world view which looks to access the knowable world [22], in this case the perceptions of important outcome domains following lower limb amputation through the lens of prosthetic users. The conduct and reporting of this review adhere to the ENTREQ guidelines (Enhancing transparency in reporting the synthesis of qualitative research) [23].

5.2.4.1.1 Search strategy

As recommended for aggregative approaches, such as ‘best fit’ framework synthesis, a systematic search strategy was undertaken to comprehensively identify all available studies and ensure that all possible data which may contribute to the synthesis were available [24-26].

The SPIDER framework[27], adapted from the PICO framework for qualitative systematic reviews, was used to define the search terms (Table 5.1).

Table 5.1 Use of the SPIDER framework to define the search terms for the qualitative synthesis

S Sample	Adults with lower limb loss
PI Phenomenon of Interest	Use of a prosthesis following lower limb amputation
D Design	Any qualitative approach
E Evaluation	views and experiences
R Research type	Qualitative

Following several scoping searches, the bibliographic databases CINAHL, Psychinfo and Web of Science were searched for relevant studies. These databases are recommended for use in qualitative syntheses as they have complete indexing for qualitative studies [24,28]. The search was limited to English language articles, published in peer reviewed journals. The Trip database was then searched to identify grey literature sources. Searches were limited to articles published in the last ten years between January 2011 and January 2023, to focus on current rehabilitation services and advances in prosthetic technology, and any shifts in societal acceptance of disability. The search strategy is described in Table 5.2.

Table 5.2 Search strategy used for qualitative systematic review

Database	Syntax
CINAHL	((Amput* OR prosthe* OR “limb loss” OR “artificial limb*”) OR (MH "Amputation" OR MH "Above-Knee Amputation" OR MH "Amputation Stumps" OR MH "Below-Knee Amputation" OR MH "Disarticulation" OR MH "Hemipelvectomy") OR (MH "Prosthesis Design" OR MH "Limb Prosthesis")) **AND** ((“lower limb*” OR leg*) OR (MH "Lower Extremity" OR MH "Ankle" OR MH "Hip" OR MH "Knee" OR MH "Leg" OR MH "Thigh") OR (MH "Leg")) **AND** ((Qualitative OR experience* OR interview* OR “grounded theor*” OR phenomenolog* OR “focus group*” OR narrative OR “thematic analysis” OR “Action research” OR ethnograph*) OR (MH "Qualitative Studies" OR MH "Action Research" OR MH "Ethnographic Research" OR MH "Ethnological Research" OR MH "Ethnonursing Research" OR MH "Grounded Theory" OR MH "Naturalistic Inquiry" OR MH "Phenomenological Research") OR (MH "Life Experiences" OR MH "Work Experiences") OR (MH "Semi-Structured Interview" OR MH "Interview Guides" OR MH "Unstructured Interview" OR MH "Unstructured Interview Guides" OR MH "Structured Interview" OR MH "Structured Interview Guides" OR MH "Interviews") OR (MH “Focus groups”) OR (MH “Narrative medicine”) OR (MH “Thematic analysis”))
Psychinfo	((Amput* OR prosthe* OR “limb loss” OR “artificial limb*”) OR (DE "Amputation" OR DE "Prostheses" OR DE "Phantom Limbs")) **AND** ((“lower limb*” OR leg*) OR DE "Thigh" OR DE "Ankle" OR DE "Knee")) **AND** ((Qualitative OR experience* OR interview* OR “grounded theor*” OR phenomenolog* OR “focus group*” OR narrative OR “thematic analysis” OR “Action research” OR ethnograph*) OR (DE "Focus Group Interview" OR DE "Focus Group" OR DE "Grounded Theory" OR DE "Interpretative Phenomenological Analysis" OR DE "Narrative Analysis" OR DE "Semi-Structured Interview" OR DE "Thematic Analysis" OR DE "Phenomenology") OR (DE "Experiences (Events)" OR DE "Life Changes") OR (DE "Action Research") OR (DE "Ethnography"))
Web of Science	(Amput* OR prosthe* OR “limb loss” OR “artificial limb*”) **AND** (“lower limb*” OR leg*) **AND** (Qualitative OR experience* OR interview* OR “grounded theor*” OR phenomenolog* OR “focus group*” OR narrative OR “thematic analysis” OR “Action research” OR ethnograph*)
Trip database (Grey literature)	Amputation **AND** Prosthesis **AND** qualitative

5.2.4.1.2 Screening process

Two reviewers (CO and AD) undertook title and abstract screening using Rayyan, a web application for systematic reviews (Rayyan Systems Inc.). Following the removal of duplicates, CO screened all articles with AD screening a random sample of 13% of abstracts. Agreement between reviewers was 99.6% with a single paper requiring discussion before it was excluded. CO then undertook full text screening using the inclusion and exclusion criteria (Table 5.3). Studies including mixed populations, i.e., prosthetic, and non-prosthetic users, were only included if data specific to the population of interest was presented independently in the analysis to ensure the outcome domains of importance were relevant to lower limb prosthetic users. Undecided papers were reviewed by AD and MDH and agreed upon following discussion.

Table 5.3 Inclusion and exclusion criteria used for screening of articles

Inclusion Criteria
Adult populations 18yrs and older
Included participants with a major lower limb amputation (At level of ankle and above)
Included prosthetic limb users
Use of qualitative study design (i.e., interviews, focus groups, grounded theory etc.)
Studies exploring views and experiences of life with a prosthetic limb
Presenting first person accounts
Exclusion Criteria
Included participants with upper limb or minor lower limb amputations (i.e., toes or partial foot) or studies which combined these populations with major lower limb amputations
Included those not using a prosthetic limb or studies which combine these populations with limb wearers
Studies only exploring prosthetic service provision

5.2.4.1.3 Critical appraisal

Critical appraisal within a qualitative synthesis is controversial [28]. Researchers dispute whether or not to undertake it, *how* to do it, whether to exclude studies as a result of it, and finally how to integrate critical appraisal findings into the main body of the synthesis [24,29]. Despite these questions there is a growing trend towards including critical appraisal within a qualitative synthesis, and it is recommended as part of the ‘best fit’ framework synthesis approach [25,26].

The critical appraisal process was used to give context to the findings presented in the synthesis, and comment on the quality of the overall sample [25,26]. The CASP tool [30] was used to undertake critical appraisal. Initially 10% of the papers were appraised by two reviewers (CO and MDH) to set quality expectations within each CASP question and compare and agree on the appraisal approach. CO then continued to appraise the remaining papers seeking advice and agreement from MDH where required. To summarise the findings, each quality appraisal response from the CASP tool was allocated a score from 1-3 (1=yes, 2=can't tell and 3=no). No studies were excluded due to perceived poor quality, to ensure all possible outcomes of importance were considered at this stage, and instead they were ranked in terms of quality.

5.2.4.1.4 Data extraction

Data extraction was undertaken by CO in two stages. Firstly, study-related data were extracted including the aim, design, sample size, recruitment setting, data collection method and geographical location, as well as details about the included population such as time since amputation, cause of amputation, sex, level of amputation and age range. Data were extracted to describe the studies and the characteristics of the study samples.

The second phase of data extraction addressed the qualitative findings of the included studies. Data were considered as that which were presented in the results or findings sections of the papers, and included both verbatim quotations and interpretations made by the study authors which were clearly supported by the study's data [29]. Data were imported into NVIVO software (QSR International, Melbourne, Australia) for analysis.

5.2.4.1.5 Stages of analysis

Stage 1. Framework development

'Best fit' framework synthesis [25] uses an 'a priori' framework based on an existing conceptual model to synthesise study data and examine and develop new iterations of the model based on findings from the wider literature. An initial conceptual model of outcome domains of importance was developed by these authors using a primary qualitative approach to explore the lived experience of prosthetic users and is published elsewhere [20]. This work involved interviews and focus groups with thirty-seven lower limb prosthetic users from four English prosthetic centres. Data were analysed using reflexive thematic analysis to develop five themes, with ten associated subthemes, which describe outcome domains of importance from the patient's perspective. The five themes were visualised into an initial conceptual model (Figure 5.2). This first stage model acted as the pre-existing conceptual model underpinning the 'a priori' framework, and for clarity will now be referred to as the pre-existing model.

An *'a priori'* framework was developed (Table 5.4) by deconstructing the pre-existing model into its comprising themes and subthemes. This created an in-depth framework grounded in the findings from the authors previous qualitative study [20]. The themes, referred to in the framework as domains were described using first person statements to ensure that the voice of the prosthetic user was not lost during the synthesis process. Each framework domain was also accompanied by an in-depth description to aid consistency of coding [25,26].

Table 5.4 Domains from the pre-existing conceptual model, including detailed definitions, which make up the 'a priori' coding framework

Framework domain	Definition
Domain 1 - I am able to participate in my important activities	
1.1 Walking again	*Walking is the first step in the recovery process and is important in feeling normal again*
1.2 Important activities at home	*Being able to do household tasks again, in a standing position, and get out of the house, even if only into the garden*
1.3 Important activities in my community	*Being able to undertake whatever activities are important to me, and having the mobility skills i.e., on uneven ground and slopes, to be able to do so*
Domain 2 - I can participate in my important activities in the *way* I want to	
2.1 Doing my activities independently	*Being able to do important activities independently without having to rely on anyone else*
2.2 Doing my activities easily	*Mastering my important activities so I don't have to think about what I'm doing, and I feel confident doing them.*
2.3 Doing my activities without falling over	*I can do my important activities without falling over, or fear that I will fall, and I can get up on my own if I do fall.*
2.4 Doing my activities with as little equipment as possible	*I only use equipment that I really need to allow me to do my important activities. Less equipment makes me feel more normal*
Domain 3 - My prosthesis is comfortable and easy to use	*My prosthesis is comfortable to wear for as long as I need, and for the different activities I want to do. It does not damage my skin or make me too sweaty. My prosthesis is easy to get on and off and not too burdensome to use throughout the day as the fit changes*
Domain 4 - If I have pain, I am able to manage it	*If I have pain, I can manage it in a way that enables me to accept and live with it.*
Domain 5 - I am able to accept my new normal	
5.1 Chasing normality	*I feel I am back to normal and the person I was before the amputation*
5.2 Adjusting to limb loss	*Adjusting is hard but my family and I have adjusted to the amputation and are able to accept what I can do now and how I now look*
5.3 Sense of achievement	*I have achieved my goals and feel proud of myself. I will continue to set goals in the future.*

Stage 2: Analysis

Data describing the included studies and their samples were analysed using descriptive statistics to give context about the qualitative approaches taken and the overall review population.

Data synthesis from the 'findings' sections of the included articles was undertaken in two steps. Step one involved open line by line coding of the data, codes were then mapped onto the domains and subthemes described in the '*a priori*' framework (Table 5.4).

Codes that did not fit easily into the framework were collated separately in NVIVO and analysed in a second step, independent of the framework synthesis, using thematic analysis as described by Braun and Clarke [31-33]. This dual approach using inductive thematic analysis in addition to the more deductive framework synthesis (Table 5.5) allowed previously unidentified concepts related to outcome domains of importance to arise from the data.

Table 5.5 Description of 'Best fit' framework synthesis and accompanying thematic analysis.

Phase	Description of process
(1) Familiarisation with the data	The results sections of the included studies were read and reread to increase familiarity with the data (CO).
(2) Coding	Open, line by line coding of the data was performed separately by the lead author (CO). Extracts of text were coded in as many ways as needed. A reflective journal was completed throughout the analysis process to encourage awareness of the researcher's own views and assumptions (CO).
(3) Coding into the framework	Codes were reviewed and mapped onto the domains and subthemes described in the 'a priori' framework by two researchers (CO and MDH). Data which did not map easily into the framework were collated separately.
(4) Reviewing left over codes	For codes not easily represented by domains set out in the framework a thematic analysis was undertaken. Left over codes and coded data were examined (CO and MDH), similarities and overlap were identified between codes and potential patterns relevant to the research question were created (CO and MDH)
(5) Generating and developing new themes	A visual map of initial themes not represented in the framework was created and compared (CO and MDH). All results sections were re-read and the fit of initial themes reviewed in relation to the full data set, coded data and the framework (CO). This process was then repeated by members of the research team (MDH).
(6) Refining, defining and naming new themes	The full set of concepts from both the framework and the additional thematic analysis were then reviewed and refined. Themes were collapsed or expanded in order to present coherent patterns within the data (CO). The research team reviewed newly developed concepts and subthemes to ensure they captured important new meaning in relation to the research question, and to assist reflection on researcher assumptions (CO, MDH, AD,

Phase	Description of process
	CM). A person-centred approach was taken to naming new domains and subthemes in order to capture the voice of participants (CO).

Stage 3: Conceptual model development

The findings from the framework synthesis were reviewed by the research team to understand where the review data supported pre-existing domains and where they did not. Newly identified themes were reviewed against the pre-existing conceptual model and through discussion and reflection, were added or used to refine the model until consensus was reached on a second iteration.

5.2.5 Results

5.2.5.1 Summary of included studies

Searches identified 2709 records, which were filtered down to 101 potentially relevant articles following removal of duplicates and screening of titles and abstracts. Thirty-nine of these studies met the inclusion criteria, with an additional study identified via citation chaining (Figure 5.3).

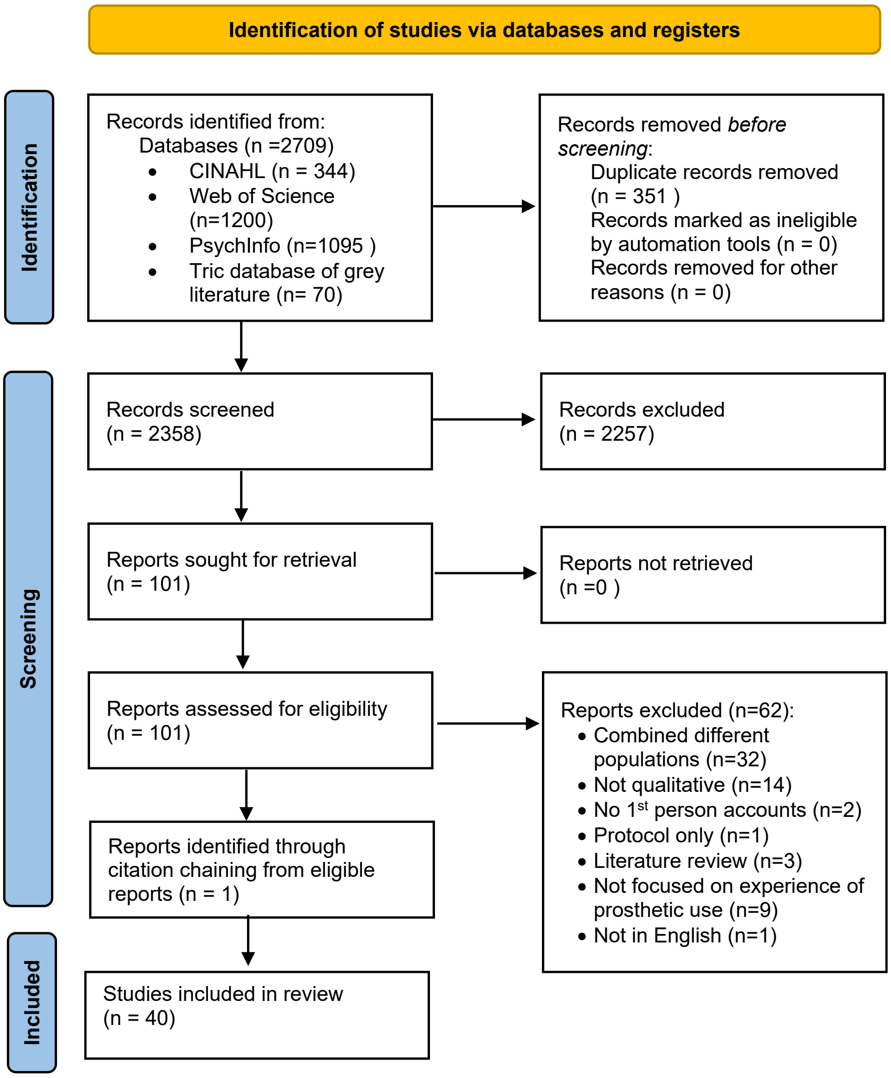

Figure 5.3 PRISMA diagram describing the process of identifying, screening and selecting articles for inclusion in the qualitative synthesis

The studies identified explored the experiences of 539 participants, 193 of whom were female (35.8%). Demographic data regarding cause of amputation were available from 31 studies representing 444 participants (82.3%). Across all studies, the causes of amputation were trauma (n=206, 46.4%), diabetic dysvascularity (n=130, 29.3%), cancer (n=44, 10%), infection (n=37, 8.3%) and congenital aetiologies (n=6, 1.4%). Demographic data describing level of amputation were available from 34 studies (n= 499, 92.6%). The levels of amputation were transtibial level (n=286, 57.3%), transfemoral (n=128, 25.7%), ankle (n=13, 2.6%), knee (n=22, 4.4%) and hip (n=6, 1.2%) disarticulation amputations. Forty-three participants experienced bilateral limb loss (8.6%). The age of participants ranged between 18-81 years. The study aims and sample characteristics are described in Table 5.6.

Table 5.6 Summary of study aim and sample characteristics from papers included in the qualitative synthesis

Study	Aim	Location	Sample size (n)	Sample characteristics
Abouammoh et al. (2021) [34]	Explore the adjustment experiences of amputees in Saudi Arabia and their needs before and after amputation	Saudi Arabia	8	5 females. Level: 1 symes, 3 TTA, 9 TFA, 6 bilat. Age range 26-71 yrs. Time since amp 4-15 yrs
Batten et al. (2020) [35]	Investigate barriers and enablers to community walking among people with lower limb amputation who have returned to live in a community setting	Australia	14	5 females. Cause: 1 trauma, 9 diabetic dysvascular, 2 infection, 1 cancer, 1 other. Level: 13 TTA, 1 TFA, 2 bilat. Median age 58 yrs. Age range 49-62 yrs. Time since amp 4-24 months
Bragaru et al. (2013) [36]	Identify personal barriers and facilitators that influence participation in sports of individuals with LLA	Netherlands	26	7 females. Cause: 7 trauma, 15 diabetic dysvascular, 4 tumour. Level: 1 symes, 9 TTA, 7 KDA, 7 TFA, 2 HAD, 2 bilat. Age range 21-77 yrs. Time since amp 2-35 years.
Camacho et al. (2021) [37]	Explore the lived experience of support group participants who are survivors of LLA living with PLP and understand the adaptation process postoperatively	USA	10	6 females. Cause: 2 trauma, 5 diabetic dysvascular, 1 infection, 1 tumour, 1 congenital. Level: 4 TTA, 5 TFA, 1 HAD, 1 bilat. Age range 22-70 yrs. Time since amp 1-53 yrs.
Christensen et al. (2018) [38]	Increase understanding of the military identity influence on the organization of rehabilitation and investigate factors of importance for successful rehabilitation services	Denmark	6	All male. Level: 5 TTA, 1 TFA. Mean age 32 yrs. Age range 25-46 yrs. Time since amp 2-17 yrs
Crawford et al. (2016) [39]	Investigate barriers and facilitators to Physical Activity participation for men with transtibial osteomyoplastic amputation	USA	9	All male. Level: all TTA. Age range 31-35 yrs. Time since amp 2-33 yrs
Day et al. (2019) [40]	Explore the everyday experiences of people with an amputation using a good day/bad day approach	UK	22	14 females. Cause: 9 Trauma, 3 diabetic dysvascular, 5 infection, 4 tumour, 1 congenital. Level: 18 TTA, 4 TFA, 4 bilat. Mean age 42 yrs. Age range 23-60. Time since amp 1-27 yrs
Devan et al. (2015) [41]	Explore the perceptions of adults with lower limb amputation and LBP as to the factors contributing to and affecting their LBP.	New Zealand	11	3 female. Level: 8 trauma, 1 tumour, 1 congenital, 1 other. Level: 8 TTA, 3 TFA. Age range 18-70 yrs. Time since amp 3-54 years

Study	Aim	Location	Sample size (n)	Sample characteristics
Ennion and Manig (2019) [42]	Explore the experiences of current lower limb prosthetic users in relation prosthetic service delivery and the value of their prosthesis in a rural setting	South Africa	9	1 female. Cause: 8 trauma, 1 infection. Level: 3 TTA, 6 TFA. Mean age 44 yrs. Age range 33-64 yrs. Time since amp 3-34 yrs
Hafner et al. (2016) [43]	Explore how prosthetic limb users conceptualize mobility with a prosthetic limb, construct a conceptual model of prosthetic mobility meaningful to people with lower limb loss, confirm key definitions, and inform development of items for the Prosthetic Limb Users Survey of Mobility (PLUS-M)	USA	37	11 females. Cause: 25 trauma, 3 diabetic dysvascular, 11 infection, 2 tumour, 3 other. Level: 25 TTA, 1 KDA, 11 TFA, 1 HDA, 9 bilat. Mean age 50.4 yrs. Age range 22-71 yrs. Time since amp 0.5-60 yrs
Hanna and Donetto (2021) [44]	Understand more about the reproductive experiences of amputee women who are living with amputation	Global	6	All female.
Hansen et al. (2018) [45]	Examine the process of becoming a user of a transfemoral osseointegrated prosthesis, from the beginning of rehabilitation (after second stage surgery) and forward, as seen from the user's perspective.	Denmark	7	2 females. Cause: 4 trauma, 3 tumour, Level: All TFA. Age range 37-70 yrs
Heavey 2018 [46]	Use a case study approach for analysing space as a narrative resource in stories about illness and recovery	UK	1	All Female, Cause: Diabetic dysvascular. Level: TFA. Age 60 yrs, Time since amp 50 yrs
Horne and Paul (2019) [47]	Understand the subjective experiences with chronic amputation pain and responses from family members, friends, and health care providers	USA	11	5 females. Mean age 60.82 yrs
Jarnhammer et al. (2018) [48]	Explore experiences of persons in Nepal using lower-limb prostheses	Nepal	16	6 females. Cause: 11 trauma, 2 infection, 2 tumour, 1 other. Level: 11 TTA, 1 KDA, 4 TFA. Mean age 38 yrs. Age range 21-67 yrs. Time since amp mean 10 yrs
Jeppsen et al. (2019) [49]	To better understand the resilience among Veterans who experienced combat-related amputations.	USA	6	Cause: 6 trauma
Keeves et al. (2022) [50]	Explore the barriers and facilitators experienced by people with lower limb loss following a traumatic amputation that influence social and community participation between 18months and 5-years post amputation.	Australia	9	2 females. Cause: 9 trauma. Level: 5 TTA, 4 TFA. Median age 59 yrs. Age range 50-64. Mean time since amp 35 months

Study	Aim	Location	Sample size (n)	Sample characteristics
Kim et al. (2021) [51]	Explore lived experiences, and identify common themes as well as vocabulary associated with fall-related events in LLP users	USA	25	9 females. Cause: 14 trauma, 6 diabetic dysvascular, 3 infection, 1 tumour, 1 other. Level: 2 symes, 14 TTA, 1 KDA, 9 TFA, 4 bilat. Mean age 59.6 yrs. Age range 25-81 yrs. Time since amp 1-51 yrs
Koszalinksi and Locsin (2015) [52]	Describe the meaning of the experience of persons being cared for with prosthetic devices after lower limb amputation	USA	12	Unknown
Lee et al. (2022) [53]	explore the experience of self-managing after limb loss/limb difference from the perspective of prosthesis users, prosthetists, and physical therapists.	USA	10	6 females. Cause: 4 trauma, 2 diabetic dysvascular, 1 cancer, 3 congenital. Level: 5 TTA, 5TFA. Mean age 53.1 yrs. Mean time since amp 25.7 yrs
Lee et al. (2022) [54]	Examine the effects of the COVID-19 pandemic on physical activity levels in persons with limb loss	USA	13	Not known
Lehavot et al. (2022) [55]	Understand the experience of female veterans with prosthetic care and their prosthesis to inform direction of future research and clinical practice	USA	30	All female. Cause: 11 trauma, 9 diabetic dysvascular, 7 infection, 3 other. Level: 14 TTA, 15 TFA, 1 bilat.
Mathias and Harcourt (2014) [56]	Gain an in-depth understanding of the experiences and emotional responses of women with below-knee amputations to dating and intimate relationships	Jamaica, Columbia and USA	4	All female. Cause: 3 Trauma, 1 cancer. Level: All TTA. Age 18-29 yrs
Mattick et al. (2022) [57]	explore the factors influencing motivation of lower limb amputees engaging with prosthesis services in Mombasa, Kenya	Kenya	10	2 females. Cause: 7 trauma, 3 diabetic dysvascular. Level: 10 TTA. Mean age 39 yrs. Age range 24-60 yrs. Time since amp 2-25 yrs.
Mayo et al. (2022) [58]	Interview persons with LEA about their mental health needs and to gauge their attitudes towards iCBT and/or online mental health supports	Canada	10	1 female. Cause: 3 trauma, 6 diabetic dysvascular, 1 infection. Level: 7 TTA, 1 TFA, 1 bilat. Mean age 55.6 yrs. Age range 43-77 yrs.
McDonald et al. (2018) [13]	Explore outcomes that matter to prosthesis users who have experience using two different types of prosthetic feet	USA	5	1 female. Cause: 2 Trauma, 1 diabetic dysvascular, 2 Infection. Level: All TTA, 2 Bilat. Mean age 45.6 yrs. Age range 41-59 yrs. Time since amp 2.7-14.5 yrs
Miller et al. (2020) [59]	Describe resilience characteristics meaningful to people with TTA in middle age or later, who use a prosthesis	USA	18	3 females. Cause: 13 diabetic. Level: TTA. Mean age 60 yrs. Mean months since amp 60 yrs

Study	Aim	Location	Sample size (n)	Sample characteristics
Miller (2021) [60]	To identify psychosocial factors with potential to influence clinically relevant measures of physical activity, physical function, and disability in light of participants' narratives	USA	20	2 females. Cause: All diabetic dysvascular. Level: 15 TTA, 2 TFA, 3 bilat. Mean age 63.4 yrs. Mean time since amp 5.5 yrs
Morgan et al. (2020) [61]	to evaluate an existing conceptual measurement model of mobility and identify high-level activity item content to include in an expanded PLUS-M item bank	USA	29	6 females. Cause: 20 trauma, 2 diabetic dysvascular, 2 infection, 3 cancer, 2 other. Level: 23 TTA, 6 TFA, 4 bilat. Age range 25-74. Time since amp 0.9-49.8 yrs
Norlyk et al. (2016) [62]	Explore the lived experience of becoming a prosthetic user as seen from the perspective of persons who have lost a leg.	Denmark	8	2 females. Cause: 2 trauma, 5 diabetic dysvascular, 1 infection. Level: 9 symes, 4 TTA, 4 TFA. Age range: 33-74 yrs
Poonsiri et al. (2020) [63]	Explore consumer satisfaction with prosthetic sports feet and the relative importance of different dimensions regarding prosthetic sports feet	Netherlands	16	6 females. Cause: 5 trauma, 2 diabetic dysvascular, 2 infection, 5 tumour, 2 other. Level: 8 TTA, 6 KDA, 2 TFA. Mean age 37.5 yrs
Roberts et al. (2021) [64]	Gain an indepth understanding of prosthesis use from the perspectives of individuals with major LLAs	Canada	10	4 females. Level: 5 TTA, 1 KDA, 4 TFA. Mean age 63.3 yrs. Age range 47-78 yrs.
Stucky et al. (2020) [65]	Explore the lived experience of people in Bangladesh following LLA and prosthetic rehabilitation to understand the facilitators and barriers to their work participation	Bangladesh	10	3 females. Cause: 9 trauma, 1 diabetic dysvascular. Level: 7 TTA, 3 TFA, 1 bilat. Mean age 34.6 yrs, Age range 23-63 yrs
Taylor (2020) [66]	Explore whether subjective statements, justifying a patient preference for microprocessor controlled prosthetic limbs over non-microprocessor controlled limbs, involves themes other than functional improvement	UK	15	All male. Cause: all trauma. Mean age 34.7 yrs. Age range 23-51 yrs
Turner et al. (2022) [67]	To understand the experiences of people with LLA during rehabilitation with a prosthesis	UK	10	4 females. Cause: 3 trauma, 3 diabetic dysvascular, 1 cancer, 3 other. Level: 8 TTA, 1 TFA, 1 bilat. Mean age 53.7 yrs. Mean time since amp 6.53 yrs
Van Twillert et al. (2014) [68]	to provide a better understanding of the impact of barriers and facilitators on functional performance and participation and autonomy post-discharge	Netherlands	13	4 female. Cause: 4 trauma, 8 diabetic dysvascular, 1 other. Level: 10 TTA, 2 KDA, 1 TFA. Age range 29-73 yrs.
Verschuren et al. (2014) [69]	to explore qualitatively how persons with a lower limb amputation describe and experience (changes in) sexual functioning and sexual wellbeing after LLA	Netherlands	26	9 females. Cause: 7 trauma, 7 diabetic dysvascular, 4 infection, 6 cancer, 2 other. Level: 15 TTA, 1 KDA,

Study	Aim	Location	Sample size (n)	Sample characteristics
				6 TFA, 2 HAD, 2 bilat. Mean age 47 yrs. Age Range 22-71 yrs
Wadey and Day (2018) [70]	To provide an original and rigorous account of Leisure Time Physical Activity among people with an amputation in England	UK	22	14 females, mean age 42 yrs. mean time since amp 5 yrs
Ward Khan et al. (2021) [71]	To gain an in-depth understanding of women's experience of sexuality and body image following amputation of a lower limb to inform rehabilitation and clinical practice	Ireland	9	All females. Cause: 2 trauma, 5 diabetic dysvascular, 1 cancer, 1 other. Level: 6 TTA, 2 TFA, 1 Pelvic. Age range 35-62 yrs. Time since amp 1.5-31 yrs
Young et al. (2022) [72]	understand current and former military experiences when using MPK primary and backup devices with a view to helping guide decisions related to policy and potentially improve rehabilitation services	Canada	6	0 females. Cause: 5 Trauma, 1 diabetic dysvascular. Level: 2 KDA, 4 TFA. Mean age 44.6 yrs.

Cause=Cause of amputation. Level = Level of amputation. TTA = Transtibial amputation, KDA = Knee Disarticulation Amputation, TFA = Transfemoral Amputation, HAD= Hip Disarticulation Amputation. Bilat = Bilateral amputation.

The studies were undertaken in 15 different countries (Figure 5.4), with 486 (90.2%) participants living in high-income countries, according to the World Bank definition [73]. Eleven (2%) participants lived in upper middle-income countries, 36 (5.7%) in lower middle-income countries and 6 were not stated (2.1%). No participants were included from low-income countries.

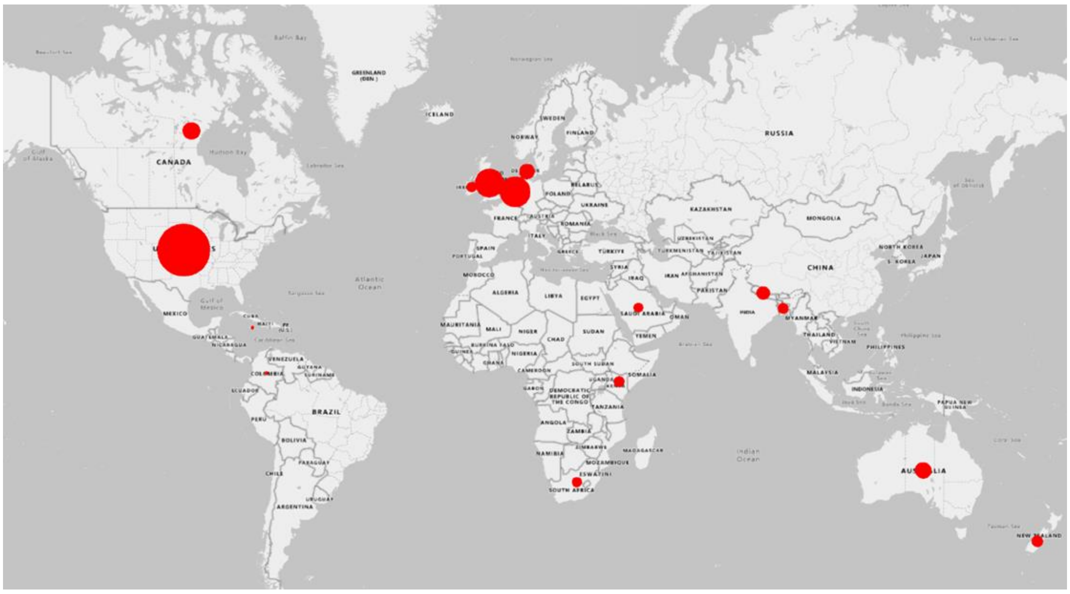

Figure 5.4 **Map of the world illustrating the geographical spread of participants involved in the included studies**

5.2.5.2 Methodological quality of included studies

The quality of papers included varied considerably. Overall, there was a little consideration of the relationship between the researcher and the participants, which was only adequately discussed in 12 of the 40 studies. Critical examination of the potential influence the researcher may have is important to provide insight into how their assumptions may have impacted or introduced bias to the results [74].

The other notable quality concern was recruitment of participants. Only 23 of the studies adequately described why participants selected for the study were appropriate to answer the research question. Many studies used convenience sampling approaches which may have led to samples with little variation, which do not represent the characteristics of target population [34,42,69,72,48,50,52–54,58,65,67]. CASP scores (out of 27, higher indicating poorer quality) ranged from 9-22. It is important to note that the findings described in this paper are supported by articles scoring across this range. The results of the critical appraisal process are summarised in Table 5.7.

Table 5.7 Study design and critical appraisal of study quality using the CASP qualitative appraisal tool

(Yes = Green(1), Can't Tell = Yellow(2), No = Red(3))

				CASP tool Section A						CASP tool Section B			Total Score
Author	Methodology	Data Collection approach	Analysis approach	Was there a clear statement of the aims of the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	
Day et al. (2019) [40]	Qualitative exploratory	FG	Inductive TA	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	9
Hansen at al. (2019) [45]	Descriptive phenomenology	In depth Interview	RLW guiding principles	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	9
Mathias and Harcourt (2014) [56]	IPA	On-line SSI	IPA	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	9
McDonald et al. (2018) [13]	IPA	FG	IPA and adapted GT	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	9
Morgan et al. (2020) [61]	Not stated	FG	TA	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	9
Wadey and Day (2018) [70]	Longitudinal qualitative	FG, Obs, unstructured and SSI	Inductive TA	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	9
Mattick et al. (2021) [57]	Qualitative	SSI	TA	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	9
Norlyk et al. (2016) [62]	Phenomenology RLR	Longitudinal interviews	Thematic RLR	🟩	🟩	🟩	🟩	🟩	🟨	🟩	🟩	🟩	10
Batten et al. (2020) [35]	Not stated	FG	Content / TA	🟩	🟩	🟩	🟩	🟩	🟨	🟩	🟩	🟩	10
Devan et al. (2015) [41]	Qualitative	FG	General Inductive approach	🟩	🟩	🟩	🟩	🟩	🟨	🟩	🟩	🟩	10
Kim et al. (2021) [51]	Qualitative	FG	Adapted GT	🟩	🟩	🟨	🟩	🟩	🟩	🟩	🟩	🟩	10
Ward Khan at al. (2021) [71]	IPA	SSI	IPA	🟩	🟩	🟩	🟩	🟩	🟩	🟨	🟩	🟩	10
Stuckey et al. (2020) [65]	Not stated	SSI	TA	🟩	🟩	🟩	🟨	🟩	🟨	🟩	🟩	🟩	11

Bragaru et al. (2013) [36]	Phenomenology	SSI	Thematic codebook	🟩	🟩	🟩	🟩	🟩	🟥	🟩	🟩	🟩	11
Camacho et al. (2021) [37]	Phenomenology	SSI	TA	🟩	🟩	🟩	🟩	🟩	🟨	🟩	🟨	🟩	11
Hanna and Donetto (2021) [44]	Qualitative exploratory	Online posts	TA	🟩	🟩	🟩	🟩	🟩	🟥	🟩	🟩	🟩	11
Horne and Paul (2019) [47]	Empirical Phenomenology	SSI	Empirical Phenomenology	🟩	🟩	🟩	🟩	🟩	🟥	🟩	🟩	🟩	11
Keeves et al (2022) [50]	Qualitative exploratory	SSI	TA	🟩	🟩	🟩	🟨	🟩	🟩	🟩	🟩	🟨	11
Miller et al. (2020) [59]	Mixed methods	SSI	Directed content analysis	🟩	🟩	🟩	🟩	🟩	🟨	🟨	🟨	🟩	12
Miller (2021) [60]	phenomenology	SSI	Six step method by Cresswell	🟩	🟩	🟨	🟩	🟩	🟨	🟩	🟨	🟩	12
Hafner et al. (2016) [43]	Not stated	FG	TA	🟩	🟩	🟩	🟩	🟩	🟥	🟨	🟩	🟨	13
Jeppsen et al. (2019) [49]	conceptual framework	SSI	Content	🟩	🟩	🟩	🟨	🟩	🟥	🟩	🟨	🟩	13
Verschuren et al. (2015) [69]	Descriptive qualitative approach	SSI	TA	🟩	🟩	🟩	🟨	🟩	🟥	🟨	🟩	🟩	13
Lee et al. (2022) [53]	Qualitative	Interviews	Constant comparison method	🟩	🟩	🟨	🟨	🟩	🟥	🟩	🟩	🟩	13
Lehavot et al. (2022) [55]	Qualitative	SSI	Content analysis	🟩	🟩	🟨	🟩	🟩	🟥	🟩	🟩	🟨	13
Poonsiri et al. (2020) [63]	Mixed methods	SSI	Qualitative interpretation	🟩	🟩	🟨	🟩	🟨	🟥	🟩	🟩	🟨	14
Taylor (2020) [66]	Pilot	Written statements	TA	🟩	🟩	🟩	🟩	🟨	🟥	🟩	🟥	🟩	14
Jarnhammer Et al. (2018) [48]	Qualitative	SSI	Content	🟩	🟩	🟨	🟨	🟩	🟥	🟩	🟨	🟩	14
Koszalinski and Locsin (2015) [52]	HPA	SSI	HPA	🟩	🟩	🟨	🟥	🟨	🟩	🟩	🟩	🟨	15
Christensen et al. (2017) [38]	Qualitative exploratory	SSI and obs	Inductive latent TA	🟩	🟩	🟩	🟨	🟨	🟥	🟨	🟩	🟨	15
Mayo at al. (2022) [58]	CFIR	Interviews	Codebook TA	🟩	🟩	🟩	🟨	🟨	🟥	🟩	🟨	🟨	15

Young et al. (2021) [72]	IPA	SSI	IPA	🟩	🟩	🟩	🟨	🟨	🟨	🟥	🟩	🟨	15
Ennion and Manig (2019) [42]	Qualitative exploratory	SSI	TA	🟩	🟩	🟨	🟨	🟨	🟥	🟩	🟨	🟨	16
Heavy (2018) [46]	Narrative	In depth Interview	Unknown	🟨	🟩	🟩	🟨	🟩	🟩	🟥	🟥	🟨	16
Van Twillert et al. (2014) [68]	Mixed methods	SSI	Framework analysis using ICF	🟩	🟩	🟨	🟩	🟨	🟥	🟨	🟥	🟩	16
Abouammoh et al. (2021) [34]	Phenomenology	FG and SSI	TA	🟩	🟩	🟩	🟥	🟨	🟥	🟨	🟨	🟨	17
Roberts et al. (2021) [64]	Qualitative descriptive	SSI	TA	🟩	🟩	🟩	🟨	🟨	🟥	🟨	🟥	🟨	17
Crawford et al. (2016) [39]	Observational qualitative	SSI	TA	🟩	🟩	🟨	🟥	🟨	🟨	🟨	🟨	🟥	18
Lee et al. (2022) [54]	Mixed methods	SSI	Constant comparison method	🟨	🟩	🟨	🟥	🟥	🟥	🟥	🟥	🟨	22
Turner et al. (2022) [67]	Mixed methods	SSI	TA	🟨	🟩	🟥	🟨	🟥	🟥	🟥	🟥	🟨	22

PA – Interpretive phenomenological approach, RLW- Reflective life world research, GT – Grounded theory, TA- Thematic analysis, HPA – Hermeneutic phenomenological approach, CFIR - Consolidated Framework for Implementation Research, SSI – Semi structured Interview, FG – Focus Group, Obs – Observations

5.2.5.3 Best Fit Framework Synthesis

The ‘best fit’ framework synthesis illustrated that the experiences discussed within the included papers, undertaken in a variety of contexts, fit well into the pre-existing conceptual model. All of the model’s domains were supported by the qualitative data (Table 5.8).

Table 5.8 Examples of how data from the qualitative synthesis support the pre-existing framework domains.

Pre-existing framework domains and subthemes	**Examples from qualitative synthesis data**
Domain 1 - I am able to participate in my important activities	
Subtheme 1.1 - **Walking again** (10 papers - [13,34,35,39,43,52,57,62,64,72])	*I just wanted to get prosthesis and be able to walk again, those were my expectation, I had been told that there are false legs that one can get and they help one to be able to walk. (Juma)* (Merrick et al., 2022 [75]) *I would be tempted to add something to [a definition of mobility] about the ability to accomplish wanted or needed tasks.PT2.6* (Hafner et al., 2016 [43])
1.2 - Important activities at home (11 papers- [35,41,72,43,48,52,62,64–66,68])	*This leg [prosthesis] has managed to help me a lot; because of this leg [prosthesis] I’m able to do work, go to the toilet and carry things around my house, and I can travel and walk. (Female N, living in urban area*) (Jarnhammer et al., 2018 [48]) *For most participants, the prosthesis was actively used to complete activities of daily living such as cooking, cleaning, and laundry. One individual explained, “Well, because it’s a pain in the ass trying to cook it all from your wheelchair, especially in front of the stove. Right, because I’m terrified of something like the pot tipping over, whatever and scalding me.” (Participant 08)* (Roberts et al., 2021 [64])
1.3 - Important activities in my community (24 papers-[13,34–36,39,42,43,45,48–52,54,57,58,61,62,64–66,68,70,72])	*Expanded mobility, perhaps the most important and commonly reported outcome for study participants, was experienced in a unique way for each individual person and his or her lifestyle.* (McDonald et al., 2018 [13]) *Another participant expressed immense satisfaction that her prosthesis allowed her to engage in physical activity with her family, “We do a lot of swimming, we do badminton, we played as a team outside of the house, I play volleyball…” (Participant 14)* (Roberts et al., 2021 [64])

Pre-existing framework domains and subthemes	Examples from qualitative synthesis data
	One example was characteristics of the terrain, such as sand or uneven terrain: "I cried the first time I was on sand. I thought I would never be able to walk on sand again. I had to leave the beach" (PT1.3). (Morgan et al., 2020 [61]) *Another participant had changed work roles as she was unable to walk the distances required to be a professional cleaner. One participant was unable to walk the required distance to public transport for work.* (Batten et al., 2020 [35])
Domain 2 - I can participate in my important activities in the *way* I want to	
2.1 - Doing my activities independently (14 papers- [13,34,40,43,45,47,48,50,52,57,61,62,64,65])	*Since receiving the prosthetics, he had opened his own barber shop and how he could now "depend on myself." He was not alone; others spoke significantly about reduced dependency: I can take myself to the shop without any help, unlike there before when I used to depend on people to help me, I can go by myself to the toilet without asking for help (Mohamed)* (Mattick et al., 2022 [57]) *There was a reluctance to ask for support from their spouse or extended family – to not to be a burden; particularly given that failure to fulfil an expected role left some women feeling their spouse may leave: If I ask someone [to help] it might be hard for them too. It becomes very difficult for my mother and sister-in-law when I go home. When I am dependent on them, this actually increases their workload. – Fatima (F, 23)* (Stuckey et al., 2020 [65])
2.2 - Doing my activities easily (21 papers- [13,35,36,39–41,43,45,46,52,59–63,65,66,68,70–72])	*You need to create a day-to-day life, where you do not think so much about it anymore. It needs to become a routine that you need to put on a sock in the morning, and remember to wash it before going to bed in the evening . . . it should be like brushing your teeth. Something you do without even thinking about it. (Daniel, third interview) (*Norlyk et al., 2016 [62]) *Additionally, participants described some physically focused activities that were no longer possible after LLA because the effort, adaptation, and/or time were too great. For example, some participants reported that they no longer mow their lawn because the effort, adaptation, and time to push the lawn mower, maintain balance, and manage the associated tasks were too great following LLA.* (Miller 2021 [60])

Pre-existing framework domains and subthemes	Examples from qualitative synthesis data
2.3 - Doing my activities without falling over (18 papers - [13,35,36,41,43–45,50,51,53,59–61,63,65,67,70,72])	*I got frustrated when I had tripped and fallen multiple times with my mechanical knee. It's super frustrating, obviously. I want to be able to function and not to worry about falling, like anybody."* (Young et al., 2022 [72]) *"I will go ahead and stop going to, you know, to the stores to pick up a bunch of little items because it's just not worth the hassle going by a slip hazard or a trip hazard or an ice patch, something like that." (Male, 59 years old, TT, 8 years since amputation)* (Kim et al., 2021 [51])
2.4 - Doing my activities with as little equipment as possible (11 papers - [35,37,71,43,44,51,52,57,62,64,65])	*I dare not have too high hopes . . . But I do have a dream that I can walk down the street without a stick for support, that is a big dream (emphasis) . . . and it would be a major victory for me to go shopping without anyone realizing that I walk with an artificial leg. (Hanna, third interview)* (Norylk et al., 2016 [62]) *Many participants implemented the use of mobility aids and seated rests to overcome challenges associated with community ambulation, such as unsteadiness or fatigue. One participant explained, "But, when I got my walker, I just turn it around backwards and I sit down and relax and get my breath and, get everything back to normal and then continue on." (Participant 06)* (Roberts et al., 2021 [64])
Domain 3 - My prosthesis is comfortable and easy to use (17 papers - [35,39,44,45,48,50,51,53,55,57,60-62,64,67,68,72])	*I think a lot of effort is put into the ankles and the legs…but I think actually the socket fit is something that's really important but of course not as glamorous and therefore gets forgotten." (Prosthesis User 1, Female individual)* (Turner et al., 2022 [67]) *There's been times where I've had… the occasional blister and because the stump is shrinking so much… it gets irritation on the side of the socket and then that becomes painful. That means you have to stay off your leg for a few days until the swelling goes down and then you can redo it all again… it's sort of hit and miss through the year, you never know when a blister is going to happen. [Rob_M_TKA_61-70_<3 years]* (Keeves et al., 2022 [50]) *"[Sweat] actually comes over the top of the liner…it's obviously quite uncomfortable and it can wet shorts and wet trousers because the sweat is actually coming over the top of the liner." (Prosthesis User 6, Male)* (Turner et al., 2022 [67])

Pre-existing framework domains and subthemes	Examples from qualitative synthesis data
	One participant had a suspension system that made it quick and easy to don, enabling walking. (Batten et al., 2020 [35])
Domains 4 - If I have pain, I am able to manage it (7 Papers- [37,39–41,44,47,61])	*While some participants reported that a pain-free day was possible, for most a good day involved better management of pain, allowing them to engage in activities that they wanted to do.* (Day et al., 2019 [40]) *For some participants, pain was a reason for non use of the prosthesis, "Some days I don't even put it on, don't even tell me to put it on, because I'll get mad at you. There's nothing worse than having a pain you can't control. You know, and the only way I can control it is to stay off both my feet." (Participant 02)* (Turner et al., 2022 [67]) *You know like part of the package when you got a limb you are going to get pain here and there.. ..Ah it is it can be really uncomfortable yeah, but you just got to sort of carry on through it.. . (Jack, Int 2)* (Devan et al., 2015 [41])
Domains 5 - I am able to accept my new normal	
5.1 - Chasing normality (14 papers- [34,36,38,40,41,45,47,52,56,57,60,62,66,70])	*You're making me think. I don't know. It's a deep question. I haven't addressed it, even though I think I have. I haven't addressed the fact that I'm disabled. I've come to terms with it, I get on, but I probably haven't properly. I don't really like that word. What does it mean? I don't like it. It makes me different. I don't want to be different. I just want to be the same as everyone else. I just want to just fit in. To just be.* (Wadey and Day, 2018 [70]) *Depending on the degree of regained mobility the participants strived to re-conquer a daily life that resembled their previous lives.* (Norlyk et al., 2016 [62]) *A good day is when I just feel like everybody else. [Gloria] Moving away from the amputation.* (Day et al., 2019 [40])
5.2 - Adjusting to limb loss (32 papers-[13,34–38,40,42,43,45–50,52,55–66,68–71])	*"I know that life is worth living and there is still that out there, but it's hard to come back to that."* (Jeppsen et al., 2019 [49]) *Everybody's looking to the past, how they used to be. Uh…. So for me, you go to wedding and you see*

Pre-existing framework domains and subthemes	**Examples from qualitative synthesis data**
	someone is dancing all night. I was that guy. Can I dance again all night? I had a tree at my cottage. A poplar, it was 40-50 feet tall. I climbed way over there with a chainsaw in my hands so I chop it down. Can I do that again? (ID#17, Male outpatient, 51, traumatic aetiology) (Mayo et al., 2022 [58]) *''It doesn't matter how you do it because everybody has something, then you feel more at home and less stared at …… you feel less different….and then you accept it"* (Bragaru et al., 2013 [36]) *For example, a participant stated he could not squat or be down on one knee to change a car tire and, "That's a limitation that I've adapted to. So, I just put a stool down and then sit on the stool, and then do what I gotta do. So, you just have to take the limitations, and then adapt to do things that way," (69 years old; 2.5 years post-TTA).* (Miller et al., 2020 [59]) "*Only the strong survive baby! If you don't adapt to the circumstances, my gosh, you are going to have a miserable life."* (Camacho et al., 2021 [37])
5.3 - Sense of achievement (13 papers- [13,36,62,63,70,37–40,44,46,59,60])	*Participants described pride in success, building their confidence in pursuit of challenging goals. Another participant stated, "[Being active] is incredibly gratifying. I mean, in this circumstance in particular, maybe because it's like I've been recovering something. That feeling like, yea. I mean, it makes me really proud," (54 years old; 1 years post-TTA).* (Miller et al., 2020 [59]) *Participants described personally meaningful goals and implementation of strategies, both successful and unsuccessful, to minimize identified barriers, achieve goals, and reduce their disability.* (Miller et al., 2020 [59])

5.2.5.4 Additional thematic analysis

Although additional data were identified which did not fit easily into the framework, following thematic analysis it became clear that they expanded the existing outcome domains of importance, rather than describing new ones. The next sections illustrate how each domain has been re-specified or developed and provide additional context from the synthesis with relevant quotations. Domain changes are identified in bold underlined text within the following tables.

5.2.5.4.1 Domain 1 - I am able to participate in my important activities and roles

The first domain 'I am able to participate in my important activities', set out in Table 5.9, was expanded to include an additional subtheme describing the importance of returning to valued roles. Roles were not included in the pre-existing framework which focused on participating in important activities.

Table 5.9 Development of domain 1 – I am able to participate in my important activities and roles

Pre-existing framework domain and subthemes	Newly expanded domain and subthemes
Domain 1 - I am able to participate in my important activities	**Domain 1** - I am able to participate in my important activities **<u>and roles</u>**
1.1 Walking again	1.1 Walking again
1.2 Important activities at home	1.2 Important activities at home
1.3 Important activities in my community	1.3 Important activities in my community
	<u>1.4 Fulfilment of roles</u>

Subtheme 1.4 - Fulfilment of roles

The subtheme of role fulfilment is linked to `participation in important activities', and was discussed in 13 papers [13,34,39,40,42,43,45,48,61,65,66,70,71]. Fulfilment of a role such as a parent, spouse or valued member of the community, was described as an important outcome following lower limb amputation. Role fulfilment was described alongside valued activities, but additional meaning was apparent when participation in the activity enabled previously valued self-identities, for example, holding a partner's hand when out for a walk, or being able to go to the park and play with their children.

> *"And if we go for a walk, I'm able to hold my wife's hand. I haven't been able to do that for eight to ten years. Some people might think that isn't a big deal, but to me it means a lot." (Jon)* (Hansen et al., 2019)
>
> *About 4 months later after my amputation we actually went to the park and slid down the slide with her, swung on the swing, and ran around the park. I don't even want to think about my life without doing that."* (Crawford et al., 2016)

Fulfilling previous roles appeared to create a sense of normality for participants as well as promoting adjustment by building confidence and self-worth.

> *feeling responsible for the household allowed her amputation not to matter, allowing her to go on with life despite her altered body.* (Ward Khan et al., 2021)

> *Being mobile in their communities enabled participants to actively participate in society: … I am the secretary of the ward committee. I meet in disability forums and write minutes … I go on my own.* (Ennion and Manig, 2019)

5.2.5.4.2 Domain 2 - I can participate in my important activities in the *way* I want to

A subtheme of the second domain describing *how* people with limb loss want to participate was modified from `being able to do my activities easily' to reflect being able to do activities `easily *and* well'. (Table 5.10).

Table 5.10 Development of domain 2 – I can participate in my important activities in the *way* I want to

Pre-existing framework domain and subthemes	Newly expanded domain and subthemes
Domain 2 - I can participate in my important activities in the *way* I want to	**Domain 2** - I can participate in my important activities in the *way* I want to
2.1 Doing my activities independently	2.1 Doing my activities independently
2.2 Doing my activities easily	2.2 Doing my activities easily **and well**
2.3 Doing my activities without falling	2.3 Doing my activities without falling
2.4 Doing my activities with as little equipment as possible	2.4 Doing my activities with as little equipment as possible

Subtheme 2.2 - Doing my activities easily and well

Data describing participation in sport [13,36,63] raised the issue of doing an activity well. Participants described the need to perform well during sport to be competitive, not performing well could lead to reduced participation.

> *Now, if I swim, the speed is gone and you always have a disadvantage… swimming is not what it used to be, all elderly swim faster than me……I stopped with it…''* (Bragaru et al., 2013)

5.2.5.4.3 Domain 3 – My prosthesis works for me

Originally domain three described the need for a prosthesis that is comfortable and easy to use. This domain was well supported by the data (Table 5.8); however additional data went beyond describing the comfort and ease of use, i.e., burdensomeness of the weight, fit and suspension of the prosthesis, and also described the importance of the functionality of prosthetic components, i.e., prosthetic knees and feet, in enabling valued activities. This led to the domain being restructured into three subthemes (Table 5.11). The first two subthemes describe the original domain of `comfort and ease of use' but have been presented separately as 'My prosthesis is Comfortable' and `My prosthesis is easy to use' to reflect the importance of these individual aspects of the prosthesis, as described in the data. An additional third subtheme has been developed describing the importance of prosthetic componentry which enables participation.

Table 5.11 Development of domain 3 – My prosthesis works for me

Pre-existing framework domain and subthemes	Newly expanded domain and subthemes
Domain 3 - My prosthesis is comfortable and easy to use	**Domain 3 - My prosthesis works for me**
	3.1 My prosthesis is comfortable
	3.2 My prosthesis is easy to use
	3.3 My prosthesis enables me to participate

Subtheme 3.3 - My prosthesis enables me to participate

The function of prosthetic components and how they enable people to participate was described in 18 studies [13,35,60–63,65,66,71,72,36,41–43,48,52,55,57]. Participants described wanting a leg that was waterproof so they could go fishing, or a flexible ankle so they could lift objects at work. A limb that did not enable function could prevent participation or make it more challenging [35,36,72,41,48,55,57,61,65,66,71].

> *Like the last time when I went to the Amputee Clinic, I said, 'I like to go fishing and I would like to go canoeing a little bit and stuff, but I can't get this prosthesis wet, is there a type of prosthesis I can get wet?* (Lehavot et al., 2022)

> *There's a lot of lifting in my job and fitting and stretching, not having one of the ankles, you lose a lot of balance and so you do tend to use your back like a crane a lot more than that I did when I had two legs, just 'cause it doesn't, you haven't got the balance so you just, you find yourself by necessity bending when I know I should be bending from the knees but I can't get the lift off a prosthesis in the same way (Mitchell, FG3)* (Devan et al., 2015)

Trust in the prosthesis not to give way underneath them or break also appeared to be an important factor in componentry enabling participation, particularly in relation to the prosthetic knee. [35,36,72,41,48,55,57,61,65,66,71] .

> *"It takes me a little bit to trust my leg that when I take a step, it is going to be there. I have had it break on me too. I have had to gain that trust with my leg then lost it, then gained it, then lost it. So over time it has been hard for me to really trust it. That when I take a step it's going*

> *to be there for me. It's not going to break. It's not going to send me flying"* (Morgan et al., 2020)

> *participants identified the pervasive fear of falling as the major issue, as they did not trust the knee unit to appropriately respond and provide stability. This affected mood and willingness to engage in daily activities* (Young et al., 2021)

Insufficient trust in the prosthetic componentry was shown to prevent participation in important activities or require adaptation. Conversely trust appeared to inspire confidence in the limb, as well as individual capabilities.

> *If I feel like I can trust the leg or socket, then as far as being mobile, I feel like I can do… anything."* (Hafner et al., 2016)

5.2.5.4.4 Domain 4 – If I have pain, I can manage it

The analysis did not reveal any new information relevant to this domain.

5.2.5.4.5 Domain 5 – I am able to accept my new normal

Large amounts of the data from the included studies were mapped onto this domain which has been expanded and renamed in parts (Table 5.12). The subtheme `Chasing normality' was renamed to `Feeling a sense of normality' to better capture the domain as described by people with limb loss. The subtheme `adjusting to limb loss' was expanded and is now presented in two subthemes highlighting the importance of `adapting and accepting my limitations' and `accepting my appearance'. An additional fifth subtheme was also identified describing lifelong health and wellbeing.

Table 5.12 Development of domain 5 - I am able to accept my new normal

Pre-existing framework domain and subthemes	Newly expanded domain and subthemes
Domain 5 - I am able to accept my new normal	**Domain 5** - I am able to accept my new normal
5.1 Chasing normality	**5.1 Feeling a sense of normality**
5.2 Adjusting to limb loss	**5.2 Adapting and accepting my limitations**
	5.3 Accepting my appearance
5.3 Sense of achievement	5.4 Sense of achievement
	5.5 Lifelong health and wellbeing

Subtheme 5.2 - Adapting and accepting my limitations

Data from 14 studies supported this subtheme [35,37,65,68–70,42,46,47,50,57,59,61,64]. Participants discussed the need to adjust to the changes they had experienced by adapting how they did their daily tasks.

> *For example, a participant stated he could not squat or be down on one knee to change a car tire and, "That's a limitation that I've adapted to. So, I just put a stool down and then sit on the stool, and then do what I gotta do. So, you just have to take the limitations, and then adapt to do things that way,"* (69 years old; 2.5 years post-TTA). (Miller et al., 2020)

Some participants described these adaptations as frustrating and indicative of the lives they had lost.

> *It's hard I guess you have to think about things a little bit differently. How you do things, takes a bit longer to do… and that sort of thing which is a bit frustrating… you knew what you could do before and you're never going to achieve that again now.* (Male, Transfemoral, 35-50 yrs old) (Keeves et al., 2022)

However, participants appeared to view success as accepting what they could no longer do and focusing on what they could do. This seemed to be enabled by a problem-solving attitude and engendered a sense of pride in achievements.

> *There are just so many more possibilities than you ever thought there would be. I can't do this, I can't do that. You spent so much time trying to get back to who you were, and this event says, you may be not be able to get back to who you were but look at all these amazing things you can do and can go on to achieve. It opens the gate to any other ideas you had in mind that you thought you couldn't do; it's just amazing. You realise that you are capable of so much more than you thought you were.* (Wadey and Day, 2018)

Subtheme 5.3 - Accepting my appearance

Data from 23 of the studies focused on the importance of adjusting to an altered appearance following amputation [34,35,56,57,59–61,63–66,69,36,70,71,38,40,48–50,52,55], both in terms of how participants saw themselves, and how they perceived others saw them.

> *"I admit that I wanted to quit studying at the university many times due to that feeling I had. Even if I tried to convince myself to live with my new different look peacefully and accept my new self…I am in a constant battle from the inside."* (female, 26 years). (Abouammoh et al., 2021)

This was often described in scenarios where staring or comments from others may have reinforced a negative self-image [36,71]. However, interaction with others was also described positively in accounts of acceptance from others leading to greater self-acceptance [40,56,64,69].

> *Witnessing someone else's acceptance of the prosthesis that they themselves had sometimes struggled with helped them to feel understood and accepted for who they were* (Mathias and Harcourt, 2014)

This interaction was also described in reverse with greater self-acceptance appearing to result in improved interactions with others [40,56].

> *Samantha reflects on how her own growing sense of comfort about the prosthesis had had a positive impact on the reactions of others, which in turn had increased her sense of confidence further: Once I was comfortable with it, everyone around seemed to be .. ..* (Samantha) (Mathias and Harcourt, 2014)

Ultimately these experiences of acceptance were viewed positively and indicate the importance of being able to address issues of appearance during rehabilitation and recovery. Some participants described using clothing for concealment purposes to manage concerns about appearance. However, clothing also appeared to contribute to concerns, especially in certain social situations [46,61,62,75,77].

> *I suppose it's a female thing but if you are invited somewhere and it's a posh do and you're getting dressed up and then you look down at your shoes. And then it's like bloody hell, from here [head] to here [knee] I look ok, and then I have a pair of trainers on my feet. (Carly)* (Day et al., 2019)

Other facilitators of acceptance, concerning both appearance and function, were described as a positive problem-solving attitude [13,41,49,53,55,56,58,62,63,65,66,70,74], being able to participate in important activities and roles [42,44–46,51,64,70,71,76], time since amputation [62], spirituality [40,53,63,71] and peer support [13,40–42,44–46,50,54,58,67,76,77].

> *''It doesn't matter how you do it because everybody [peers] has something, then you feel more at home and less stared at …… you feel less different….and then you accept it* (Bragaru et al., 2013)

Subtheme 5.5 - Lifelong health and wellbeing

Participants in 9 of the included studies highlighted concerns about the impact amputation and prosthesis use would have on their health and wellbeing throughout their life course

[36,39,41,44,56,60,61,70,71]. Participants described concerns about the impact of amputation on their remaining joints [61], the need to remain physically active to avoid health issues later in life, and to manage weight gain [36,39,56].

> *I think just talking about hopping. I have an example of what happens to you 20 years later. I had really bad arthritis in my knee. I have torn my ACL and if I had not [hopped on one leg] growing up, it probably would be better.* (Morgan et al., 2020)

> *For the ones who stated that they cannot live without it, ''sport is more a necessity'' and, even if it was ''not perceived as a fun activity'', the individual still participated in sports because otherwise he or she had the feeling that it would have negative consequences for his or her health.* (Bragaru et al., 2013)

5.2.5.4.6 Interconnected nature of outcome domains

Data from the qualitative synthesis demonstrated that outcome domains of importance are interconnected, which was first introduced in our qualitative paper developing the original conceptual model [20]. Many examples were presented of how the different domains interacted, for example, how socket comfort issues prevented participation which in turn impacted adjustment and mental wellbeing, or how a lack of trust in the prosthesis caused a fear of falling, which led to reduced community participation. This analysis concurs that a successful outcome appears to be multi-faceted and requires a multi-domain measurement approach, if the outcome of prosthetic rehabilitation is to be captured in a holistic, meaningful way. Figure 5.5 visualises the expanded 'ECLIPSE' model, and the interconnected nature of the domains of importance.

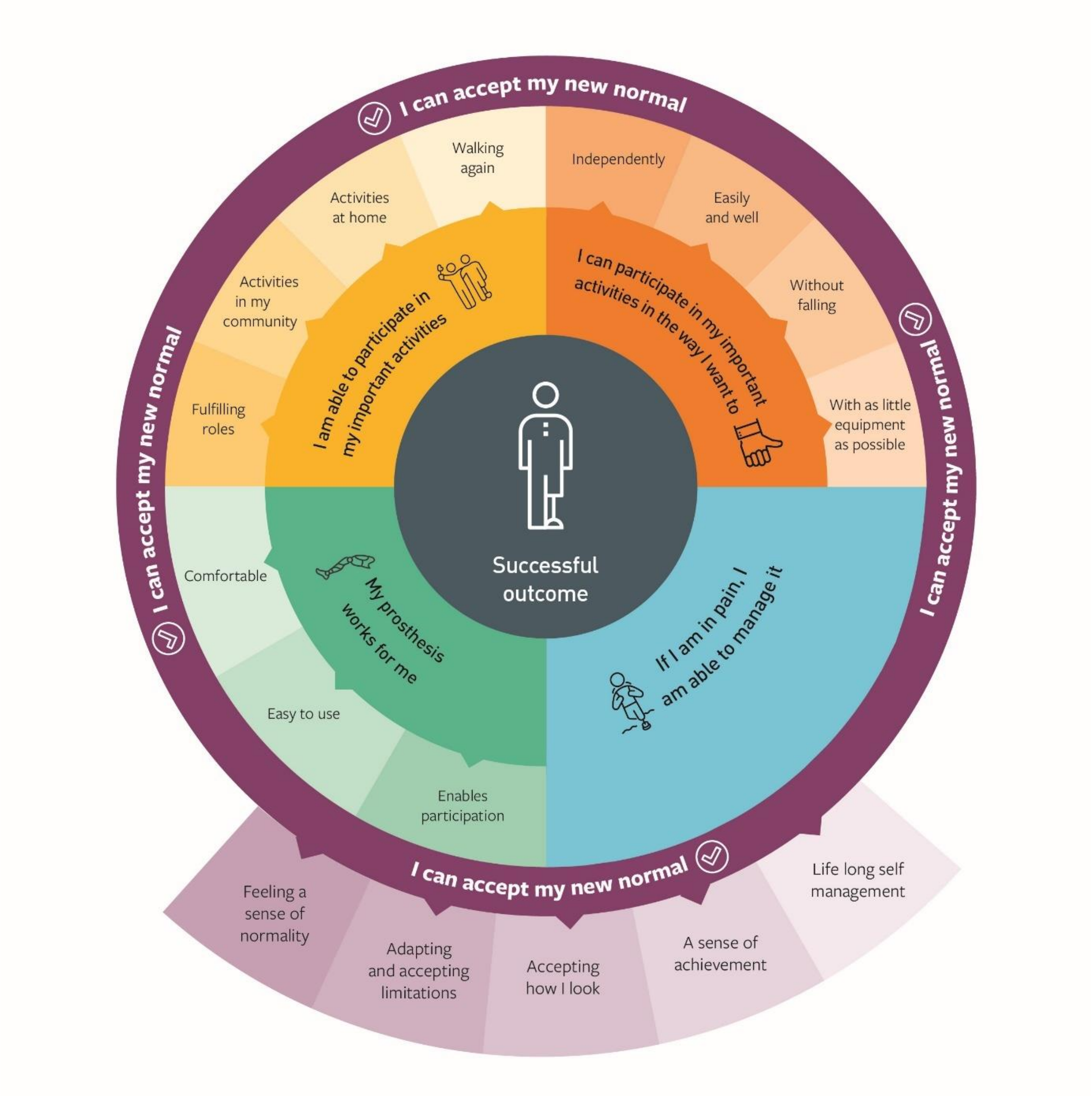

Figure 5.5 Expanded conceptual model – The ECLIPSE model of meaningful outcome domains of lower limb prosthetic rehabilitation

5.2.6 Discussion

This review presents a modified and enhanced conceptual model of outcome domains of importance following lower limb prosthetic rehabilitation from the perspective of people with limb loss. Having been initially developed during a primary qualitative inquiry with 37 prosthetic users [20], it has now been rigorously examined in this systematic review using data from 40 papers describing the experiences of 539 lower limb prosthetic users from a variety of settings. The application of 'best fit' framework synthesis allowed us to re-examine and review domains of importance in the context of the lower limb loss literature and produce a second iteration, now named the ECLIPSE model, which more comprehensively attempts to describe this phenomenon.

The systematic review demonstrated that many of the original domains in the pre-existing model were supported by data from the literature. Thus, the model illustrates the importance of domains such as being able to participate in meaningful activities in a way individuals are happy with, having a comfortable and easy to use prosthesis, being able to manage pain, and acceptance of the new normal. However, our understanding of these concepts has been deepened during this synthesis and has led to several of the domains being expanded and re-specified.

The first domain of the ECLIPSE model described the ability to participate in important activities following prosthetic rehabilitation. Data from the review identified that following limb loss people also appeared to value being able to return to important roles. Role fulfilment was often described alongside valued activities, with the valued activity appearing to gain additional meaning when participation enabled a return to previously valued roles. This phenomenon has also been described following traumatic brain injury [76], stroke [77] and during older persons rehabilitation [78]. A meta synthesis of studies exploring experiences of recovery following traumatic brain injury reported that returning to valued roles had a significant impact on individuals' self-worth and that without access to these roles people struggled to define their sense of self-identity [76]. Participation in valued roles following limb loss has been described as contributing to an individual's sense of self-identity, which can be significantly disrupted by the amputation [79,80]. However, a previous review of psychosocial adjustment to amputation suggested that successful recovery involves individuals *adapting* to changes in roles, alongside functioning and body image, and incorporating these changes into a new self-identity [80].

This review also demonstrated the importance of the right prosthetic componentry as an outcome domain of importance and led to re-specification of domain three (My Prosthesis works for me). What appeared to define 'the right' componentry (i.e., prosthetic knee, foot, suspension system etc.) was its ability to enable participation in important activities and roles, i.e., waterproofing to enable fishing, or a stable 'trusted' knee for walking on uneven ground. This has been reported in qualitative studies by Liu et al. [81] and Murray [82] who describe the prosthesis as key to enabling valued activities. Many different prosthetic components, designed to meet the varied functional needs of limb wearers are currently available [83], nonetheless, it may be challenging to identify a product that enables *all* the different activities people engage in. Having multiple prostheses for different activities could be a solution, i.e., a cycling leg or special occasion leg. However, this may be limited by financial constraints or prosthetic service provision and may not reflect the way people often transition seamlessly between activities throughout the day. The importance of prosthesis functionality, as well as the addition of role fulfilment to domain one (I am able to participate in my important activities and roles), highlights the need for considered discussion between patients and healthcare professionals to clearly define what activities and roles are *most* important, and how these can be enabled through prosthetic prescription and rehabilitation. It may also be important to discuss what functionality might be lost as prescriptions change across the life course, and how this affects participation. This patient-centred approach emphasises the need for multidisciplinary input, especially considering the role of the Occupational Therapist, both during rehabilitation and lifelong prosthetic care, to adopt an ongoing focus on participation. This focus may also challenge the current approach to outcome measurement, where tools identify the activities included in the assessment, such as walking in a crowded shopping centre or visiting a friend's house. Meaningful outcome measurement may require tools that allow patients to define what activities are most important to them as an individual, and therefore should be captured as a measure of success.

Domain five of the ECLIPSE model, 'I am able to accept my new normal', was revised most significantly during this review, with three new subthemes created. This may be due to the nature of qualitative research which focuses on views and experiences and is often used to explore adjustment following amputation. The first new subtheme, `being able to adapt to and accept my limitations' appears to be a common theme described in the rehabilitation literature characterising recovery from trauma or the management of long term conditions, i.e., anterior cruciate reconstruction [84], Parkinson's Disease [85] and traumatic brain injury [86]. A study by Rosengren et al., [85] exploring the experiences of patients with Parkinson's disease found that greater life satisfaction is achievable as people adapt to their new life situation, which involves a process of transition often based on acceptance.

This review also highlighted the need to adjust to an altered appearance following amputation. The wealth of literature describing this outcome led to its creation as a new subtheme and appeared to suggest that individuals need to adjust to how they see themselves, as well as their perception of how others see them, and that these experiences are intricately linked. This is supported by Cooley's `Looking-Glass self' theory [87] which describes how individuals base their sense of self on how they perceive others view them. The importance of adjusting to an altered appearance following limb loss is described in several studies included in a qualitative meta synthesis by Murray and Forshaw [88]. They describe the importance of using the prosthesis to moderate the reaction of others and conceal limb loss. They also highlight that adjustment to changes in self-image appear to occur over extended periods of time as people learn to accept the limitations of the prosthesis.

Both of the subthemes, `adjusting and accepting my limitations' and `accepting my appearance', as well as the final subtheme describing lifelong health and wellbeing, indicate the importance of both physical and psychosocial recovery following lower limb amputation. Rehabilitation programmes may need to address both aspects in an integrated way to provide holistic patient-centred care. However, it is clear interventions may not only be required in the immediate post amputation period, and that ongoing physical and psychosocial support may be crucial to address changing lifelong needs.

The interconnected nature of outcome domains of importance, first documented in the authors' primary qualitative work [20] and supported by this review, suggests the need for a multidomain approach to outcome measurement in prosthetic rehabilitation. Many examples of how domains may influence each other were described in this analysis, for example socket comfort issues leading to reduced participation in important activities. Although the findings presented here and visualised in the ECLIPSE model (Figure 5.5), recognise the interconnected nature of domains of importance and the need to measure them in a holistic way to capture meaningful success, further research is needed to understand the nature of the relationships between domains.

The ECLIPSE model presents a patient-centred representation of outcome domains of importance following lower limb prosthetic rehabilitation. The model could be used to direct the course of rehabilitation and highlights the need for physical and psychosocial interventions. Although several professional networks have published prosthetic rehabilitation guidelines [5,15,89,90], none include the views of patients, and no guidance is available to inform psychosocial management. Despite many papers describing the psychosocial impact of amputation [88], little research has been undertaken to evidence treatment options. Future work may be needed to understand how the domain of `accepting my new normal' might be addressed during prosthetic rehabilitation.

The ECLIPSE model also provides guidance for which domains may be most important to measure following prosthetic rehabilitation, or in research, and could underpin a future Core Outcome Set. However, given the previously described challenges of meaningful patient involvement in COS development [12], care needs to be taken that the contribution of wider stakeholders in the COS process does not diminish the voice of prosthetic users themselves. The OMERACT initiative [91] which develop COS' for Rheumatoid arthritis have acknowledged this concern and developed a patient COS which explicitly acknowledges that what is important to patients may be different and in need of specific consideration [92]. The ECLISPSE model could represent a patient Core Outcome Set, informing measurement in both research and clinical practice, and ensuring a person-centred focus. Future work is required to identify outcome measurement tools which capture these domains.

The design and quality of studies included in this review varied considerably. Critical appraisal using the CASP tool was undertaken to summarise key quality issues and provide some context to the overall findings of the review but was not used to exclude studies or indicate strength of findings. The usefulness of critical appraisal is debated in the literature due to the variation in appraisal decisions between reviewers experienced in qualitative research reported when using the same and different appraisal tools, or solely based on their independent judgement [93]. The impact of including or excluding low quality studies on the findings of a review has also been found to have little impact [94] and this is why no studies were excluded based on quality alone in this review.

Within this review the key quality issue identified in 28 of the 40 studies was undue consideration of the influence of the researcher on the research process, which could impact the dependability and confirmability of this reviews findings [95], and is considered an area of concern for qualitative research in the field of prosthetic rehabilitation. In light of this, data included consisted only of first-person quotations, or interpretations that were directly supported by first-person quotations, in an attempt to ground the findings in the experiences of participants [96].

A further quality issue in 17 studies was insufficient information about whether recruited participants were best placed to answer the research question. However, data describing the study sample characteristics was presented in 34 of the studies allowing transferability to be considered. This review captures the experiences of a large sample (n=539) of lower limb prosthetic users living in 15 different countries. Views and experiences from participants with different levels of amputation, a variety of causes and a wide age range were included, representing a varied sample capturing many different voices. However, despite the range of study settings, 90.2% of participants live in high-income countries. Far fewer qualitative studies have been undertaken exploring the lived experiences of lower limb prosthetic users living in low- and middle-income countries (LMICs). Due to limited representation of these individuals, it is unclear whether these findings are transferrable and whether the ECLIPSE model describes outcome domains of importance with a prosthesis in LMICs. Further research is required to identify and understand important domains in different social and culture settings, as well as exploring how they vary between countries. This is of particular importance as it is estimated that 80% of the world's population living with a disability live in LMICs [97], and the Global Burden of Disease study 2019 indicates an increasing international amputation prevalence of 176 million [98]. Previous outcome measure consensus work in prosthetics, undertaken by ISPO, also highlighted that many of the measurement tools for use following amputation have been developed in high income countries and call for development of measures suited to LMICs [8]. However, without first understanding which domains are most important to measure in these settings, outcome measure developers may struggle to capture what is meaningful to patients.

5.2.6.1 Limitations

When considering the findings of this review it is important to understand that the domains identified in the analysis have been generated from studies with a range of quality scores. Due to previously described issues with critical appraisal as part of systematic reviews of qualitative literature [24,28,29,93], no studies were excluded but were scored and ranked. Although this a common approach used in qualitative syntheses, it is not how the CASP tool was intended for use and should be viewed with caution.

A further limitation of the review is the potential for confirmation bias within the analysis as the authors pre-existing conceptual model was used to inform the `*a priori'* framework. Steps were taken to minimise the risk of shoehorning data into the framework by carrying out open line by line coding as the first step in the analysis process and undertaking a separate thematic analysis on data which did not fit easily into the framework, which was then used to further develop the model. A reflexive journal was also kept throughout by the lead author to critically consider methodological and analytical decisions.

The inclusion of only peer reviewed publications written in English led to a single relevant paper being excluded which may have contributed to the findings. The decision was taken not to use translation software as this may have altered the meaning of quotations. The review also took a broad approach to the search strategy, identifying studies which explored the experiences of lower limb prosthetic users, as few studies were available describing outcome domains of importance. This resulted thin inclusion of studies exploring a wide variety of phenomena. It is possible that domains of importance may have been overlooked as none of the studies set out to explore meaningful recovery following prosthetic rehabilitation. However, this wide focus ensured comprehensive inclusion of the available evidence using the research question as a compass rather than an anchor [98]. This facilitated an exploratory approach to understanding outcomes of importance, which is more aligned to primary qualitative methods. Nonetheless It should be considered that researcher judgement was required to identify data presented in the included studies which were relevant to the research question, and required researchers to view the data through a different lens than was originally intended, potentially reinterpreting its meaning.

5.2.7 Conclusion

This synthesis of qualitative findings from 40 studies representing the views of nearly 600 people provides a rigorous foundation for understanding outcome domains of importance following lower limb prosthetic rehabilitation. By focusing on the patient's perspective, the ECLIPSE model portrays a meaningful recovery in the lives of those with limb loss, particularly in high income settings.

The ECLIPSE model is an accessible patient-centred view of recovery and could be used by clinicians to shape and direct the focus of rehabilitation programmes and inform goal setting, as well as direct the evaluation of their impact through the selection of outcome measures. The apparent interconnected nature of outcome domains of importance also highlights the need for a holistic approach to outcome measurement, capturing success in all aspects of the patient's life.

The domains which comprise the ECLIPSE model could also inform the selection of outcomes within research. They could underpin a future core outcome set (COS) or represent a standalone patient COS, which may be more appropriate for rehabilitation settings where the aim is to enable return to previous lives. Future work is needed to understand how well current outcome measures capture the domains described in the model and whether new measures need to be developed.

5.2.8 References

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Chapter 6 Discussion and Conclusions

6.1 Introduction

Motivated by many years of experience in clinical practice and the practical issues of making outcome measurement useful in clinical settings, this PhD sought to understand and contribute to the body of evidence around *meaningful* outcome measurement following lower limb prosthetic rehabilitation. The work presented here provides a novel contribution by setting out what comprises meaningful outcome measurement from a clinical perspective and addressing the gap in the literature regarding what outcome domains should be measured from the patient's perspective. This research represents an important step towards the development of patient-centred outcome measurement practice in prosthetic rehabilitation.

The PhD has involved carrying out three phases of work that have been published across four research papers which make up this thesis (Figure 6.1). The papers address the following objectives:

Objective 1 - To review the current evidence base investigating outcome measurement in prosthetic clinical practice (Paper 1)

Objective 2 - To understand the patient's perspective of outcome measurement by exploring:

- Meaningful outcome domains of recovery (Papers 2 and 4)
- Patient experiences of outcome measurement in clinical practice (Paper 3)

Objective 3 - To develop a conceptual model describing meaningful recovery following prosthetic rehabilitation and outcome domains of importance to measure in clinical settings (Papers 2 and 4).

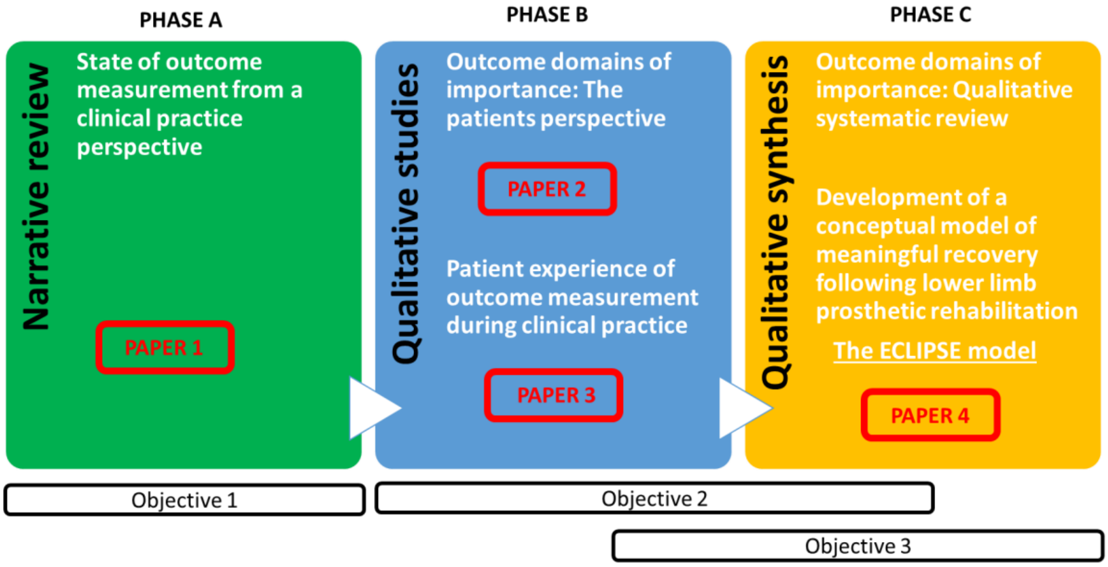


Figure 6.1 PhD structure and alignment with the objectives

This chapter will summarise and discuss the methods used and key findings from the four papers, following on to consider and position the programme of work as a whole. As one of the three phases involved using a qualitative approach, the impact of the researcher will be discussed. The strengths and weaknesses of the research will then be summarised, followed by recommendations for clinical practice, and research in prosthetic rehabilitation. Finally, building on the work described in this thesis, recommendations will be made for future work investigating meaningful outcome measurement.

6.2 Summary and discussion of findings

6.2.1 Paper one – Narrative review of outcome measurement in prosthetic rehabilitation from a clinical practice perspective

The narrative review described in paper one sets the scene for the work undertaken within this PhD. The review explored the current state of knowledge about outcome measurement in the field of prosthetic rehabilitation from a clinical practice perspective, and identified gaps in the evidence base which should be addressed in future work to make outcome measurement in clinical settings a meaningful reality (Ostler, Scott, *et al.*, 2022).

Considering the literature from a clinical perspective was essential when designing the review methodology, as well as when reviewing the individual papers. Scoping searches undertaken to inform the direction of the review indicated the current evidence base focused on outcome measurement tools. My clinical experience using outcome measures, in conjunction with background reading in different specialities indicated that the barriers to successful outcome measurement in clinical settings went beyond the measures themselves. The need for a broader scope of enquiry lent itself to a narrative review approach (Ferrari, 2015). This approach enabled an overarching view of the current state of outcome measurement, allowing the work undertaken on measurement tools to be captured, as well as permitting further exploration of what else is known about outcome measurement in prosthetic rehabilitation. Reviewing the evidence through the lens of clinicians built up a picture of the knowledge gaps and identified areas for future work that could address the gaps in a meaningful way for clinical teams. Involving clinicians from across the MDT in the review process offered a variety of insights and interpretations of the evidence.

Findings from the review highlighted that successful outcome measurement appears to be multifaceted, and a meaningful approach to measurement in prosthetic rehabilitation should focus on understanding and embedding value at every step in the process. The first two themes in the review highlighted gaps in the literature which should be the focus of future work, i.e., what outcome domains indicate a successful recovery and how should they be measured in a feasible and useful way. This focus may help establish outcome measure consensus and enable clinicians to measure what matters most consistently across services, potentially enabling service and system level routine outcome measurement. The review also introduced the concept of outcome measurement practice as an important part of a value led approach, i.e., how outcome measures are implemented (theme 4), and how data are collected and used to inform patient care. It was shown that little is currently known about outcome measurement practice in prosthetic rehabilitation. Further exploration is required to understand the process, considering what is of value to clinicians and what leads to improved patient care and outcomes.

The narrative approach adopted within this review, undertaken in a systematic way, offered a rigorous yet broad scope for exploring the literature. However, it is possible that this method, combined with the absence of critical appraisal tools may have led to potential bias in the selection of articles. For example papers were included, and findings interpreted, based on what the authors considered relevant to clinical practice (Bennett *et al.*, 2005). In recent years notable authors have refuted these criticisms and suggest that narrative reviews have an important role to play by interpreting and deepening our understanding of a subject by viewing the evidence through a specific lens, such as clinical practice. This interpretation can help readers to understand the implications of the findings, rather than just adding to the assimilation of numbers through systematic reviews (Greenhalgh, Thorne and Malterud, 2018; Furley and Goldschmied, 2021).

During publication of paper one in Prosthetics and Orthotics international (POI), the peer review process highlighted the need to clearly define the terminology used to describe outcomes, domains and measures. For example, an outcome is the result of a health intervention, a domain is the element of ‘health’ that is changed by a particular intervention, whereas a measurement tool is a standardised instrument used in research and clinical practice to capture and evaluate this change (Ostler, Scott, *et al.*, 2022). These terms appear to be used interchangeably in the outcome measurement literature. An absence of clear definitions, especially in a technical field such as outcome measurement, could make it challenging to communicate findings clearly, especially to those working in clinical practice.

Concern about the importance of clear definitions has been raised by the COSMIN initiative, with regard to the psychometric properties of outcome measures, i.e., validity, reliability, and responsiveness (Mokkink *et al.*, 2016). The COSMIN initiative involves an international multidisciplinary team of researchers who have expertise in the development and evaluation of outcome measurement instruments. They have attempted to define measurement properties through their COSMIN taxonomy of terms, developed via Delphi consensus with experts in outcome measure development (Mokkink *et al.*, 2016). COSMIN emphasise the importance of clear definitions to communicate complex messages (Mokkink *et al.*, 2016). This is especially relevant in this PhD which is highlighting important nuances in outcome measurement to the clinical population, i.e., the differences between outcome, domain and tool. Clear definitions could promote changes in understanding about how and why clinicians select and use outcome measures. By following the advice of the peer reviewer and adopting and using the definitions described above throughout paper one, we were able to clarify our thinking and language in preparation for setting out and communicating important outcome *domains* in future papers.

Publication of the narrative review initiated an important discission around outcome measurement. The peer reviewer also commented on the need for a clinical commentary around outcome measurement in prosthetic rehabilitation and the paper was in the top ten most read POI articles for 2022. Over 100 people attended a webinar hosted by ISPO to disseminate the findings and discuss meaningful outcome measurement, and the author and supervisors were invited to present at several professional meetings/webinars around the world.

The review provides a useful overview setting out what could comprise *meaningful* outcome measurement in clinical settings. The gaps identified in the current evidence base such as what domains to measure, how to measure them, and what value led outcome measurement practice looks like, set the direction for future work in this PhD, as well as the wider field of prosthetic rehabilitation research. Following the publication of the narrative review, the focus of the PhD research progressed and began to address the gap set out in the reviews first theme of `what outcome domains to measure?’.

6.2.2 Paper two – A qualitative study exploring outcome domains of importance following lower prosthetic rehabilitation from the patient's perspective

Paper two began to address the first of the findings set out in the narrative review by exploring what outcome domains should be measured following prosthetic rehabilitation. This work adopted a person-centred approach using qualitative methods to explore the question from the patient's perspective, as patients are those for whom the outcome of rehabilitation has the greatest impact (Ostler, Donovan-Hall, *et al.*, 2022).

As well as exploring this phenomenon from the patient's perspective, a person-centred approach was adopted throughout the design of the research. A group of public research partners were recruited from the Portsmouth Enablement Centre to ensure the research addressed an issue which was relevant to patients and was undertaken in a way that promoted a positive experience of participation. The group included three individuals with limb loss, two men and a woman, each with a different cause of amputation. One of the participants was older and had lost his limb due to diabetic dysvascular causes. His involvement was important. As a clinician it occurs to me that this patient group tend to be underrepresented in limb loss research, which seems to oversample younger traumatic patients, despite diabetes and peripheral arterial disease being the leading cause of amputation in high income settings (Ahmad *et al.*, 2014; Imam *et al.*, 2017; Behrendt *et al.*, 2018). Incorporating his views about recruitment and data collection helped design a project which was able to access this harder to reach group. In the study a sample with a diverse range of characteristics were recruited, which were representative of the UK limb loss population. A combination of convenience and purposive sampling was used. The addition of purposive sampling enabled older dysvascular patients who weren't initially recruited through convenience sampling, to be the focus of recruitment as the study progressed to ensure their views were included in the analysis. Participants were recruited from four NHS limb centres (Portsmouth, Roehampton, Stanmore and Wolverhampton) in order to include individuals with different backgrounds and experiences of rehabilitation. The public research partners also helped with the language used in the study and co-designed the interview guide. Language was important as the concept of outcome, which could be viewed as a medical or research term, needed to be discussed in a way that was accessible for patients (Williamson *et al.*, 2017). The group also highlighted the importance of choice for patients in how they participate and led to inclusion of telephone or face to face interviews and focus groups.

Data collection was followed by reflexive thematic analysis (Clarke and Braun, 2013; Braun and Clarke, 2021), which led to the creation of five themes representing five domains of importance. These were i) being able to participate in important activities, ii) being able to participate in the way the patient wants to, iii) having a prosthesis that is comfortable and easy to use, iv) being able to manage any pain and v) being able to accept the new normal. An accessible summary of themes, representing the five domains, was sent to participants for member checking (Birt *et al.*, 2016). This step was an important part of the person-centred approach and was undertaken to ensure that participants had the chance to reflect and feedback on the themes. The process enabled triangulation of the findings allowing participants to assess their trustworthiness.

Member checking is a controversial step in qualitative research, both in terms of its philosophy and conduct (Birt *et al.*, 2016). The inclusion and method of member checking needs to align with the researcher's epistemological position. Positivist approaches often include it to seek validation of findings (Morse, 2015), which sits in opposition to constructionist approaches where data is believed to be generated through the interaction between participant and researcher at the point in time it's undertaken (Sandelowski, 1993). This position suggests different data could be collected under different circumstances, such as later when member checking is taking place. The practical aspects of member checking such as returning interview transcripts or analysed data, or conducting member checking interviews or focus groups, are also reported in the literature (Carlson, 2010). In paper two a process described as synthesised member checking was adopted which attempted to address some of the philosophical and methodological challenges described above (Birt *et al.*, 2016). Participants were provided with an accessible summary of the study themes, allowing them to review the findings, but space was provided for participants to add data through written feedback. This approach aligned with my ontological and epistemological positions. Critical realism represents the search for a reality which sits behind different lenses, and a pragmatic approach supports the need to ensure the themes/domains resonated with the participants experiences so they could be credible with the wider limb loss population when applied in clinical practice.

The five themes highlight that important domains of recovery extend far beyond a return to walking, and what patients really value is the ability to participate in their important activities. Many outcome measures used following lower limb amputation focus on capturing the domain of mobility (Xu, 2019), and assess whether patients can undertake skills such as walking on uneven ground or climbing stairs. Although mobility skills clearly underpin the ability to participate (World Health Organization, 2001), measuring mobility alone may not capture true success as defined by patients, and fails to consider that other domains such as those identified in this study i.e., a comfortable and easy to use prosthesis, pain, or concern over falling, may impact the individuals ability to participate. This interaction between themes was most clearly demonstrated through an entwined psychosocial recovery which was characterised by the development of a new normal. The apparent interconnected nature of the physical and psychosocial recovery described by these participants also highlights that outcome domains of importance do not exist in isolation. This led to the themes/domains being visualised in an early conceptual model which demonstrated the interconnected nature of the concepts and the need for a holistic approach to measurement, considering recovery in all aspects of the patient's life.

Despite the large and varied sample used to generate these findings, the sampling approaches adopted, i.e., self-selection via convenience sampling, followed by practitioner selection of those individuals with purposively identified characteristics, may have led to potential bias. Participants who self-select may be more open and more confident to talk about their experiences (Robinson, 2014). This may be the case for participants who had a more positive experience of recovering from amputation, or who are happier with their outcome. Participants selected by clinicians may also have led to greater inclusion of those who are deemed successful, well-adjusted, or more open.

Considering these limitations and the limitations of a single qualitative study undertaken in one country (England), it was important to think about the impact the research might have, especially considering the PhD aim to drive changes in clinical practice. When reflecting on the next step the researcher contemplated what would be required to answer the question of what outcome domains should be measured in a more rigorous way and address the limitations of the current research. This led to the research described in paper four. However, data collected during the paper two qualitative study offered some additional and novel insights into patient perspectives of outcome measurement. Therefore, an additional analysis was undertaken, and the findings described in paper three.

6.2.3 Paper three – Qualitative study exploring the patient's experience and perspective of outcome measurement during lower prosthetic rehabilitation

Paper three was developed from data collected as part of the qualitative study described in paper two (Ostler, Donovan-Hall, *et al.*, 2022). The interview guide for paper two included questions about patient experiences with outcome measurement, originally planned to give additional context to paper two as it explored outcome domains of importance. However, following analysis of the full data set it was clear that the data contained valuable insights into outcome measurement practice, but from the unique viewpoint of the patient. In the paper one narrative review (chapter 2), what comprises outcome measurement practice had been identified as a gap in the literature (Ostler, Scott, *et al.*, 2022). Following a review of the evidence it was clear no previous research had been undertaken considering the process of outcome measurement from the patient's perspective, therefore it was decided to create paper three and present the additional analysis of this data.

This approach could be described as secondary data analysis (SDA). SDA is defined as investigations where data from a previous study are analysed by the same or different researchers to explore a new question, or use different analytical approaches that were not used in the primary research (Szabo and Strang, 1997). SDA has become commonplace in qualitative research (Ruggiano and Perry, 2019) and is seen as a respected, cost-effective approach that expands the usefulness of collected data (Hinds, Vogel and Clarke-Steffen, 1997). However, it is not without its problems, especially if data are analysed during another time period where social and cultural norms may have changed, or researchers undertaking the SDA were not involved in the parent study (Hinds, Vogel and Clarke-Steffen, 1997). This is obviously not the case with the research described in paper three as the same researchers were involved and analysis was carried out within the same time period. Other issues have also been described, such as how well the data addresses the new research question and whether the analysis would be impacted by the lens of the researcher from the parent study (Hinds, Vogel and Clarke-Steffen, 1997). These issues were relevant for paper three and contributed to several of its limitations which are summarised below.

The aim of paper three was to explore patient experiences and perspectives of outcome measurement during prosthetic rehabilitation. The data collected in response to the additional questions in the paper two interview guide were analysed separately and generated four themes. The themes demonstrated that outcome measurement is not a neutral activity for patients following lower limb amputation, with participants describing both positive and negative experiences. Harnessing the positive impacts of measuring outcome, reported in this study, could be used for motivation, to support adjustment and recovery, improve communication and support shared decision-making. Nevertheless, the potential for patients to respond negatively should not be overlooked and clinicians may need to consider the impact of outcome measures on psychological wellbeing. As well as a patient-centred approach it appears a holistic approach, considering multiple domains, may help to capture outcome information that is meaningful to patients. Considering the variable nature of outcome following prosthetic rehabilitation may help to accurately capture the range of recovery experienced following limb loss.

The insights from this analysis could provide useful understanding around the practice of outcome measurement. However, as this work was undertaken as SDA the study was not designed to address the research aim set out in paper three. In light of this, findings should only be viewed as initial insights. They are limited by interview questions which did not differentiate between different types of outcome measurement, such as performance-based or PROMs, which may have led to different patient experiences. Questions also did not explore the contexts in which outcome measures were used, i.e., during physiotherapy, or after prescription changes to the prosthesis. In addition to this the sample were recruited to address the aims of paper two and therefore did not include participants who had an amputation longer than five years ago who may have had a different perspective on the outcome measurement process given the lifelong nature of prosthetic care.

Despite these limitations no previous research had considered the perspective of patients in the outcome measurement process occurring during prosthetic rehabilitation. These findings could begin to highlight the importance of their perspective in this aspect of clinical care and help shape future outcome measurement practice to ensure it is patient-centred and of value to clinical services. More work is required to understand this phenomenon in greater depth including how outcome measurement could be useful to this population and what comprises patient-centred outcome measurement practice.

6.2.4 Paper four – Development of the ECPLISE model

Paper four returned the focus of the PhD to outcome domains of importance, building on the work described in paper two, to create a rigorously developed model of outcome domains of importance following lower limb prosthetic rehabilitation, the ECLIPSE model. This research addressed the previously described limitations of paper two i.e., a single qualitative study, undertaken only in England, by including domains of importance as described in the wider limb loss literature. This led to further development of the initial conceptual model described in paper two and enhanced its value to clinical practice.

As qualitative methodologies provide in depth exploration of a phenomenon of interest (Cresswell, 2014), a systematic review was adopted to identify relevant qualitative papers from the limb loss evidence base. Healthcare decision makers often rely on systematic reviews to support evidence-based practice (Bastian, Glasziou and Chalmers, 2010), therefore a comprehensive systematic approach was used throughout to ensure findings were acceptable to readers (Toye *et al.*, 2014) and resonated with the prosthetic community, which has been described as having a culture of quantitative enquiry (Dillon *et al.*, 2019).

An important step in the systematic review process is critical appraisal, which is undertaken to ensure findings are based on the best available evidence (Shea *et al.*, 2017). However, within a review of qualitative literature critical appraisal can be seen as a controversial step (Boland, Cherry and Dickson, 2017). Issues regarding whether to undertake it, how to do it, whether to exclude studies as a result of it, and finally how to integrate critical appraisal findings into the main body of the synthesis are common (Dixon-Woods *et al.*, 2006; Thomas and Harden, 2008). Despite these questions, there is a growing trend towards including critical appraisal within a qualitative synthesis and it is recommended as part of the 'best fit' framework synthesis approach used in this paper (Carroll, Booth and Cooper, 2011; Carroll *et al.*, 2013). Many tools are available to support the critical appraisal process, however they often do not differentiate between qualitative methods, such as ethnography or grounded theory (Dixon-Woods *et al.*, 2006), and their usefulness is challenged by a lack of consensus as to what good qualitative research looks like (Toye *et al.*, 2014).

A review of critical appraisal approaches within qualitative syntheses by Dixon woods and colleagues (Dixon-Woods, Booth and Sutton, 2007) found considerable variation in appraisal decisions between reviewers experienced in qualitative research, both when using the same and different appraisal tools, and when using their independent judgement. Care therefore needs to be taken when using critical appraisal to exclude studies (Dixon-Woods, Booth and Sutton, 2007). The impact of poor quality studies on the findings of a review was investigated by Carrol and colleagues (Carroll, Booth and Lloyd-Jones, 2012), who found that including or excluding low quality studies actually had little impact. However, this finding is limited by the underlying consistency issues surrounding the assessment of quality in the first place. Despite these issues, it is important that critical appraisal within a qualitative syntheses is not just a tick box exercise and provides context to the findings (Dixon-Woods, Booth and Sutton, 2007). In paper four, the CASP tool was employed to appraise the literature, producing a colour coded rank of the papers enabling the reader to contextualise the overall findings of the review in the light of any methodological issues. Key issues across the papers were also summarised in the text but no papers were excluded based on quality to find balance between the arguments presented in the literature.

The review synthesised the findings from 40 qualitative studies exploring the views of 539 participants from 15 different countries. Their experiences and perspectives were analysed using `best fit' framework synthesis (Carroll *et al.*, 2013). This approach was taken as it combined both a deductive framework synthesis and an inductive thematic analysis. This combination allowed the conceptual model to be reviewed against accounts described in the qualitative literature, but also respecified and developed with analysis of data that did not fit within the framework (Carroll *et al.*, 2013). Limitations of the best fit framework approach include the potential for shoehorning of concepts into the framework. This was of particular concern due to the researcher's familiarity and investment in the concepts identified in the paper two qualitative study. To address this, open line by line coding of the review data was undertaken prior to coding against the framework. This step helped to ensure codes that did not match the framework could be easily identified and set aside for the second stage thematic analysis.

The `best fit' framework synthesis led to the re-specification and expansion of four of the five outcome domains described in paper two, and a second iteration of the conceptual model, now called the ECLIPSE model, which describes m**E**aningful out**C**ome domains of **L**ower l**I**mb **P**ro**S**thetic r**E**habilitation. The revised domains describe the importance of participating in important roles as well as activities, being able to participate in the way a person wants to, having a prosthesis that works for them, being able to manage pain and being able to accept the new normal. Several of the subthemes that comprise these domains have also been expanded and are all now included in the model to help provide context to the overarching domain.

Limitations of the final step in the development process of the ECPLISPE model, described in paper four, include the possibility that all papers documenting the experiences of prosthetic use may not have been included. This could be due to the well documented issues around indexing for qualitative studies in bibliographic data bases (Robertson Stuart, Tansey and Quayle, 2017), or the limitation of the search to the last 10 years. Papers were also excluded where populations were mixed, such as upper and lower limb loss patients, or prosthesis users and non-users. This was the main reason for excluding studies in the review as it was not always possible to separate data. For example, not all studies indicated whether quotations came from individuals with an upper or lower limb amputation, or whether individual participants used a prosthesis or not. These groups experience of amputation and rehabilitation differ, especially considering upper and lower limb loss which vary in terms of prosthetic provision, rehabilitation process and challenges, impact on daily life, and psychosocial considerations (May and Lockard, 2011). It is possible additional information was included in these studies that could have contributed to the findings, however inclusion of concepts not experienced by those with lower limb loss could have led to the generation of themes that were not applicable. Conversely including exploration of outcomes following upper limb loss in the research question could have led to concepts unique and important to their experience being lost in a mixed approach.

Finally it should also be considered that a synthesis of qualitative data is at least three times removed from the experiences of the participants who took part, i.e., participants vs original researcher interpretation vs synthesiser interpretation (Toye *et al.*, 2014). This is compounded by the inclusion of many papers within a review and could challenge whether findings are truly grounded in the experience of patients. Toye and colleagues (2014) suggest this could be addressed through the involvement of a team with a learning culture and extensive knowledge of the clinical area, as well as making sure the synthesis methods are grounded in the original studies. The paper four research team included considerable clinical and academic expertise within prosthetic rehabilitation and was undertaken as part of a formal learning experience, i.e., a PhD.

Another approach may have been to include patients and the public in the systematic review analysis and development of the model, especially given the patient-centred nature of this work. This approach was discussed when planning paper four and co-producing the final model with people with limb loss was considered. However, each stage of the model's development widened the contributing voices, i.e., 37 English participants in the qualitative study followed by 539 international participants included in the systematic review studies. Co-producing the final model with a smaller group of individuals with limb loss could have led to the addition or removal of domains based on the views of a few, or even a single strong voice, which could have diminished the transferability of the findings.

The final iteration of the ECLIPSE model presents a patient-centred accessible representation of recovery and indicates what outcome domains could be measured following lower limb prosthetic rehabilitation in order to capture success in a meaningful way. The model could also be used to direct the focus of rehabilitation to ensure interventions and goal setting centre around what is important to patients. The interconnected nature of outcome domains of importance highlights the need for a holistic approach to outcome measurement, capturing success in all aspects of the patient’s life. However, despite the clear connections between domains, the exact nature of how they influence each other remains unclear. More research is needed to explore the relationship between domains to deepen our understanding of recovery following limb loss.

6.3 Discussion of the programme of research as a whole

The work undertaken as part of this PhD has contributed to the evidence base investigating outcome measurement following lower limb prosthetic rehabilitation and has expanded our understanding of meaningful person-centred approaches to measuring outcome. The narrative review (Paper 1, chapter 2) explored the current outcome measurement evidence base in prosthetic rehabilitation from a clinical perspective and set out gaps where future work is required. This initial step set the scene for what comprises *meaningful* outcome measurement.

As introduced in chapter one of this thesis, outcome measurement was proposed as a key aspect of a data driven care environment. Alongside demographic data and treatment information, outcome data can enable clinical teams to understand the impact of their interventions, identify what works for different patient groups and where service improvement is required (Devlin *et al.*, 2010). The narrative review findings expand the outcome measurement segment visualised in the data driven care environment diagram (Figure 6.2). This provides a greater understanding of meaningful outcome measurement i.e., understanding outcome **domains** of importance, feasible and fit for purpose outcome **measures**, and outcome measurement **practice** that adds value to patient care.

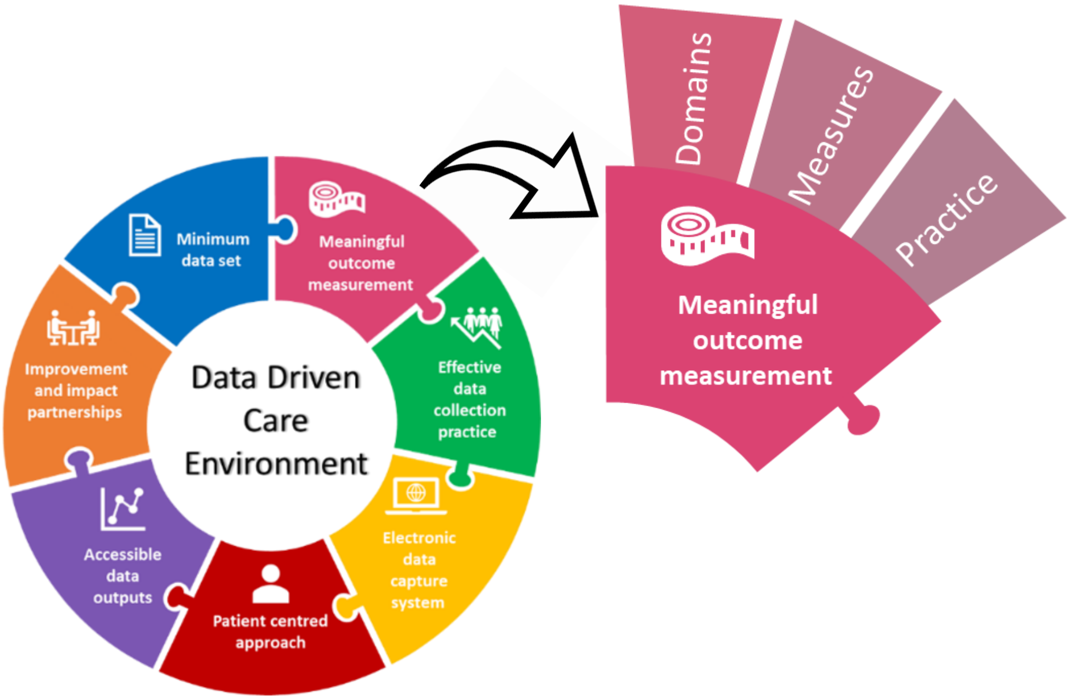


Figure 6.2 Factors comprising meaningful outcome measurement in the context of a data driven care environment

These three notions indicate where future work is needed to address clinically relevant gaps in the literature and have directed the work undertaken in this PhD. The following sections will now discuss the PhD programme of work as a whole and have been structured to reflect the three notions introduced in Figure 6.2, demonstrating the novel contribution this research makes.

6.3.1 What outcome domains should be measured? – The ECLIPSE model

The main body of work described in papers two and four has attempted to address the first problem posed in the narrative review i.e., ‘What outcome domains should be measured?’. The identified domains have been developed iteratively from the perspective of individuals living with limb loss across two studies (Papers 2 and 4), and are presented in a conceptual model, the ECLIPSE model.

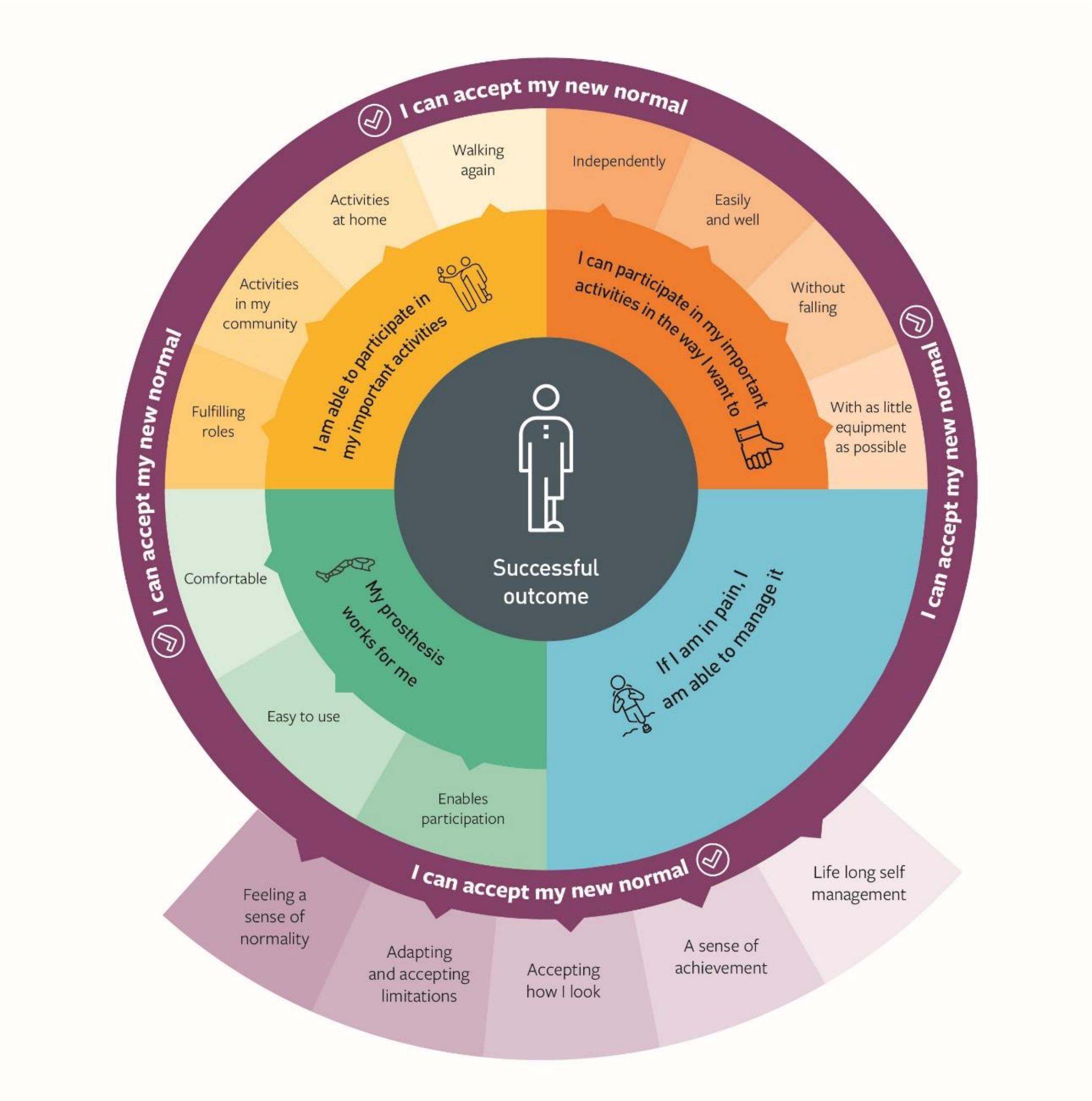


Figure 6.3 The ECLIPSE model of mEaningful outCome domains of Lower lImb ProSthetic rEhabilitation

The ECLIPSE model addresses the gap in the literature regarding what outcome domains could be measured and makes a novel patient-centred contribution to the current evidence base. The model describes five overarching domains of importance. These domains define success following prosthetic rehabilitation as described by prosthetic users, breaking down into additional subthemes which provide more detail about how the domains could be interpreted and implemented in clinical settings. The model can direct clinicians on which domains could be measured on completion of a programme of rehabilitation to capture success as defined by patients. It also indicates which domains could be measured as part of routine outcome measurement programmes aimed at providing data to prosthetic services to direct and inform service improvement work. It could also inform the selection of domains to be measured as part of larger system level data collection initiatives which could inform policy making and research development. The person-centred nature of the model helps to ensure future research or improvement work evaluated using these domains will highlight improvements in patient care and prosthetic innovation that are meaningful to prosthetic users.

6.3.1.1 A multidomain approach

The process of identifying meaningful domains of recovery described in papers two and four also indicate that the domains described in the ECLIPSE model do not exist in isolation for patients. Numerous examples were described in the analyses of both papers two and four, which demonstrate that difficulty in one domain could impact recovery in another. For example, poor socket comfort can limit the ability to participate in important activities which can impact mental wellbeing and the ability to accept the new normal. These interactions suggest the need for a multidomain approach to measuring outcome following prosthetic rehabilitation, which allows success to be captured across each of these important areas. Capturing the outcome of rehabilitation in this way will ensure that interventions, services and research and development efforts, are evaluated holistically. This holistic approach could also help clinicians to understand where problems in a patient's recovery may lie and where to direct resources to have the greatest impact on outcome.

6.3.1.2 The ECLIPSE model as a Core Outcome Set

When reflecting on the application of the ECLIPSE model to direct outcome measurement in clinical settings and research, it needs to be considered in light of wider outcome domain consensus approaches in healthcare, such as those described by COMET (Core Outcome Measurement in Effectiveness Trials initiative) or ICHOM (International Consortium for Health Outcomes Measurement). Development of the ECLIPSE model did not follow the standardised method to generate 'core outcome sets' (COS) as described by consensus organisations such as ICHOM and COMET. COSs are standardised sets of outcome domains that should be measured and reported in all clinical trials for a specific health condition (Williamson *et al.*, 2017). They help to address the issue of domain consensus in research but have also been used in clinical settings. COMET advocate for an initial systematic review of clinical trials to identify a long list of possible domains (Williamson *et al.*, 2017). Some COS developers also include interviews and focus groups with patients and clinicians in this phase, or a qualitative synthesis, to capture the patient's perspective. This is followed by a multistakeholder consensus process, such as Delphi, to agree which domains should comprise the final COS (Williamson *et al.*, 2017).

The ECLIPSE model could be integrated as part of a COS for prosthetic rehabilitation, perhaps representing a rigorous investigation of domains important to patients which could then be integrated with the views of other stakeholders. During the course of this PhD a COS has been developed for studies involving patients undergoing lower limb amputation for peripheral arterial disease (Ambler *et al.*, 2020). However, this set focuses on a single cause of amputation and only considers short- and medium-term outcomes. Nonetheless, like the ECLIPSE model it highlights the importance of pain, socket comfort, independence, and participation in life activities as important domains. The development of this COS followed the standardised approach described by COMET, but only included three patients in the qualitative phase alongside 15 clinicians, and no information was provided about patient representation in the Delphi process which included 91 individuals. The extent of patient involvement in this COS raises questions about whether it reflects outcome domains important to patients, especially in the light of evidence suggesting patients and clinicians prioritise different outcomes following prosthetic rehabilitation (Schaffalitzky *et al.*, 2011).

COMET advocate for the involvement of patients in the COS process, and it is one of their core development standards (Kirkham *et al.*, 2017). However, evidence to date highlights that many COS developers fail to involve patients in the process, or involvement is inadequate and poorly reported (Gargon *et al.*, 2014). Research by COMET found that including patients in the early COS development process, i.e., to create a long list of domains, through approaches such as interviews and focus groups, led to the identification of more domains than identified by clinicians alone (Gorst *et al.*, 2019). Identifying domains solely from clinical trials can overlook outcomes which are important to patients and tend to reflect the perspectives of researchers and clinicians (Gorst *et al.*, 2019). Patient involvement in the later consensus stages used to finalise the COS has also been examined. Jones et al. (2017) found that healthcare professionals make up the majority of contributors in several consensus approaches commonly used in COS development, and suggest that even if patients contribute to the long list of outcome domains their voice may get drowned out in the consensus process, with the final COS not representing what is important to them. Utilizing the ECLIPSE model within the development of a multistakeholder COS could offer a strong patient-centred foundation to the development process. However, incorporating wider views and undertaking the subsequent consensus phase could alter the patient focus of the model, resulting in inclusion of domains which are not relevant in the lives of patients, or excluding issues of importance.

These concerns have led to the development of a *patient* COS in rheumatoid arthritis (RA) (Sanderson *et al.*, 2010), building on the extensive work carried out by OMERACT in developing COSs for RA (Tugwell *et al.*, 2007). The patient COS does not attempt to integrate domains important to patients with those of other stakeholders, but explicitly acknowledges that what is important to patients may be different and in need of specific consideration (Sanderson *et al.*, 2010). In rehabilitation specialities, such as prosthetics, where the focus of interventions is returning the individual to their previous lifestyle, domains prioritised by patients may be particularly important. The ECLISPSE model could represent a patient-centred COS, informing measurement in both research and clinical practice and ensuring a person-centred focus. Development of the model using interview/focus groups, followed by a qualitative systematic review and best fit framework synthesis, could also contribute to the generation of person-centred methods for developing future patient COSs.

6.3.1.3 The ECLIPSE model to direct rehabilitation

As well as directing outcome measurement, the ECLIPSE model also provides a rigorously developed model of rehabilitation priorities which could be used by clinicians and service providers to direct the rehabilitation process. Current guidance on rehabilitation following lower limb amputation is available from several professional networks which comprise the prosthetic MDT. These include the British Association of Chartered Physiotherapists in Limb Absence Rehabilitation (BACPAR), the British Society of Rehabilitation Medicine (BSRM), the British Association of Prosthetists and Orthotists (BAPO) and the College of Occupational Therapists (COT). Much of this guidance addresses the processes surrounding provision of prosthetic rehabilitation, but several of the documents raise the importance of rehabilitation focusing on outcome domains described in the ECLIPSE model, such as participation in important activities, managing pain, self-management (College of Occupational Therapists, 2011; Broomhead *et al.*, 2012; British Society of Rehabilitation Medicine, 2018), the prevention of falls (College of Occupational Therapists, 2011; Broomhead *et al.*, 2012), promoting independence (College of Occupational Therapists, 2011; Broomhead *et al.*, 2012; British Society of Rehabilitation Medicine, 2018; Orthotists, 2021), and the importance of the right prosthesis (College of Occupational Therapists, 2011; British Society of Rehabilitation Medicine, 2018). All these documents advocate for a multidisciplinary approach which enables different professionals to address the holistic domains of the ECLIPSE model through their professional roles.

When considering this guidance, it is worth noting that all guidance for use in prosthetic rehabilitation settings has been produced by clinicians working in the field. BACPAR and the BSRM used a consensus approach in combination with available evidence, although both documents commented on the low quality and paucity of evidence to guide recommendations (Broomhead *et al.*, 2012; British Society of Rehabilitation Medicine, 2018). BAPO and COT used an expert working party. None of the guidance included the perspective of patients. This approach may have led to guidelines focusing on the role and priorities of professionals rather than taking a patient-centred view on the overall outcome of the rehabilitation process. Understanding and incorporating the perspectives of those using a prosthetic limb could inform future iterations of clinical guidelines. The ECLIPSE model could also act as a stand-alone framework to guide treatment planning, goal setting and decision-making during rehabilitation, ensuring services are delivering patient-centred care which is focused on achieving success in the five overarching domains of the model.

Interestingly no guidance is available specifically addressing the psychosocial recovery of people following lower limb amputation, which is described in the ECLIPSE model as 'being able to accept my new normal'. This may be because no professional network represents counsellors or psychologists in this field. BACPAR, COT and BSRM guidance only highlight this domain as an area which requires consideration during rehabilitation, with the BSRM and COT guidance providing additional information about appearance (College of Occupational Therapists, 2011; British Society of Rehabilitation Medicine, 2018). No other guidance or recommended interventions are available to address adjustment following amputation, despite considerable evidence highlighting the psychosocial challenges of amputation, as set out in the paper four manuscript. There is also very little literature documenting the development or impact of psychosocial interventions following limb loss, with only a few papers describing small-scale interventions or educational programmes (Srivastava and Chaudhury, 2014; Turner *et al.*, 2021). Nonetheless, these approaches do report significant improvements in psychosocial functioning and therefore warrant consideration. However, further research is needed to understand how the domain of `accepting my new normal' can be addressed during prosthetic rehabilitation. The ECLIPSE model could provide a useful framework to underpin the development of novel interventions. By highlighting this domain as an important component of a successful outcome for patients, the ECLIPSE model could help to steer the field away from a focus on physical interventions and assistive technology development, towards more patient-centred and holistic models of care, addressing both physical and mental health simultaneously.

6.3.1.4 Limitations of the ECLIPSE model

When considering adoption of new research into a clinical setting it is important to consider the limitations of the work. A significant limitation of the ECLIPSE model is the extent to which it describes outcome domains of importance outside of high-income (HIC) settings. The World Health Organisation (WHO) estimate 30 to 40 million people are living with limb loss in Low-and-middle-income Countries (LMICs) (World Health Organization, 2005). The initial paper two qualitative study was undertaken in England and few studies identified in the paper four systematic review explored the experiences of lower limb prosthetic users living in LMICs. Further work is required to identify what domains characterise a successful recovery in LMICs, but also how well these domains are represented by the ECLIPSE model. Having a single definition of domains of importance across the world would contribute to understanding the state of prosthetic rehabilitation globally. Reliable health data, including outcome information, could help provide invaluable insights to guide policy decisions, funding and research to identify and address gaps in service provision (World Health Organization, 2023). The international society of prosthetics and orthotics (ISPO) have cited the lack of standardised data and information about outcomes as a major impediment to investment in and expansion of prosthetic services in LMICs (International Society of Prosthetics and Orthotics, 2021).

However, despite the importance of a standardised approach to data collection, it is important that any global model of outcome domains represents what is important to individuals living in different social and cultural situations. A rapid review of qualitative studies exploring patient perspectives of type two diabetes, undertaken for development of a core outcome set, found different domains of importance in the LMIC and HIC literature (Gorst *et al.*, 2019). LMIC based studies identified more domains related to life impact, such as role functioning which was not discussed in HIC. Being unable to participate in life roles may be more detrimental to those living in LMICs (Gorst *et al.*, 2019). A greater understanding of what defines a successful outcome for people living in LMICs is required to enable meaningful outcome measurement and data collection at a global level.

However, in future work it may be important to consider how the world view of the research team impacts the development of models such as the ECLIPSE. A possible limitation of the ECLIPSE model is that it has been developed from the world view of a clinician working within a specific UK NHS prosthetic service, which promotes a holistic patient centred approach to care and delivers prosthetic services in an integrated multidisciplinary way. Other UK services or healthcare systems around the world, such as private/insurance-based practice or those in less resourced settings such as LMICs, may not choose to or have capacity to adopt this integrated MDT approach. For example, some services may lack of access to occupational therapists or psychological services, or may focus limited resources solely on prosthetic provision. The holistic multi domain approach described in the ECLIPSE model may direct measurement and rehabilitation towards aspects of recovery perceived as outside the scope of practice of prosthetic services in different healthcare systems, which may make the model feel irrelevant or unachievable. A counterargument could be that the ECLIPSE model fosters holistic approaches to prosthetic rehabilitation, potentially promoting and informing the development of patient-centred services. However, any future work aimed at understanding outcome domains in different settings, especially low- and middle-income countries, may need to contextualise findings so they are relevant to local healthcare systems. Projects could be led by or at least involve researchers/clinicians embedded in those systems.

Another possible limitation of the model is whether it represents outcome domains of importance across groups within prosthetic rehabilitation that are known to differ, especially considering the impact these differences can have on outcome (Wu, Chan and Bowring, 2010). For example, those with varying levels of physical ability (clinically described as high or low activity patients), or the length of time since amputation i.e., new patients versus those who are more established limb wearers. Varying activity levels within the limb loss population are often due to the variety of causes of amputation, the presence of co-morbidities and the wide age range of individuals undergoing amputation (Darter *et al.*, 2018b). This has led to discussion about ceiling or flooring effects in the outcome measurement literature (Ostler, Scott, *et al.*, 2022), as single measures struggle to capture the full range of ability, resulting in development and recommendation of specific measures for high activity patients (Gailey *et al.*, 2013). This thesis attempted to address these concerns by recruiting a sample with a wide variety of characteristics, including different ages, causes and activity levels, for the paper two qualitative study to ensure experience of patients with a range of outcomes was captured. This range of experiences and outcomes was then broadened by incorporating views and experiences of participants from the wider limb loss literature, which also included participants with a wide age range and variety of causes of amputation. This allowed analysis of a successful outcome as viewed by people with different levels of activity, and enabled consideration of common themes describing success across the whole group. This can be seen most clearly in the participation domain, which does not list activities people may participate in but rather suggests success occurs when people are able to participate in what is important for them. This aligns with examples of patient centred outcome measure tools such as the Canadian Occupational Performance Measure (Law *et al.,* 1990) or the Patient Specific Functional Scale (Horn *et al.,* 2012), where the items captured by the measure are selected by patients themselves.

When considering how groups may differ depending on time since amputation, a sub analysis of the data collected during the paper two study appeared to suggest that participants who were more than two years since their amputation discussed the `acceptance of the new normal’ domain more frequently. Although it is important to note that this sub analysis was not the aim of the research (Ostler, Donovan-Hall, *et al.*, 2022). The changing nature of outcome domains of importance over time has been highlighted in a study by Joslin and colleagues (Joslin, Donovan-Hall and Roberts, 2021) who found that children with chronic pain identified turning points during their treatment where domains of importance changed. Although the stage two qualitative study only included participants who were within five years of their amputation, the qualitative synthesis attempted to address this limitation by including participants at any stage in their post amputation life. Nonetheless, despite these attempts, qualitative research is not undertaken to generalise findings to the wider population, but to provide rich insights and deepen understanding (Clarke and Braun, 2013). Further work could be undertaken to explore whether the ECLIPSE model represents outcome domains of importance for different well described subgroups within the amputation population, such as different mechanisms of limb loss, levels of limb loss, sex, or age, or whether domains change over time as patients become more established in their prosthetic use. This could be particularly important with this population as prosthetic services provide lifelong care and management. This work could provide insight into whether a core set of domains that captures outcome in a meaningful way is possible for all prosthetic limb wearers.

As the aim of this current work was to identify outcome domains of importance following prosthetic rehabilitation, the ECLIPSE model does not consider outcome domains that are important to people who do not use a prosthetic limb. When considering outcomes presented in Scottish limb loss data, it has been shown that 60% of people who undergo an amputation in this context do not use a prosthetic limb (Carr *et al.*, 2023). Hence there is a need to understand success from the perspective of those who do not wish to or cannot use a prosthesis and explore how to enable recovery through rehabilitation. Anecdotally individuals who do not use a prosthesis do not appear to be routinely managed by prosthetic rehabilitation services and are often not included in professional guidance (Broomhead *et al.*, 2012). Considering that elements of the ECLIPSE model, such as ‘being able to participate in important activities’, ‘manage pain’, or ‘accept limitations’, may be universal in rehabilitation settings, then people who do not use a prosthesis are likely to have specific rehabilitation needs related to wheelchair rather than prosthesis use. For example, how patients participate in their important activities using a wheelchair and what interventions may be required to support this. In light of the challenges of wheelchair use in today’s physical and social environment, and the impact this could have on the patient’s mental health, considerable therapeutic input may be required to support psychosocial recovery for those who are not able to wear a prosthesis. Due to the estimated size of this population, further research is required to understand success from the perspective of non-limb wearers which could be crucial to not only capture outcome but perhaps more importantly highlight rehabilitation needs for this often-overlooked group.

Limitations of the ECLIPSE model which are particularly relevant to clinical settings are the expansion of the model from five overarching domains to a more detailed model also visualising the 16 contributing subdomains. This increase may make the model less feasible for clinicians to use as they consider how to measure all 16 subdomains.

It is also possible that clinicians and patients may see the domains in a prescriptive way, i.e., in order to experience a successful recovery people have to accept their limitations or appearance. We acknowledge that sometimes not accepting the status quo can bring about change for the better and suggest that when using the model to direct rehabilitation that it could be a useful conversation starter to help manage and track progress. We recognise the complexities of adjustment and acceptance, and more work may be required to explore these domains further. However, the aim of rehabilitation is to foster a more positive situation for people. The ECLIPSE model may be useful to raise awareness of these domains for patients and clinicians and consider available management options if required.

Finally, when considering the limitations of the ECLIPSE model It is also worth taking into account that the qualitative approaches used to develop the model did not follow the recommended process for core outcome set development (Williamson *et al.*, 2017), i.e., they did not take a consensus generating approach, but rather used two different qualitative methods to collect and interpret data from different sources. It is therefore likely that the analysis, interpretation, and presentation of the final model were influenced by the researchers involved. The influence of the researcher and supervisors on this thesis, which is part of the essence of qualitative research, will be explored in more detail in section 6.4.

6.3.2 How should outcome domains of importance be measured?

The second question identified by the paper one narrative review was how outcome domains of importance can be measured. The ECLIPSE model provides a rigorously developed and patient-centred understanding of which domains should be measured following lower limb prosthetic rehabilitation and addresses the first lack of consensus described in the narrative review. However, the review also highlighted a second absence of consensus regarding which outcome measurement tools should be used in clinical settings and research. Despite providing guidance on *what* to measure, the ECPLISE model does not provide clinicians with a core set of outcome measures.

6.3.2.1 Update on outcome measure consensus

During the course of this PhD the International Society of Prosthetics and Orthotics (ISPO) undertook a global consensus exercise aimed at generating an agreed set of outcome measures for use following lower limb amputation (Tan *et al.*, 2023). The author of this thesis was asked to represent NHS England during the process and contributed to the global Delphi consensus. The final output is a set of six outcome measures which make up the COMPASS (Consensus of Outcome Measures for Prosthetic and Amputation ServiceS). These six measures are supplemented by an additional two high activity measures known as the COMPASS+ and two further measures known as the COMPASS adjunct (Table 6.1) which can be used at the clinician's discretion (Tan *et al.*, 2023).

Table 6.1 The outcome measures which comprise the COMPASS

COMPASS Outcome measures	COMPASS+ outcome measures
Timed Up and Go (TUG)	Comprehensive High-level Activity Mobility Predictor (CHAMP)
Amputee Mobility Predictor (AMP)	Six-minute Walk Test
Two-minute Walk Test	**COMPASS adjunct outcome measures**
Trinity Amputation and Prosthesis Experience Scale (TAPES-R)	Patient Specific Function Scale (PSFS)

COMPASS Outcome measures	**COMPASS+ outcome measures**
Prosthesis Evaluation Scale (PEQ) - subscale Residual Limb Health	A generic health related quality of life measure i.e., Patient Reported Outcome Measures Information System – 29 item profile (PROMIS-29) or EuroQoL (EQ-5D-5L)
Prosthesis Evaluation Scale (PEQ) – subscale Utility	

Despite this much needed progress towards outcome measure consensus, the approach adopted in the development of the COMPASS did not begin by considering what domains to measure to inform the selection of measurement tools. This step is advocated for by consensus organisations such as COMET and ICHOM. COMET work in partnership with an organisation known as COSMIN - COnsensus-based Standards for the selection of health Measurement INstruments – who describe standardised approaches for using domains generated through the COS process to identify instruments (Prinsen *et al.*, 2016).

Nonetheless, the COMPASS project *did* use the approach set out by COSMIN to identify and assess outcome measures from the literature, including the use of their `gold standard' Risk of Bias tool (RoB) (Mokkink *et al.*, 2016). The project included a systematic review which identified 60 different measures for use with patients following lower limb amputation (40 PROMS, 18 performance-based measures and 2 hybrid measures). The COSMIN RoB tool was used to identify measures with sufficient psychometric properties to enable recommendation for clinical use. Despite quality appraisal scores ranging from `inadequate' to `very good', no measure was of a high enough quality to be recommended following the RoB assessment (Tan *et al.*, 2023). To enable the project to progress an expert panel of nine individuals was convened to re-review the psychometric properties of the measures and select tools which could be taken forward into the consensus process (Kohler *et al.*, 2023). Twenty-two measures were taken forward for Delphi consensus. The Delphi process included 39 participants (12 from LMICs and 27 from HIC) from a variety of professional backgrounds within the prosthetic MDT, as well as prosthetic users, who took part in four-, two- and half-hour long virtual consensus meetings. Measures were recommended following discussion and online voting, with a threshold of 70% agreement to reach consensus (Tan *et al.*, 2023). Six core measures were endorsed with four additional measures making up the COMPASS+ and COMPASS adjunct (Table 6.1). The 10 measures covered 12 chapter level ICF categories, as well as three additional concepts not included in the ICF, such as socket comfort (Tan *et al.*, 2023). The time burden of the COMPASS is estimated to be around 45 minutes, with 20 minutes required to undertake performance-based measures and 25 minutes for patients to complete the PROMS. Extra time for scoring and interpretation of the measures is also required (Tan *et al.*, 2023).

The COMPASS project addresses a gap in the literature identified in the paper one narrative review i.e. a lack of outcome measure consensus (Ostler, Scott, *et al.*, 2022), helping to promote the routine use of outcome measures in prosthetic rehabilitation across the world. However, the focus on measures before domains and the limitations of the project need to be considered. Firstly , none of the measures included in the COMPASS and identified via the systematic review had robust enough psychometric properties to be recommended using the gold standard COSMIN RoB tool (Kohler *et al.*, 2023). Secondly, the tools selected for the consensus process were based on expert opinion. A number of the experts involved in the panel had developed several of the tools they were reviewing, introducing a potential conflict of interest. The authors reported this risk of bias was minimal as a maximum of two experts were involved in the development/validation of any single measure which did not allow for a majority vote in the recommendation process (Kohler *et al.*, 2023). Thirdly, during the Delphi process, participants were asked to vote on their preferred measures. This assumed they had experience with all 22 measures included in the consensus exercise, which is unlikely given the low levels of engagement with outcome measures amongst clinicians (Ostler, Scott, *et al.*, 2022). Lack of knowledge and experience with the measures may have made it difficult to prioritise, resulting in participants voting for measures they were familiar with rather than the `best’ measure. Finally, the process only included five prosthesis users compared to 34 clinicians, academics and researchers (Tan *et al.*, 2023).

Despite these limitations the COMPASS provides a useful first step towards a global consensus on outcome measurement which could raise awareness of the need to capture outcome globally, as well as guide future research towards establishing and improving the psychometric properties of the recommended tools. The project also highlighted that no outcome measures had been developed in LMICs, with all 60 outcome measures identified in the systematic review developed in high income settings (Tan *et al.*, 2023).

6.3.2.2 The ECLIPSE model and the COMPASS

The approach taken by the COMPASS developers did not initially take into consideration ‘what’ outcome domains need to be measured using the tools in their recommendations. Reviewing the COMPASS against the ECLIPSE model could provide useful insights into whether the included measures capture a meaningful outcome as described by patients and identify areas where additional measures may be required. Table 6.2 summarises an initial review of the domains measured by the six tools included in the main COMPASS recommendations, as described in the papers documenting their development.

Table 6.2 Overview of domains captured using the COMPASS outcome measures

Outcome measure	Domains
Timed up and go	Mobility
Two-minute walk test	Mobility
AMP	Functional mobility
TAPES-R	General adjustment Social adjustment Adjustment to limitations Activity restriction Social activity restriction Functional satisfaction with prosthesis Aesthetic satisfaction with prosthesis
PEQ subscale Residual Limb Health	Residual limb health
PEQ subscale Utility	Prosthesis utility

Of note, three of the measures (Timed up and go, two-minute walk test, and the AMP) capture the domain of mobility, which considering the measurement burden on clinical staff and patients may be unnecessary duplication. The outcome domains captured by the recommended PROMs cover a broader range, especially the TAPES-R. A useful next step would be to undertake a mapping exercise to explore how the above domains capture the domains described in the ECLIPSE model. This could inform clinicians how well the COMPASS captures the holistic range of domains which prosthetic users have identified as important. However, consideration may need to be given to the mapping process to account for potential differences in the language used to describe the same domain. Development of a systematic process, perhaps involving prosthetic users themselves could promote rigour.

The ECLIPSE model could also be useful for other organisations seeking to recommend outcome measures to their networks or working towards OM consensus. UK based organisations such as BACPAR, a professional network of physiotherapists working in amputation rehabilitation settings. BACPAR have developed an Outcome Measures Toolbox (Scopes *et al.*, 2015) that includes 10 measures that have been selected according to the preference of a working group of clinicians, which is currently being updated. As a member of the BACPAR community, the author of this thesis could frame the ECLIPSE model as an opportunity for BACPAR to take a different approach to selecting outcome measures for use in clinical practice by considering measures which capture domains important to patients. The rigour underpinning the development of the ECLIPSE model could make future BACPAR recommendations more robust as well as more patient centred. The updated outcome measures toolbox could be strengthened further by adopting existing methods described by organisations such as COSMIN that set out systematic approaches to identify appropriate measures (Mokkink *et al.*, 2016). An organisation such as BACPAR who have extensive clinical influence due to the relatively small number of clinicians working in the field and their need for peer support, could have a significant impact on how clinical services perceive and capture outcome. A patient centred outcome measurement recommendation from BACPAR could move the field towards more meaningful measurement.

As part of informing outcome measure recommendations, the ECLIPSE model may also highlight gaps where additional measures need to be identified or developed. Considering the lack of evidence to support the psychometric properties of current outcome measures, described in both the narrative review (Paper 1) and the COMPASS systematic review (Tan *et al.*, 2023), the ECLIPSE model could direct the focus of research undertaking psychometric testing of outcome measurement towards measures which capture important domains.

However, it is possible that the range of measures required to capture the ECLIPSE domains may present a significant measurement burden to clinicians and patients. Future work could focus on the ECLIPSE model as the foundations for a patient-centred PROM, with five core subscales. This could address measurement burden and capture outcome in a holistic way, as well as enabling exploration of how the different subdomains interact.

A core set of outcome measures, or a single holistic tool, which captures domains that are important to prosthetic users would contribute to meaningful outcome measurement, as described as part of a Data Driven Care Environment, set out in chapter one. A core set of measures could also contribute to establishing a minimum data set and help promote a patient-centred approach to data collection within prosthetic rehabilitation.

6.3.3 What comprises outcome measurement practice?

The final theme introduced in the narrative review (Paper 1) centres around the concept of outcome measurement practice i.e., how outcome measurement data can be collected and used, ensuring measurement is of value to clinicians and patients. Domains of importance, fit for purpose measures, and outcome measurement practice, appear to embody meaningful outcome measurement. Since the publication of the paper one narrative review two further articles have been published exploring outcome measurement practice in the United States (Morgan, Balkman, *et al.*, 2022; Morgan, Rowe, *et al.*, 2022). The first was a qualitative study examining the views and experiences of prosthetists, physiotherapists, and rehabilitation consultants, of assessing mobility in people with lower limb amputation (Morgan, Balkman, *et al.*, 2022). Although the study focused only on performance-based measures it identified several factors influencing the use of outcome measures, and for the first time considered members of the MDT other than the prosthetist. Barriers to measurement were time and space which appeared to vary in their impact between the MDT groups i.e., physiotherapists had greater access to large gym spaces. Participants also discussed the value of outcome measures, highlighting the need for useful information that supported clinical decision making at the individual patient level (Morgan, Balkman, *et al.*, 2022). The second paper built on this qualitative work and developed a survey exploring performance-based and PROM use amongst prosthetists only (Morgan, Rowe, *et al.*, 2022). This work also found that time and space were barriers and raised concerns about the lack of standardisation when implementing measures, which could impact the usefulness and comparability of results (Morgan, Rowe, *et al.*, 2022).

This work supports the findings from the paper one narrative review (Ostler, Scott, *et al.*, 2022) and suggests outcome measurement practice in prosthetic rehabilitation is complex and may vary across the MDT. Value for clinicians appears to lie in the usefulness of information to guide clinical decision making for individual patients (Gaunaurd *et al.*, 2015; Hafner *et al.*, 2017; Young, Rowley and Lalor, 2018). However, both of Morgan and Colleagues papers described above discuss the value of outcome measurement to motivate and support communication with patients, which was highlighted in findings from paper three of this thesis. The author of this PhD did not initially set out to explore outcome measurement practice itself, however findings collected during the paper two qualitative study identified an important, previously unexplored perspective on outcome measurement in clinical settings, which became paper three. Paper three describes the impact measurement can have on patients and provides a unique patient-centred insight into outcome measurement practice. The paper describes both positive and negative experiences, as well as highlighting issues of value and accuracy. All of which have been described in the wider PROM literature (Chen, Ou and Hollis, 2013; Campbell *et al.*, 2022; Carfora *et al.*, 2022).

Paper three was undertaken as a secondary analysis of data collected as part of paper two, and subsequently has considerable limitations which need to be taken into account (Szabo and Strang, 1997). However, the research does provide some interesting insights into outcome measurement practice, and for the first time with this population, considers this element of clinical practice from the patient's perspective. An interesting theme identified through this analysis raised the question of who outcome measurement is for and highlighted that patients did not consider outcome measurement a process that was of value to them. Experiences described by patients in paper three suggested that outcome measurement could be useful to motivate patients, to help them evaluate their progress and develop a sense of achievement, which is highlighted in the ECLIPSE model as an important outcome domain. However, patients may only benefit from this potential value if they had access to measurement results and a discussion of the findings was included in clinical consultations. This feedback step is highlighted in several systematic reviews exploring the experiences of patients taking part in routine PROM programmes (Chen, Ou and Hollis, 2013; Campbell *et al.*, 2022; Carfora *et al.*, 2022). Without feedback patients are locked out of any value measurement may offer them. These systematic reviews also suggest that feeding back and discussing scores can improve communication and make patients feel like consultations are focused on what is important to them rather than the clinician (Chen, Ou and Hollis, 2013; Campbell *et al.*, 2022; Carfora *et al.*, 2022). However, this could depend on which measures were used, as tools which fail to capture domains of importance from the patient's perspective could steer the conversation away from what is important to the patient.

This complex picture and absence of evidence exploring outcome measurement from the patient's perspective in prosthetic rehabilitation highlights the need for future research to explore this phenomenon in more depth and deepen our understanding. Insights from paper three highlight the need to explore how outcome measurement could be useful for patients, and how it could contribute to an improved experience of care, as well as improved rehabilitation outcomes.

In addition, outcome measurement practice in prosthetic rehabilitation also needs to be considered from the perspective of wider stakeholders, especially when positioned within a multi factorial data driven care environment. More research is required to understand the perspectives of MDT clinicians, managers, commissioners, policy makers, researchers, and industry partners to understand and develop data collection and measurement processes that are meaningful and add value to prosthetic rehabilitation.

The author of this PhD, in collaboration with the PhD supervisors, academics from other universities and a patient representative, have been successfully awarded an NIHR Research for Patient Benefit grant to explore multi-stakeholder perspectives, including the perspectives of patients, on the value of health care data and outcome measurement in prosthetic rehabilitation. It is hoped that this work will form the foundations of a nationwide patient-centred data collection initiative which is positioned around the needs of patients and clinicians. The findings from paper three were instrumental in informing the need to include the patient's perspective in data collection for this project.

This funding will help to understand patient, clinician, and wider stakeholder requirements for data collection initiatives in prosthetic rehabilitation. Future work building on these recommendations could include the development of a nationwide data collection initiative which includes routine outcome measurement. This initiative would offer invaluable learning for the field of prosthetic rehabilitation. Intelligence could be gained not only through insights explored using the collected data but also through learning about how data is actually utilised in clinical settings and beyond. Lived experience of using healthcare data is invaluable. This author's clinical experience with outcome measurement as part of the Microprocessor knee policy raised many practical issues which led to this PhD, such as how to interpret scores on different measures and what a change in score meant for patients. Understanding how data is used in practice at the individual, service and system levels, by different stakeholders, alongside clinical intuition and experience, could help inform and develop best practice for outcome measurement in clinical settings, as well as wider use of healthcare data.

6.4 The impact of the researcher

Reflexivity is a key element of qualitative research and considers the impact of the researcher on the research process (Finley, 1999). This influence extends to the generation of research questions, the selection of methods, development of data collection materials, the collection of data, and its interpretation. Within qualitative studies it is well recognised that the researcher is instrumental in the generation of research data and findings (Braun and Clarke, 2021), however this influence also extends to the narrative and systematic reviews included in this PhD. The process of reflexivity explores the researchers own unconscious reactions and the dynamics of research-participant relationships, which can offer interesting insights and uncover implicit biases. By engaging in reflexivity, the researcher can offer an open and transparent account, allowing scrutiny of research integrity (Finley, 1999).

6.4.1 The impact of the researcher on this research

The reflexive approaches taken during this PhD can be characterised as introspection and intersubjective reflection, which consider the researchers own experiences and personal meanings, and how they interact with others in different contexts, respectively (Finley, 1999). These approaches to reflexivity align with my ontological position. Critical realism acknowledges an objective reality that sits behind and is viewed through different lenses or prisms (Gorski, 2013). Introspection and intersubjective reflection consider the lens of the researcher, reflecting on how the researcher views reality, how they view reality viewed through the lens of the participant and how these myriads of views interact. In this section I focus on my own assumptions and position as both a clinician and researcher and consider how they may have impacted the interactions with participants who took part in the studies. Throughout the PhD I used a reflexive journal to document the process, several accounts have been included in Appendices J and K.

My previous clinical experience and the frustration of using outcome measurement in clinical practice led me to focus on meaningful outcome measurement in prosthetic rehabilitation. My experience of the Microprocessor knee policy (MPK), implemented by NHS England in 2016 encompasses many of the problems (NHS England, 2016). The policy stated clinical teams should use outcome measures to indicate whether a patient could be prescribed an MPK. Measures were taken before and after a four-week trial with the MPK and if the patient's scores improved the MPK could be issued. This experience highlighted several feasibility issues such as the amount of time to complete tools and lack of space in clinical areas, as well as problems with interpretation as we didn't know how much improvement on each measure was enough to enable us to prescribe, and which measures were more important to consider. These problems were not just experienced by my team but were the topic of conversation at many professional network meetings in the field. Clinicians expressed frustration that what should be useful information to our decision making didn't seem to work well in practice and in some cases became burdensome to clinicians and patients. This experience positioned me as an insider to the overarching aim of the PhD, as I sought to explore meaningful outcome measurement, and risked my views and experiences dominating the narrative review which set the scene for subsequent research. Awareness of this position led to the involvement of additional clinicians from across the MDT in the review process. This helped to sense check what I thought was clinically relevant and should be included in the review and incorporated other perspectives in the analysis and interpretation. The process of discussion with MDT clinicians helped me to consider some of the financial implications of routine outcome measurement, as well as include new and novel approaches, such as computerised adaptive testing.

The position of insider was reversed in the subsequent papers, which used qualitative methods to explore the experiences of prosthetic users. This could have led to research questions that were not relevant to prosthetic users themselves or asking about their experiences in the wrong way. PPIE work was undertaken to help address these concerns. Our group of public research partners helped develop the interview guides for papers two and three, to ensure questions were relevant to people with lower limb loss and used language that was accessible.

When undertaking papers two and three, I reflected on my position as a physiotherapist. There were many ways this role could influence the development, data collection and analysis. As a physiotherapist I am focused on rehabilitating people following lower limb amputation, providing information, and supporting patients to achieve their goals. During data collection I was aware of my tendency to revert to this clinical position which could result in me wanting to offer the participant advice for problems they described rather than listening to their experiences and trying to understand. This has been described in the literature as a righting reflex, which is defined as "the desire to fix what seems wrong with people and set them promptly on a better course" (Miller and Rollnick, 2002, Page 6). Awareness of this reflex, identified through reflexive accounts and PhD supervision, helped me to manage its impact on data collection. If any specific issues were raised by the participant during the interview that appeared to be causing them distress, I briefly noted them down and raised them with the participant on completion of the interview. I also included these interactions in my reflexive accounts and considered their influence on the interview. One such occasion led me to recommence recording of the discussion as raising the problem generated more conversation relevant to the research question.

I also reflected on the fact that I worked clinically at one of the recruiting centres and patients who were recruited in that centre may have been treated by me in a clinical capacity or may have known that I was a physiotherapist. Those that had been treated by me in the past were interviewed by Dr Donovan-Hall (primary supervisor) but may have known of my involvement as I was the primary contact on the PIS and may have been referred to by my colleagues as they recruited patients. This could have influenced which patients agreed to take part, how participants considered the interview questions i.e., they may have focused more on experiences of physiotherapy rather than MDT rehabilitation, or how they talked about their outcome, i.e., presenting a more positive view of their recovery. The awareness of this role may also have influenced the perception of power between the researcher and participants, especially as some participants were interviewed at the limb centre, compounding the potential biomedical perception of their status as a patient. However, not all of the patients were recruited from the limb centre I worked in, and those that were not didn't know I was a physiotherapist. Some participants were also interviewed in different settings, i.e., their own homes or over the phone, and some took part in focus groups where there may have been additional influence from other participants. These different approaches may have varied the impact of my physiotherapy/researcher role on participants. Conversely my in-depth knowledge of the rehabilitation pathway following amputation, as well as my experience talking with and supporting many individuals with limb loss may also have helped me to build rapport with patients. By asking appropriate questions and demonstrating an understanding of their experiences, I may have enabled them to discuss issues openly with me, which allowed generation of deeper insights.

During the analysis of paper two I reflected on my role as a physiotherapist again. It was acknowledged that this perspective may tend towards a focus on more physical outcome domains of importance. The involvement of Dr Donovan-Hall (a health psychologist) in the analysis and interpretation of the findings introduced a psychosocial focus which helped challenge my physically grounded interpretations and encouraged me to consider other meanings. For example, in paper two my early analysis initially focused on the importance of the physical abilities' which participants described needing to regain following amputation. Following discussion and a review of the data with Dr Donovan-Hall it was clear that the physical abilities underpinned the important domain of being able to participate in valued activities, therefore we revised the theme. This additional perspective provided a higher level of verification and trustworthiness, strengthening the rigor and credibility of our approach.

During paper four I was aware of my closeness to the themes identified in paper two and how they may influence my analysis and interpretation of the limb loss literature. I was concerned that if I undertook a thematic synthesis of the entire data set, I would not be able to see domains other than those reported in paper two. A period of desk research identified `Best Fit’ framework synthesis as a possible solution. This approach acknowledged the existence of the initial conceptual model from paper two and allowed it to be reviewed in light of the wider evidence, but at the same time offered space to collate and analyse findings that did not appear to fit. The adoption of open line by line coding of data also helped prevent shoe horning of data into the framework. A reflexive diary and involvement of the PhD supervisors in development of the ECLIPSE model also provided a method to challenge my assumptions.

Overall, the development of the ECLISPSE model could have been influenced by my clinical experiences, such as well-known pressure on clinical time influencing a desire to not include too many domains to measure as I attempted to offer feasible solutions to the problems identified in the narrative review. Conversely the perspective of a physiotherapist in clinical practice may have given a unique insight into the creation of themes that are accessible to patients and clinicians and influenced my choice to describe domains using the voice of the patient.

6.5 Strengths and limitations

The following section summarises the strengths and limitations of the work undertaken as part of this PhD.

6.5.1 Paper 1

Strengths

- The aims of the research were derived from problems faced in clinical practice and sought to address a real-world problem facing prosthetic rehabilitation.
- Multi-disciplinary perspectives informed the review of the literature which set the clinical focus for the work undertaken within the PhD.
- The broad scope of the review allowed consideration of outcome measurement as a whole and ensured subsequent research within the PhD addressed questions that were relevant and important.

Limitations

- The narrative approach could have led to cherry picking of papers that aligned with the views of the contributing authors rather than including the full range of available evidence.
- The absence of critical appraisal could have led to the inclusion of low-quality papers which may have influenced the final themes.

6.5.2 Papers 2 and 3

Strengths

- Patient involvement in the design of the empirical qualitative research ensured questions were accessible for participants and the research design did not cause inconvenience for prosthetic limb wearers.
- The combined convenience and purposive sampling approach generated a large heterogenous sample, recruited from four NHS limb centres, and included views from individuals with characteristics representative of the UK limb loss population.
- Member checking validated the initial domains of importance identified through the qualitative study (Paper 2) and visualised in the first iteration of the conceptual model, suggesting they may be transferrable to other patients undergoing prosthetic rehabilitation.
- Unexpected findings from the paper two study allowed novel insights about outcome measurement practice from the patient's perspective to be identified and documented in paper three. These insights could shape outcome measurement practice in clinical settings and encourage clinicians and service providers to consider the patient's experience of taking part in outcome measurement.

Limitations

- The qualitative study recruited participants from a single country i.e., England, which may limit the transferability of findings to patients living in different social and cultural settings.
- Utilising clinicians to carry out convenience and purposive sampling could have resulted in the inclusion of patients who were more adjusted to their amputation or had a more successful outcome.
- As the PhD researcher was a practicing physiotherapist within a prosthetic rehabilitation centre, her interpretation and analysis of interview and focus group data could have led to more physically focused outcome domains of importance.
- Paper three was undertaken as a secondary data analysis of data collected as part of the paper two qualitative study. As the sample was not recruited to answer the paper three

research question the researchers did not consider their experience with different types of measurement, when in the rehabilitation process they took part, and with which professionals, which could have influenced the findings.

- The involvement of paper three participants in the paper two study, where they discussed outcome domains of importance, could also have influenced their responses to the paper three interview questions.

6.5.3 Paper 4

Strengths

- Paper four led to development of the second iteration of the conceptual model following a systematic search of the qualitative limb loss literature, ensuring all relevant publications contributed to its development.
- Utilising the qualitative limb loss literature led to the views of 539 participants from 15 different countries shaping the final iteration of the ECLIPSE model.
- The framework developed for synthesis of the qualitative literature was based on the first iteration of the model (Paper 2), allowing the synthesis to be grounded in the experiences of prosthetic users.
- The 'best fit' framework synthesis approach allowed development of the conceptual model, clearly demonstrating how the qualitative literature revised and expanded the domains of importance.
- Naming of the domains of importance using first person language maintains and promotes the patient-centred focus of the ECLIPSE model.
- The researcher's role as a practicing physiotherapist in prosthetic rehabilitation ensured that the ECLIPSE model was developed and presented in an accessible and feasible way to enable use in clinical settings.

Limitations

- The qualitative studies included in the paper four systematic review didn't focus on outcome domains of importance but instead explored a wide variety of experiences associated with prosthetic use. This led to the researcher interpreting findings from these studies in the context of a different research question which may have led to misinterpretation.
- Data included in the synthesis was collected from participants by a variety of different researchers before being interpreted by the PhD candidate. This interpretation of an interpretation is at least three times removed from the source of the data.

- The samples of the included studies involved very few participants living in LMICs. It is therefore unclear if the ECLIPSE model represents the views of those individuals and limits its global application.
- The `best fit' framework developed to enable synthesis of the qualitative evidence was based on the initial model developed by the PhD candidate. Ownership of the model and investment in its development could have led to overfamiliarity and confirmation bias which could have influenced both the analysis and findings.
- Expansion of the ECLIPSE model from five overarching domains to a more detailed model also visualising the 16 contributing subdomains may make the model less feasible for clinicians to use as they may consider how to measure all 16 subdomains.

6.6 Recommendations

This section summarises the recommendations emerging from the work undertaken within this PhD. It considers recommendations for clinical practice and research settings in the field of prosthetic rehabilitation. Future research, building on this PhD will be discussed in the following section.

6.6.1 Recommendations for clinical practice

- Clinical teams should consider outcome measurement as part of routine data collection, as well as a key part of a data driven care environment
- However, clinical conversations about outcome measurement need to move beyond just the selection of measurement tools and consider value to clinical practice through exploring the why, what, and how of measurement.
- When considering what outcome domains to measure the ECLIPSE model offers a rigorously developed selection of domains derived from the experiences of lower limb prosthetic users across the world.
- The ECLIPSE model could be used to inform the selection of outcome measures for future NHS prosthetic service specifications or component policies, ensuring the process of evaluating interventions is meaningful.
- Clinical teams undertaking outcome measurement or developing routine outcome measurement programmes should consider the perspective of the patient. Outcome measurement practice should be patient-centred, ensuring measurement is of value to patients through feedback and discussion about results, as well as considering its psychosocial impact and offering opt out options.

- The ECLIPSE model could be used to direct the focus of rehabilitation and design of future prosthetic services, especially the development of psychosocial interventions. The model could also inform future prosthetic rehabilitation clinical guidelines.
- The ECLIPSE model could inform future outcome measurement consensus work undertaken by BACPAR, or ISPO via their COMPASS initiative. Version two of the COMPASS could focus on identifying measures which capture meaningful outcomes more holistically.

6.6.2 Recommendations for using the ECLIPSE model in research

The ECLIPSE model could be used in prosthetic rehabilitation research settings as well as clinical settings. The recommendations below describe how the ECLIPSE model could be used in the design and delivery of prosthetic research. Future research building on this PhD is described in section 6.7.

- The domains described in the model could guide the selection of primary and secondary outcomes for prosthetic research to ensure studies capture outcomes which are important to patients.
- The ECLIPSE model could also guide the prioritisation of research activity within prosthetic rehabilitation, by focusing on devices and interventions that address outcome domains of importance.

6.7 Future research building on meaningful outcome measurement

Future research building on the work undertaken within this PhD needs to focus on identifying outcome measurement tools to capture the domains described in the ECLIPSE model. Without recommended measures clinicians will continue to find selecting outcome measures challenging.

Initial work could focus on mapping current outcome measures onto the ECLIPSE model. This could involve the full range of tools developed for use following lower limb amputation, or focus on measures recommended in the recent ISPO consensus work, the COMPASS (Tan *et al.*, 2023). However, the process for mapping outcome domains for PROMs may need careful consideration. This could involve the development and comparison of domain definitions to ensure the domains reportedly captured in PROMs match those of the ECLIPSE model. This work has already been started as part of an undergraduate student project to understand how the COMPASS domains map against the ECLIPSE model, and to explore the mapping process.

Once measurement tools have been identified future research is required to establish their psychometric properties. Many of the systematic reviews identified in the paper one narrative review highlighted the absence of psychometric properties within prosthetic rehabilitation measures, especially responsiveness which is critical for meaningful use in clinical settings (Ostler, Scott, *et al.*, 2022). This finding was supported by the COMPASS initiative which was unable to recommend any measures based on the COSMIN Risk of Bias check list (Tan *et al.*, 2023). Once measures have been identified which capture the ECLIPSE domains, research is required to investigate their validity, reliability and responsiveness, with a focus on minimal clinical difference values, and perhaps more importantly minimal clinically important difference values to enable clinicians and patients to understand when a meaningful change has occurred (Ostler, Scott, *et al.*, 2022).

Outcome measure development may need to be undertaken where there are gaps in coverage of the models' domains. In light of previously described barriers to outcome measurement in clinical settings, such as a lack of time (Hafner *et al.*, 2017), future work could focus on creation of a new multi-domain PROM which captures the ECLIPSE model domains within one measure. Work undertaken in this PhD could underpin the creation of a new PROM embedded in the experiences of lower limb prosthetic users.

In light of poor representation of participants from LMICs in the development of the ECLIPSE model, future work should also consider outcome domains of importance in different social and cultural settings, as well as considering the impact of different healthcare systems in LMICs, and within private/insurance-based systems. Research could focus on whether domains differ across the world to help inform global data collection initiatives and ensure measurement is relevant to different settings.

Finally, future work is required to further understand outcome measurement practice in the context of wider prosthetic routine healthcare data collection. Little is known about how clinical services collect and use data, including outcome data, how data could be of value to patients and clinicians, and what the barriers and facilitators to outcome measurement across the MDT are. The author of this thesis, in collaboration with the project supervisors and academics from Nottingham Trent University has recently been awarded an NIHR Research for patient benefit grant to explore this problem and consider what is required to develop a nationwide prosthetic data collection initiative. The lay summary for the project can be found in Appendix L. By understanding current data collection and outcome measurement practice from the perspective of patients, clinicians, and wider stakeholders we can work towards a national data collection initiative that enables data driven care environments throughout prosthetic rehabilitation, realising the value of data to improve patient care and outcomes.

6.8 Conclusions

The aim of this research was to understand and contribute to the body of evidence around meaningful outcome measurement following lower limb prosthetic rehabilitation, and drive changes in clinical practice that foster person-centred approaches to measuring outcome. The work described in the four papers which comprise this thesis have attempted to define meaningful outcome measurement as 1) measuring what matters most, 2) using fit for purpose tools that provide useful information to clinical teams, and 3) to practice outcome measurement in a way that uses information to improve patient care and outcomes at the individual, service, and system levels.

This PhD predominantly focused on measuring what matter most by addressing current gaps in the evidence base concerning what outcome domains to measure following prosthetic rehabilitation from the patient's perspective. Papers two and four used different research methods to explore what patients felt were outcome domains of importance, allowing triangulation around this phenomenon, and leading to the rigorously developed ECLIPSE model.

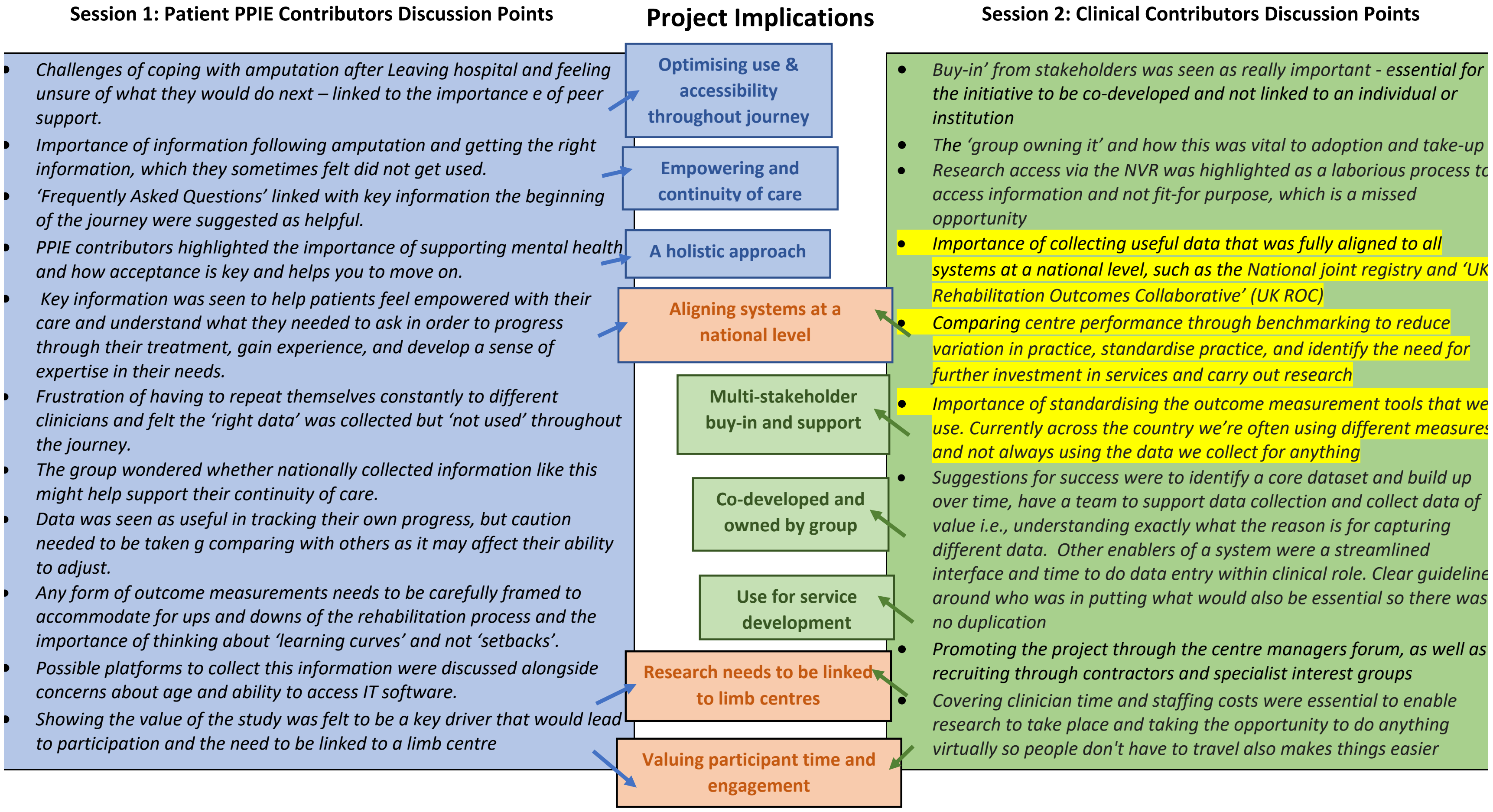
The ECLIPSE model provides a patient-centred, accessible model of outcome domains of importance. It describes five core domains and presents the associated subdomains to promote greater understanding. Domains of importance have been highlighted as 1) I am able to participate in my important activities and roles, 2) I am able to participate in the way I want to, i.e., independently, easily and well, without falling over and with as little equipment as possible, 3) my prosthesis works for me, 4) If I am in pain, I am able to manage it and 5) I am able to accept my new normal.

The model can be used to direct the selection of outcome measures, or the focus of rehabilitation to ensure services consider success as defined by prosthetic users. The ECLIPSE model could contribute to a future prosthetic rehabilitation core outcome set or represent a *patient* core outcome set in its own right. Using the model to identify outcome measures could indicate areas where future tools need to be developed or focus psychometric testing on specific measures, helping to generate tools that are fit for purpose and provide patients and clinicians with useful information. Future work could focus on developing a patient-centred PROM based on the ECLIPSE model, which captures all domains of importance and enables consideration of how domains interact during recovery. Patient-centred outcome measures would contribute to a minimum data set for prosthetic rehabilitation and support future data driven care environments.

This PhD also presented insights into outcome measurement practice, through paper three, which consider the patient's perspective. Novel insights indicated that outcome measurement can have both a positive and negative impact on patients. Outcome measurement could be used to motivate patients, improve communication, and support adjustment, however the potential for negative responses should not be overlooked. Adopting a patient-centred approach could make outcome measurement more meaningful and therefore beneficial for patients themselves.

Further research is needed to provide greater understanding of outcome measurement practice from the patient's viewpoint as well as from the perspective of wider stakeholders in prosthetic rehabilitation, especially when positioned within a multi factorial data driven care environment. Research is also required to explore the requirements of a data driven care environment, especially considering it from a patient-centred perspective. A recently awarded NIHR Research for Patient Benefit grant will continue this work to understand and develop data collection, and measurement processes that are meaningful, add value to prosthetic rehabilitation and realise the potential of data to improve patient care and outcomes.

Appendix A Patient and public involvement report



Session 1: Patient PPIE Contributors Discussion Points

- *Challenges of coping with amputation after Leaving hospital and feeling unsure of what they would do next – linked to the importance e of peer support.*
- *Importance of information following amputation and getting the right information, which they sometimes felt did not get used.*
- *'Frequently Asked Questions' linked with key information the beginning of the journey were suggested as helpful.*
- *PPIE contributors highlighted the importance of supporting mental health and how acceptance is key and helps you to move on.*
- *Key information was seen to help patients feel empowered with their care and understand what they needed to ask in order to progress through their treatment, gain experience, and develop a sense of expertise in their needs.*
- *Frustration of having to repeat themselves constantly to different clinicians and felt the 'right data' was collected but 'not used' throughout the journey.*
- *The group wondered whether nationally collected information like this might help support their continuity of care.*
- *Data was seen as useful in tracking their own progress, but caution needed to be taken g comparing with others as it may affect their ability to adjust.*
- *Any form of outcome measurements needs to be carefully framed to accommodate for ups and downs of the rehabilitation process and the importance of thinking about 'learning curves' and not 'setbacks'.*
- *Possible platforms to collect this information were discussed alongside concerns about age and ability to access IT software.*
- *Showing the value of the study was felt to be a key driver that would lead to participation and the need to be linked to a limb centre*

Project Implications

Optimising use & accessibility throughout journey

Empowering and continuity of care

A holistic approach

Aligning systems at a national level

Multi-stakeholder buy-in and support

Co-developed and owned by group

Use for service development

Research needs to be linked to limb centres

Valuing participant time and engagement

Session 2: Clinical Contributors Discussion Points

- *Buy-in' from stakeholders was seen as really important - essential for the initiative to be co-developed and not linked to an individual or institution*
- *The 'group owning it' and how this was vital to adoption and take-up*
- *Research access via the NVR was highlighted as a laborious process t access information and not fit-for purpose, which is a missed opportunity*
- *Importance of collecting useful data that was fully aligned to all systems at a national level, such as the National joint registry and 'UK Rehabilitation Outcomes Collaborative' (UK ROC)*
- *Comparing centre performance through benchmarking to reduce variation in practice, standardise practice, and identify the need for further investment in services and carry out research*
- *Importance of standardising the outcome measurement tools that we use. Currently across the country we're often using different measures and not always using the data we collect for anything*
- *Suggestions for success were to identify a core dataset and build up over time, have a team to support data collection and collect data of value i.e., understanding exactly what the reason is for capturing different data. Other enablers of a system were a streamlined interface and time to do data entry within clinical role. Clear guideline around who was in putting what would also be essential so there was no duplication*
- *Promoting the project through the centre managers forum, as well as recruiting through contractors and specialist interest groups*
- *Covering clinician time and staffing costs were essential to enable research to take place and taking the opportunity to do anything virtually so people don't have to travel also makes things easier*

Appendix B Paper one publication in Prosthetics and Orthotics international

Narrative Review

Prosthetics and Orthotics International

From outcome measurement to improving health outcomes after lower limb amputation—A narrative review exploring outcome measurement from a clinical practice perspective

Chantel Ostler[1], Helen Scott[2], Imad Sedki[3], Sisary Kheng[4], Margaret Donovan-Hall[5], Alex Dickinson[5] and Cheryl Metcalf[5]

Abstract

Outcome measurement is essential to understand the impact of clinical interventions and the performance of services. Despite national and professional body encouragement, and successful examples of system level outcome measurement within some health care settings, many barriers still exist preventing outcome measurement from becoming embedded in clinical practice. This paper presents a narrative review which aims to describe the state of the outcome measurement evidence base in prosthetic rehabilitation, as applied in clinical practice, with a view to identifying areas for future work aimed at making outcome measurement in prosthetic rehabilitation a meaningful reality. A literature search of four databases was undertaken, following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis principals appropriate to narrative reviews, and using the search terms outcome, measur*, tool, scale, instrument, prosthe*, amput* and limb loss. A total of 1116 papers were identified. Following screening 35 papers, focusing on four main themes, were included in the review. Themes were: 1) What outcome domains should be measured? 2) How can these outcome domains be measured? 3) What are the barriers to outcome measurement? and 4) What can be learnt from examples of ROM in prosthetic rehabilitation? Findings suggest that successful outcome measurement is multifaceted. Understanding and embedding value at every step appears to be key to success. Addressing the questions of 'what' outcome domains to measure and 'how' to measure them, may help establish consensus. Routine outcome measurement practice at the clinical level should ensure data collection is valuable to clinical practice, makes use of information technology solutions and has organisational engagement.

Keywords

outcome measurement, prosthetic limbs, amputation, rehabilitation, prosthesis, value, clinical practice

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Background

Measuring health outcomes is especially relevant in today's increasingly evidence-based health services. When facing growing demands on resources, as well as the expectation of a culture of continual improvement, services need to consistently demonstrate their value and impact.[1] Outcome information can provide an understanding of the impact health services and interventions have on the health and well-being of patients.

The term outcome measurement can be better understood by breaking it down into the outcome domain being measured and the measurement tool used for the task. An outcome domain can be defined as an element of health (i.e. pain, physical function, emotional well-being, or social activity) that is changed by a particular intervention.[2] A measurement tool can be defined as a standardized instrument used in research and clinical practice to capture and evaluate this change.[3]

Within clinical practice, outcome measurement in the form of professional reported measures, performance-based measures, or patient/self-reported outcome measures (PROMs)[3] can be used in a number of different ways. On an individual basis, the use of an outcome measure (OM) can be helpful to capture changes in a patient's status after an intervention or when monitoring patients over time.[3] This information can be shared with the patient to review progress throughout rehabilitation, and increase motivation, or can be used by the clinician to highlight areas of concern, direct treatment planning, or justify requests for the funding of interventions or devices,[4] for example, the National Health Service (NHS) England Microprocessor Knee Policy within the United Kingdom.[5]

A more coordinated approach to outcome measurement along a pathway of care can be described as routine outcome measurement (ROM). ROM is defined as "the systematic use of a standardized OM(s) in clinical practice with every patient as part of a standardized assessment practice guideline."[6] This systematic approach to outcome measurement can provide individual services or departments with a wealth of information on the quality of care and interventions they are delivering.[7] Data can be

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used to direct and inform improvement work and evaluate the changes resulting from services or departments developing new ways of working. When coordinated ROM is commenced in a number of services, benchmarking can be undertaken[8] and a system-wide approach adopted, that is, undertaken across organizations that deliver the same services to a target population. This system-level approach to ROM can be useful in several contexts, especially if widely accessible. It allows comparison of the performance of different healthcare providers and gives patients valuable information on the best performing organizations, enabling informed decisions on where to receive care.[1] Benchmarking can also help to identify services where outcomes are good and use those as exemplars to raise standards across the NHS, reducing variation in the system. Collating large data sets concerning a specific population, such as lower limb amputation, can also be useful for research purposes to strive to understand, and influence, the factors that may have an impact on clinical outcome.

Outcome measurement is crucial to inform and therefore improve clinical decision-making. If healthcare services want to ensure they are delivering the most effective care, they need information, specifically about the outcome of care, which can both direct the focus of meaningful improvement programs and evaluate their impact.[9]

The potential for using ROM to evaluate, inform, and improve clinical practice at the system level has been realized in several UK clinical settings. Two notable examples are the NHS PROMs programme and the UK Rehabilitation Outcomes Collaborative (UKROC).

The NHS England PROMs programme[10] collects PROMs data for hip and knee replacements, before and after surgery. Data are collected nationally and allow comparison of surgical centers and informed patient choice of centers with the best outcomes. Crucially this program is linked to the National Joint Registry, which collects implant safety data from across the United Kingdom on all joint replacement surgery.[11] Combining these data sets allows the value of joint replacement on patients' lives to be assessed, as well as a comparison of the performance of different implant componentry, providing evidence for interventions, service performance, patient safety, and component selection.[12]

UKROC applies system-wide ROM in the context of rehabilitation and aims to provide data that can inform the provision of cost-effective neurorehabilitation services in the NHS.[13] The collaborative developed a national clinical database combining data on rehabilitation needs, the interventions patients received, and importantly their outcomes. Data collected were used to demonstrate that specialist neurorehabilitation was a highly cost-effective intervention compared with potential lifelong care needs. This evidence led to significant investment in rehabilitation services throughout the NHS, alongside the development of evidence-based standards of care that have reduced variation across the system and driven up quality.[14]

However, even within these valuable examples of system-wide ROM, engaging clinicians in outcome measurement is a challenge,[15] and it is widely acknowledged that OMs are not routinely used in clinical practice.[4] NHS policy[16] and prosthetic rehabilitation professional bodies, such as the British Association of Prosthetists and Orthotists and the British Associations of Chartered Physiotherapists in Amputation Rehabilitation, have issued advocacy and guidance on OMs in clinical services.[17,18] However, the use of OMs has yet to become embedded, and there is currently no UK outcome data collection initiative capturing the inherent usefulness of this information after amputation.[4] Despite the common view that it is due to ambivalence of clinicians[19] and a resistance to change and innovation among service providers,[20] a systematic review by Duncan and Murray[4] exploring barriers and facilitators to OM use among allied health professionals (AHPs) suggests this is not the case. Successful implementation needs multifactorial efforts, overcoming barriers such as lack of time, unfeasible OMs, perceived lack of value in measurement, and insufficient organizational support.

To make ROM a meaningful reality after lower limb amputation, which has the potential to evaluate and direct improvements in the care provided to patients, it is important to understand what is already known about outcome measurement within this context. As described above, there are many factors that may need to be identified and considered in this setting. Therefore, a narrative review has been undertaken to enable a broad approach to surveying and critically synthesizing the current state of knowledge on outcome measurement within the field of prosthetic rehabilitation and identify problem areas for future work that will have clinical value.

Methods

Narrative approach

A narrative approach was chosen for this review to allow for a broader exploration of the outcome measurement literature within the prosthetic rehabilitation evidence base. This broad approach fits well with the narrative review methodology because it does not stipulate the formulation of a specific research question, as required for scoping or systematic reviews, which may have resulted in relevant issues being overlooked.[21] For example, a review of systematic reviews in Norway, generated to inform policy-making, found that the evidence base included in the systematic reviews was narrow and represented only a small proportion of questions relevant to public policy.[22]

However, there has been much criticism of narrative reviews in the past, and they have often been described as inferior to systematic reviews.[23] Criticism includes the absence of a method that can be peer reviewed, or the potential introduction of conscious or unconscious bias by the researcher because they select studies to be included without any inclusion or exclusion criteria, or quality assessment.[24] More recently, Furley and Goldshmeid[25] challenged this hierarchical stance and suggested that narrative reviews should be seen as complimentary to systematic reviews rather than inferior. They suggested that the lens of the authors—in this case a range of experienced interdisciplinary international clinicians and academicians working within the field of prosthetic rehabilitation—can be used to help those viewing outcome measurement through a similar lens and to understand the implications of the evidence. Perhaps in a similar way to qualitative research, where the researcher is seen as part of the research process and encouraged to be reflexive about their impact, the role and assumptions of the researcher in narrative reviews should also be considered.

Greenhalgh et al[23] also suggested that narrative reviews can be an important start in a field where little is known or summarized about a subject, such as outcome measurement in prosthetic clinical practice. This approach can help contextualize the evidence base and pose unanswered questions for more informed future work.[23] The voice of the clinical narrative thread may have been lost within the constraints of more systematic methodologies[26]; therefore, this broad overview may be a useful starting point which sets the scene for more systematic approaches in the future. However, in light of published criticisms, in order for a narrative review to be meaningful, a rigorous approach should be adopted, using processes drawn from systematic reviews, such as search methods, selection criteria, data extraction, and interpretation.[25,26]

Search strategy

A literature search was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis principles appropriate to narrative reviews, as set out by Ferrari,[26] and is described here in two steps. Step 1 describes the initial literature search and the selection of articles from reviewing titles and abstracts. Step 2 describes the selection of articles after full-text review and inclusion of additional papers identified through searching reference lists and gray literature sources.

Step 1

The CINAHL, Medline, ScienceDirect, and PsycInfo bibliographic databases were searched in July 2020. The keyword outcome AND (measur* OR tool OR scale OR instrument) was combined with AND (prosthe* OR amput* OR "limb loss") and searched in titles and abstracts. An English language filter was used with no specified date range to include all relevant publications. This identified 1116 papers, which after the removal of duplicates was reduced to 777 records. The following selection criteria were used to identify relevant papers, from the 777 records identified, for full-text review:

Inclusion criteria were as follows:

- papers exploring how to measure outcome after lower limb amputation,
- papers that focused on outcome measurement in prosthetic clinical practice settings, and
- papers describing outcome measurement tool development or psychometric property testing for use after lower limb amputation.

The exclusion criterion was as follows:

- studies using outcome measurement for research purposes.

This resulted in 78 papers for full-text review.

Step 2

Step 1 yielded a number of Systematic Reviews (SRs) (10) exploring the development and psychometric properties of OMs for use after lower limb amputation. Primary studies of individual OMs were therefore excluded to avoid duplication. The following exclusion criteria were added:

- primary studies exploring the development of outcome measurement tools and
- primary studies exploring the psychometric properties of outcome measurement tools.

This resulted in 25 papers. An additional 11 papers were identified through searching of reference lists and gray literature sources. Thirty-six papers were therefore included in the narrative review. See Figure 1.

Critical assessment

Because the aim of this review was to explore the current state of knowledge, including gray literature, no formal critical appraisal tool was used to exclude any papers based solely on their quality. However, principles of critical appraisal were integrated throughout the review to evaluate and highlight any variability in the quality of the evidence. This approach was taken to ensure all key issues were included at this early scoping stage.

Data extractions and theme development

Key themes were developed to synthesize findings across the papers. This involved the lead author reading and critiquing the papers, and developing early concepts, which were discussed and refined with the wider team into a clear set of initial themes. These themes were then reviewed and posed as questions to directly address the narrative review aims to (1) survey the state of knowledge on outcome measurement within the field of prosthetic rehabilitation from a clinical practice perspective and (2) identify areas for future work aimed at making ROM a meaningful reality in clinical settings. The four themes are as follows:

- *What outcome domains* should be measured?
- *How* can these outcome domains be measured?
- *What are the barriers* to using OMs?
- *What can be learned* from examples of ROM in prosthetic rehabilitation?

Results

What outcome domains should be measured?

In 2014, a study by Heinemann et al[27] identified 43 unique measurement instruments designed to capture outcome after lower

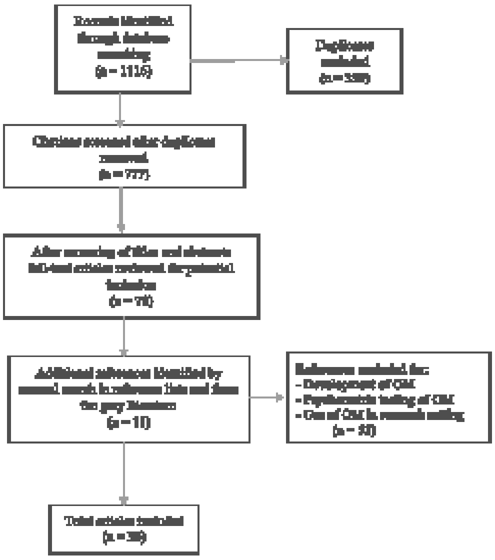


Figure 1. Narrative review process flow chart.

limb amputation. This wide variety of tools measured an extensive range of outcome domains, such as mobility, falls risk, balance, function, quality of life, socket comfort, psychological adjustment, and satisfaction with devices and services. In a number of cases, many tools or tests had been developed to capture the same domain, that is, mobility. Several authors exploring measurement tools have raised the issue that there is no consensus around which tools should be used.[28,29] This plethora of tools and absence of consensus also seems to be evident in the current UK health policy and professional guidance, where long lists of OMs are suggested for use in the Prosthetic National Service Specification,[30] the NHS Microprocessor Knee Policy,[5] the British Associations of Chartered Physiotherapists in Amputation Rehabilitation OMs toolbox,[18] and the British Association of Prosthetists and Orthotists OM guidance.[17] These resources seem to recommend the use of many different measures, with little consistency, and often include different measures that capture the same outcome domain.

This lack of consensus around measurement tools is a major barrier to system-wide ROM but may in fact be underpinned by another lack of consensus, that is, what outcome *domains* should be measured. This raises two separate unanswered questions within the field of lower limb prosthetic rehabilitation: *What* outcome domains should be measured and *how*, that is, with which tools, should they be measured? The studies identified in this review addressing *what* outcome domains should be measured will be discussed in this theme. Studies exploring *how* they should be measured will be reviewed in the theme exploring outcome measurement tools.

Three studies were identified that explored the theme of *what* domains should be measured. A study by Xu et al[31] approached this question by exploring possible outcome domains that capture the concept of health, as defined using the International Classification of Functioning. The authors identified a core set of International Classification of Functioning domains which define health as it applies to people after amputation. Currently, this work has yielded large numbers of domains which could be measured. However, capturing them all may be impractical in clinical practice, and this approach does not give an indication of which of the domains may be most meaningful to measure, especially to prosthetic users themselves, for whom the outcome of prosthetic rehabilitation has the greatest impact.

A more patient-centered approach to outcome measurement in prosthetics was called for in a review by Gallagher and Desmond in 2007[32] who suggested measuring quality of life may be an important first step in this process. Subsequently two studies have taken this patient-centered approach further by using qualitative methods to explore outcome domains that matter to patients. McDonald et al[33] used focus groups to explore meaningful outcome domains when prescribing prosthetic feet, and Schaffalitzky et al[34,35] explored user, clinician, and wider stakeholder views on the outcome of prosthetic prescription through interviews, focus groups, and a Delphi consensus process. Both studies focused on the prescription of components rather than holistic rehabilitation postamputation, and McDonald et al[33] only included six participants. However, they found that qualitative methodologies work well to explore successful prosthetic prescription and highlighted outcome domains that were important to users such as balance and safety, independence, and not being in a wheelchair. Interestingly Schaffalitzky et al[34] also found that clinicians and patients often prioritized different domains, that is, quality of life, which was prioritized as a domain by clinicians but not by prosthetic users. Users instead seemed to describe *the ways* in which their quality of life could be improved as the important domains. Because clinicians are most likely to select what outcome domains are measured, it is possible that services may not be capturing the outcome domains that really matter.

Despite this valuable exploratory work, domain consensus remains elusive in prosthetic rehabilitation and without understanding *what* domains to measure, achieving consensus around *how* to measure them becomes even more challenging. Despite this many of the studies identified in this review focus on how to measure outcome, which will be discussed in the next theme.

How can these outcome domains be measured?

The main focus of the outcome measurement literature identified in this review was the development and psychometric testing of measurement tools themselves. Ten SRs were identified in the literature which collated and critiqued measurement tools for use after lower limb amputation (Table 1). The tools identified in the reviews varied in the quality of their methodological development and the different psychometric properties which had been investigated (i.e. the level of measurement, validity, reliability, and responsiveness).[36] Seven of the SRs used scoring systems to rate the quality of the instruments they included; however, different scoring approaches led to variation in recommended measures.[37–43] This variation, in combination with large numbers of measures, and gaps in the reporting of psychometric properties for many measures, may contribute to a lack of 'gold standard' OM or OM consensus. In the most recent SR by Balk et al, the need for a core set of validated OMs is raised to enable comparability across studies and increase their overall value.[37]

Among the many outcome measures described in these SRs, two reviews[27,37] included measures that use item banks (Patient-Reported Outcomes Measurement Information System [PROMIS] and the Prosthetic Limb Users Survey–Mobility [PLUS-M][44]), which have interesting implications for clinical practice. An item bank, developed using item response theory,[45] consists of different questions exploring the same outcome domain, which are individually validated and calibrated on a single scale. The items from the bank can then be used as required by individual clinicians or researchers to develop specific short forms or be administered through computer adaptive testing.[46] Computer adaptive testing uses algorithms to select items from the bank for individual patients based on their responses to previous questions.[47] This tailored approach is able to achieve the same reliability with fewer questions therefore reducing the measurement burden on patients.[46] Despite the use of different questions with each patient, the results are comparable because all items in the bank are drawn from the same scale. Both the PROMIS and the PLUS-M item banks allow comparison of scores to a large development sample allowing clinicians to compare scores with normative data. In the case of the PLUS-M, these data are specific to the limb loss population. Normative data for an outcome measure can be useful for clinicians to compare individual patient or service outcome scores, giving meaning to scores because they are viewed in the context of the wider limb loss or general population. However, few measures for use after amputation have published normative data.[40]

Despite the advantages of this approach, as with all OMs, consideration must be given to the population used to develop the OM or select items for an item bank, especially in limb loss research

Table 1. Summary of systematic reviews of outcome measure tools for use after lower limb amputation.

Authors	Outcome domains included	Key findings
Rommers et al 2001[28]	Mobility	19 different measurement tools were identified that differ in method and measuring range, and there is no consensus about measuring mobility in the current literature.
Condie et al 2006[29]	Mobility Function Quality of life	25 measurement tools were identified from 28 different studies. The complexity of studies makes it too difficult for clinicians to use the findings in the literature to inform their choice of outcome measure.
Deathe et al 2009[43]	ICF domain of activity	17 instruments were identified, but there is a lack of evidence about the responsiveness of all measures included.
Hebert et al 2009[40]	ICF domain of body function and structure	16 measurement tools were identified, but not many comprehensively validated tools exist to measure the domain of body function and structure. For all the tools identified in this review responsiveness to interventions has not been established.
Xu et al 2011[31]	All domains measured after limb loss	113 outcome measures were identified. 90% of the concepts measured could be linked to ICF categories, and these categories could be used to develop an ICF core set for amputation.
Heineman et al 2014[27]	Mobility Function Quality of life	This review replicated the review by Condie et al 2006 to update the evidence base. Only a few of the included measures present MCID values which is vital for tools to be clinically useful, and significant work is required to develop both these values and population norms.
Hawkins 2014[38]	Function Quality of life	21 different assessment tools were identified from 40 studies. Only 5 tools were used in more than 3 studies, and the heterogeneity of the measures used makes it difficult to compare lower limb outcome studies.
Scopes 2016[42]	Physical function	37 measures were identified, but there is a paucity of high-quality studies exploring the psychometric qualities of outcome measures of physical function. The responsiveness of these measures is generally unknown and limits their use in evaluating the effectiveness of interventions.
Resnick et al 2017[41]	Participation	34 measures and 94 subscales were identified, but most measures had limited evidence around psychometric properties.
Balk et al 2019[37]	Function Ambulation Quality of life	50 instruments were identified, but the numerous instruments available have variable psychometric properties, and there is no evidence as to whether tools designed for use or used prior to prosthetic prescription are predictive of outcome.

Abbreviations: ICF, International Classification of Function; MCID, minimal clinically important difference.

which can oversample people with traumatic limb loss[48] and those living in high-income countries. This may raise questions about how transferrable OMs are to different populations and subgroups who were not well-represented by the development sample, that is, older dysvascular patients, or those from different social and cultural backgrounds. This is a global consideration for the OMs described in the SRs. Many of the measures have been developed in English and although some have now been translated and validated in other languages, which is important for use in today's diverse society, and across the world, the challenges of using OMs in different languages is not just about translation. Ensuring the measure is meaningful in different social and cultural settings is often overlooked, for example, measuring an individual's ability to stand from a chair may not be as meaningful in countries where much time is spent sitting or squatting at floor level.

However, whatever the measure, a key concern highlighted in seven of the 10 SRs was responsiveness or the ability to detect change when it has occurred,[27,29,38-40,42,43] which is a priority when using OMs to evaluate rehabilitation interventions in clinical settings.[49] Many of the SRs described an absence of data regarding the ceiling or flooring effects of OMs.[38,43] The presence of a ceiling or flooring effect limits a measures' ability to detect change at either end of its scale. In a population where outcomes of rehabilitation can vary substantially between young individuals with a transtibial amputation and more elderly dysvascular persons with a transfemoral amputation, this information is crucial to help understand whether a single measure can be used to capture the outcome of the limb loss population as a whole or whether different OMs are required for subsets of the population, that is, high activity patients, to generate more meaningful information for clinical practice.

When considering the responsiveness of an OM, two important values exist to help clinicians interpret OM findings, the minimal detectable change (MDC) and the minimal clinically important difference (MCID) values. The MDC is the smallest change that can be detected by the OM which is not due to an error in measurement, that is, a real change,[50] and the MCID is the smallest change in the score that indicates an important change for the patient, that is, a meaningful change.[51] Five of the systematic reviews described OMs with these values.[27,37,39,42] MDC (or its equivalent values, i.e. smallest detectable difference, smallest detectable change, and smallest real difference) was established for 20 measures, whereas three reviews identified only two measures with an MCID value.[37,39,42] Although the MDC value can be useful clinically, without MCID values, clinicians and patients do not know whether the change they have recorded represents a meaningful change to patients' lives, whether clinical interventions were effective, and importantly, whether the investment in rehabilitation was justified. However, reflecting on the first theme of this narrative review, MCID values may only be truly meaningful if the OM captures an outcome domain which is meaningful to the patient's perception of recovery in the first place.

For clinicians, evaluating and understanding the OMs evidence base presented in these SRs to help make an informed choice of which OM to use can be challenging. This has been attributed to the technical nature and jargon-filled literature describing psychometric properties, as well as considerations over tool development and the appropriate population for use.[29,39] This process may be especially challenging when considering ROM at the service or system level, where OM selection is not guided by an individual patient's problems or needs.

What are the barriers to outcome measurement?

Several studies (4) have explored OMs in prosthetic practice in an attempt to understand what factors may influence their use[52-55]; however, it should be noted that two of them focus on the same group of clinicians.[52,53] The barriers identified in this review focus on the experiences of prosthetists, of whom only 28%–44% describe themselves as routine users of OMs.[42,52,53,55] Interestingly, a thesis study of physiotherapists working in amputation rehabilitation settings found that 100% used OMs regularly, but no information was available exploring the drivers for this level of engagement.[42] Therefore, our understanding of the barriers to outcome measurement in prosthetic rehabilitation is limited to the perceptions of prosthetists, which may not reflect the views of the wider prosthetic rehabilitation multidisciplinary team.

In all the studies included in this theme, insufficient time was identified as a key barrier because clinicians struggled to integrate outcome measurement into their usual clinical routines.[52,53,55] Although time was identified as a barrier, the studies did not objectively produce an actual time for OM administration, suggesting that time may be more of a perceived than an actual barrier. A further impediment to the use of OMs identified in these studies was an often described lack of confidence and knowledge of the tools themselves. Challenges are commonplace, including choosing a measure that is meaningful, psychometrically sound, and easy to use and interpret within a clinical session. These challenges are reportedly particularly difficult for many clinicians who lack knowledge and understanding in this highly technical field, which is not always covered at an undergraduate level.[52,53,55]

An interesting finding from the study by Hafner et al[52] exploring perceptions of outcome measurement among 66 US prosthetists showed that a third of participants did not agree that outcome measurement provides useful data. The issue of the value of outcome measurement for clinicians was highlighted again in the same study where prosthetists reported they were more likely to use the Amputee Mobility Predictor[56] measure than the quicker-to-administer Timed Up and Go.[57] The authors discussed that this may be because the Amputee Mobility Predictor was designed to guide the prescription of prosthetic componentry to insurance companies. This is supported by a study from Borrenpohl et al[58] who found that regular OM use increased to 77% when prosthetists were specifically asked about using OMs to support payment claims. These findings demonstrate the impact of the perceived value in engaging clinicians in the measurement of outcome.

Solutions to address these barriers were also discussed in the same articles. The need for efficient measures, use of PROMs instead of more time-consuming observed measures, and electronic data collection at the point of care, which is integrated with health records, were all suggested to help overcome time-related barriers.[52,53] An educational program focused on improving prosthetist knowledge and skills concerning outcome measurement was tested by Gaunard et al and was found to improve confidence, which was maintained 1 year later.[52] However, these findings should be viewed with caution because they did not include a control group, and participation in the studies may have been more attractive to those who were particularly interested in learning about outcome measurement.

What can be learned from examples of ROM in prosthetic rehabilitation?

Despite the many barriers identified in this review, examples of system-wide ROM in prosthetic settings were identified and have been explored in this theme to consider any learning for future work. A single study by Heinemann et al explored the use of routinely collected PROMs data to inform quality improvement (QI) activities across seven US prosthetic clinics.[54] The authors described the implementation of ROM as challenging with only two of the seven clinics involved actually collecting enough data to undertake QI projects.[54] However, because the study was undertaken as research, there was a higher administration burden, which was identified by the authors as the main factor for clinics dropping out.[54] Clinics that were successful in implementing ROM demonstrated high levels of organization related to the project, integrated data collection with their electronic records, and had well-defined pathways of care. Clinicians in these centers reported being motivated by the chance to use PROMs to improve the care they provided to patients; however, expert external facilitation was described as being crucial to increase QI knowledge within the clinical team, interpret aggregated data, and translate ROM findings into improvement work.[54]

Two further examples of ROM identified in this review can be found within national registries, and as with the National Joint Registry, they attempt to link demographic, surgical information and interventions with outcome data to understand the impact of lower limb amputation on patients, healthcare providers, and society. Although in some cases registries can operate separately from clinical settings and may seem inaccessible to clinical practice, they are often dependent on clinical services to collect and input data (i.e. the two examples included). This requires the implementation of data collection processes, including ROM, and therefore,

these examples have been included in this theme as they may provide interesting insights.

The two registries identified in this review are the Scottish Physiotherapy Amputee Research Group (SPARG) data initiative which collects data on all patients undergoing amputation in Scotland[59] and SwedeAmp which is the national lower limb amputation registry from Sweden.[60] Both registries attempt to evaluate the whole pathway after lower limb amputation, collecting demographic details, surgical and rehabilitation interventions, prosthetic supply, and outcome information, in partnership with local clinicians and services. For SwedeAmp, the authors describe implementation across the country as slow, and after 9 years, the registry only captures 62% of amputations,[60] perhaps illustrating the challenges related to multidisciplinary system-level data collection. Despite this, data were collected on 5762 people after amputation; however, the size of the sample described in the presentation of outcome data collected at 12 and 24 months, using the EQ-5D-5L, had notably decreased to n = 247 and n = 156, respectively. No information was presented to explain this outcome measurement attrition, but insights from the project team would be useful to reflect on ROM in these settings.

By contrast, SPARG, which is a small group of 20 clinically based physiotherapists, currently captures 90% of amputations in Scotland and has been conducted for more than 20 years.[52] The size and uniprofessional nature of the group may account for its success in data capture, alongside the availability of disaggregated data for benchmarking, and ongoing improvement work,[61] but also places a limitation on the scope of the data set.

These projects demonstrate that system-wide data collection of outcome information is possible in this field. Further publications regarding the implementation of these registries, especially regarding ROM implementation and data collection by clinical partners, may have value for the development of similar projects elsewhere. The potential value of the experiences of the SPARG and SwedeAmp creators may also include understanding how the outcome domains were selected and why, how the data are shared with clinical practice, and how it informs local and national improvement activities, as well as how data privacy, security, and governance were addressed, and finally how the barriers described in this review were overcome.

Discussion

This review has identified many barriers to outcome measurement in prosthetic rehabilitation; however, the examples of system-wide outcome measurement presented here also give an indication of what may facilitate ROM in prosthetic clinical settings and suggests that barriers can be overcome, but important lessons may need to be learned to ensure success.

Despite the fact that only the views of prosthetists have been explored regarding outcome measurement in prosthetic clinical practice, their experiences are mirrored by those of other AHPs documented in the wider literature. Insufficient time for both patients and clinicians to complete and score measures in time-pressured clinical consultations, difficulties in selecting a measure, and interpreting results, combined with low confidence and limited knowledge of outcome measurement, are all commonly reported.[4,20,62-64]

This review identified that establishing value in outcome measurement could be a potential facilitator to addressing barriers to implementation. The issue of value has been raised in previous ROM initiatives. A multistakeholder consultation on the NHS PROMS programme in 2017 found that many clinicians and managers believed it was not worth continuing with the program despite 8 years of data collection.[65] The consultation reported that the data collection was not useful to clinical practice and could not be used during clinical consultations and that reports took too long to be published, so findings were out of date.[65] This lack of perceived value was also described in mental health settings where clinicians believed that ROM using the Health of the Nation Outcome Scale was overly bureaucratic, only concerned with performance management, lacked feedback of results, and presented no relative meaning for their role.[66] It seems clear that establishing the value of ROM to clinical stakeholders is key for success.[67-70]

Understanding *what* outcome domains are important and meaningful to measure, especially from the patient perspective, and *how* to measure them effectively after lower limb amputation could help make outcome measurement more useful to all stakeholders and underpin future consensus work. An absence of consensus on outcome measurement[29] is not unique to prosthetic rehabilitation, and attempts have been made to address the issue in several areas of health such as rheumatology[71] and women's health,[72] especially when related to research. The reporting of numerous outcomes in clinical trials can make the synthesis and comparison of different studies near impossible.[73] This problem has led to the development of initiatives such as Core Outcome Measurement in Effectiveness Trials (COMET) who seek to develop consensus around *what* domains to measure through core outcome sets (COS) to be recorded in all clinical trials of a specific condition.[74] They also highlight that this approach can be useful to build consensus around outcome measurement in clinical practice.[73] COMET adopt a multistakeholder approach to identifying outcome domains of importance and seek to build consensus that can then be championed by the stakeholders involved. Importantly, COMET advocate the inclusion of patients at the center of this process, ensuring that a COS is measuring domains that matter most to the people affected by the outcome of an intervention.[73] The studies identified in this review by Schaffalitzky et al and McDonald et al have made some progress toward understanding the domains that define successful prosthetic prescription from a user's perspective, especially focusing on the need to measure psychosocial outcomes.[33-35] Schaffalitzky et al also highlight that clinicians and patients view important outcome domains differently. This difference has been reported in other studies exploring UK orthotists' perspectives of clinical outcomes,[75] and in the development of a COS for rheumatoid arthritis,[76] and suggests that when seeking to build consensus around important outcome domains for measurement, that the patient's voice is properly represented, especially in commonly used, but arguably less accessible, consensus building techniques such as Delphi.[73]

A rigorous foundation understanding which outcome domains are most important after prosthetic rehabilitation could lead to a consensus on outcome domains for measurement both clinically and in research, which would then direct the recommendation, or development of, a set of accompanying OMs. This set would need to play its part in overcoming some of the barriers to measurement described here, such as capturing meaningful changes over time, feasibility of use and ease of interpretation in busy clinics, and not overburdening patients themselves. This process is unlikely to be simple, as highlighted by the UKROC project when developing a national set for neurorehabilitation. They describe a tension between identifying measures that have robust psychometric properties that generate data that are useful for quantitative analysis and measures that are feasible to use in clinical settings and that clinicians themselves *want* to use as part of the clinical decision-making process.[15]

Usefully COMET have also defined "Consensus-based Standards for the selection of Health Measurement Instruments," which is a systematic approach to identifying, selecting, and assessing the quality of relevant tools, to capture the important outcome domains agreed on in a COS,[77,78] thus defining a framework for *how* to measure an outcome.

It seems the final piece in the value puzzle may go beyond *what* to measure and *how* to measure it and focus on how outcome measurement data can be collected and used, which is described here are as outcome measurement practice. This review identified that many prosthetists believed that outcome measurement was not useful[52] which is supported by concerns described in the NHS PROMS programme consultation,[65] mental health examples,[66] and the wider AHP literature.[64]

All these examples report that the ability to use OM data as part of usual care to inform treatment planning and monitor the progress of long-term conditions in real time are key.[52,65,66] The use of electronic record systems, as described by Heinemann as a facilitator of success,[54] is increasing rapidly throughout healthcare organizations and presents opportunities to develop IT that supports OM collection. One of the aims of outcome measurement practice could therefore be to integrate results with clinical records and present findings instantly, enabling real-time use, as well as for locally owned reporting, and upload to national data sets which could be accessed for research.[79] The UKROC programme attributed its consistent high-quality data collection to the fact that OM data collated on their electronic system was available "live" for clinicians. This access combined with careful integration of OMs into all aspects of clinical care, such as managing bed capacity and discharge planning, ensured OMs were useful to clinical teams and promoted delivery of the best care.[15]

Although the use of electronic platforms could allow for less burdensome OM completion, collation, and real-time feedback to clinicians, successful clinical uptake is likely to lie in the cost of the system and the accessibility of both the electronic version of the measure during data collection with patients and the mode of presenting information and reporting in an accessible way for interpretation. A qualitative study of UK orthotists' perceptions of outcome measurement identified technology as a potential enabler of OM use as long as it was usable, enabled interpretation of reports and met clinical need.[75]

Being able to interpret OM data may be key to outcome measurement practice and could improve acceptance, especially when using aggregated OM data.[3,80] Expert external facilitation was championed by Heinemann et al[54] and has been described as part of other system-level OM initiatives.[15] Facilitation could be useful to support clinicians who report low levels of knowledge and confidence in using OMs, as well as working in busy clinical environments where there is often little time for anything other than treating patients.[52,53]

Developing partnerships with academic institutions or QI teams may help clinicians with the interpretation of findings and address educational needs through joint working. Academics often have highly developed data analysis skills and increasingly need to demonstrate the real-world impact of their work, for example, in the UK's Research Excellence Framework and Knowledge Exchange Framework. Clinical academic roles, improvement fellowships, or partnerships with universities could bridge the expertise gap between clinical practice, academia, and QI.[81] This is critically important when attempting to translate outcome data into improvements in care. Outcome data at the service or system level, without the context of the individual patient's problems and goals, do not itself inform what the underlying cause of a poor outcome is, and only indicates where a problem may lie. Further work, as described by Heinemann et al, is then required to investigate causes, implement change, and evaluate its effectiveness.[54,61,81] Individuals with this valuable "know-how" may be critical to making outcome measurement practice really work in multidisciplinary clinical settings.

Limitations

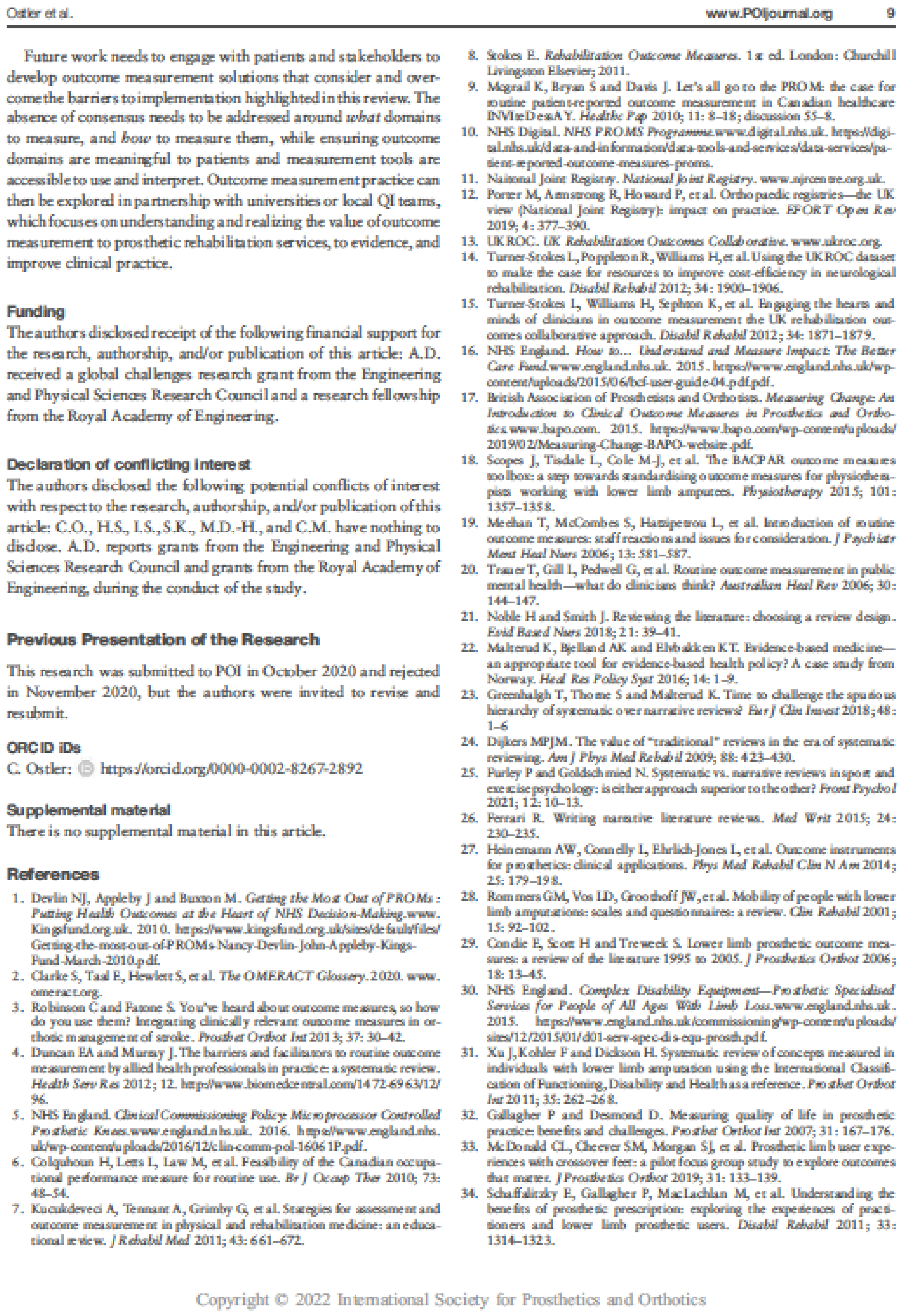
Although a rigorous approach was taken in an attempt to address previous criticisms of narrative reviews,[82] the broad nature of this specific review and the absence of critical appraisal tools may have led to potential bias in the selection of articles deemed as relevant to the aims of the review. For example, the selection of papers for inclusion within the review and the interpretation of the findings were based on what the authors believed was relevant to clinical practice. This could result in bias arising from the authors interpretations and possible "cherry-picking" of papers to address the review aims. However, recent publications by Greenhalgh et al[23] and Furley and Goldschmeid[25] challenge this criticism and suggest no reviews, even systematic ones, are unbiased and that the aim of a narrative review is to interpret the evidence and deepen understanding around a subject rather than just add to the continued assimilation of numbers.[23] This broad overview, with early scoping objectives, should be seen as a useful starting point which sets the scene for more systematic approaches in the future to explore some of the themes identified here in more detail.

It should also be considered that this review identified OMs in the form of scales, tools, or questionnaires and does not include other outcomes that may be in use clinically, or of importance to prosthetic users, such as hours of limb use or limb abandonment.

Conclusion

This narrative review takes a broad look at outcome measurement in prosthetic rehabilitation from a clinical perspective and has suggested that successful implementation is complex and multi-faceted. Understanding and embedding value at every step may be key to success.

Measuring the outcome of interventions is important to understand the impact on patients and the performance of services. However, it is more than just selecting an OM. Clinically, there is a need to understand the "why," "what," and "how" of outcome measurement. "Why" measure, that is, to inform at the individual or system level, "what" domains to measure, that is, capturing outcome domains that are meaningful, and "how" to measure them, that is, the best tools for the job used in a systematic way that adds value to clinical practice.



Future work needs to engage with patients and stakeholders to develop outcome measurement solutions that consider and overcome the barriers to implementation highlighted in this review. The absence of consensus needs to be addressed around *what* domains to measure, and *how* to measure them, while ensuring outcome domains are meaningful to patients and measurement tools are accessible to use and interpret. Outcome measurement practice can then be explored in partnership with universities or local QI teams, which focuses on understanding and realizing the value of outcome measurement to prosthetic rehabilitation services, to evidence, and improve clinical practice.

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Supplemental material

There is no supplemental material in this article.

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Appendix C Infographic for dissemination of Paper 1

RESEARCH FINDINGS

Outcome Measurement following lower limb amputation

A NARRATIVE REVIEW FROM A CLINICAL PRACTICE PERSPECTIVE

Chantel Ostler, Helen Scott, Imad Sedki, Sisary Kheng, Maggie Donovan-Hall, Alex Dickinson, Cheryl Metcalf

Outcome measurement is essential to understand the impact of clinical interventions and the performance of services, but many barriers can prevent it from becoming embedded in clinical practice.

We undertook a narrative review to explore the current state of the outcome measurement evidence base in prosthetic rehabilitation, as applied in clinical practice.

A literature search was conducted using a systematic approach. 1116 papers were identified and following screening 35 papers were included in the review.

WHAT DID WE FIND?

Scan for paper

WHAT OUTCOME DOMAINS SHOULD BE MEASURED?

The review identified an absence of consensus around what outcome domains to measure following prosthetic rehabilitation. This may be because we don't know what outcome domains define success and are most important from a patients perspective

HOW CAN DOMAINS BE MEASURED?

Despite 10 systematic reviews exploring outcome measurement tools there is also no consensus about which measures should be used. Current tools vary in their feasibility for clinical use and whether their validity and reliability has been established. It is also unclear whether current tools/measures can detect change when it has happened

WHAT ARE THE BARRIERS TO OUTCOME MEASUREMENT?

The current evidence base suggests that outcome measures are not routinely used by prosthetists. Key barriers such as the perceived lack of time and difficulty in selecting and interpreting measures were described, along with the view that outcome measurement does not provide information of value to clinical practice

WHAT CAN WE LEARN FROM EXAMPLES OF OUTCOME MEASUREMENT IN THIS SETTING?

3 papers describing routine outcome measurement in prosthetic rehab settings were found. Authors described slow uptake of the process, and that measurement appears to be facilitated by IT solutions and academic support

IN CONCLUSION

Measuring outcome is more than just selecting measurement tools. Clinically there is a need to understand what domains to measure, ensuring they are meaningful indicators of recovery for patients. Tools need to be easy to use and interpret. The practice of outcome measurement should add value to prosthetic rehabilitation.

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People
Powered
Prosthetics

Appendix D Paper two publication in Disability and Rehabilitation

DISABILITY AND REHABILITATION
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ORIGINAL ARTICLE

OPEN ACCESS

Exploring meaningful outcome domains of recovery following lower limb amputation and prosthetic rehabilitation: the patient's perspective

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ABSTRACT

Purpose: There is currently no consensus regarding what outcome domains to measure following lower limb prosthetic rehabilitation. Prosthetic users have a unique insight into important outcome domains, little is currently known about their critical viewpoint.

Materials and methods: A total of 37 participants who underwent lower limb amputation in the last five years were recruited from UK limb fitting centres and social media. Data were collected using focus groups and interviews and analysed using reflexive thematic analysis.

Results: Five themes were identified. 1) The ability to participate in important activities, 2) *how* participants were able to undertake these activities, i.e., independently, with ease, safely and with minimal equipment. 3) A comfortable, easy-to-use prosthesis, 4) the importance of managing pain and finally, 5) adjusting and accepting their new normal. These five themes, or outcome domains, did not exist in isolation, but appeared to interact with each other, contributing to, or inhibiting the participant's holistic sense of recovery.

Conclusions: Understanding important outcome domains that define what recovery means to people following amputation can help to inform domain consensus, as well as direct the focus of rehabilitation. Domain consensus would guide the selection of measurement tools that evaluate prosthetic interventions in a meaningful way.

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KEYWORDS
Outcome; measurement; prosthetic; amputation; qualitative; meaningful; experience; recovery

➢ IMPLICATIONS FOR REHABILITATION

- There is currently no consensus around which outcome domains should be measured following prosthetic rehabilitation.
- Outcome domains of importance from a patient's perspective focus on participation in important activities, prosthesis comfort, pain management, and acceptance of their new normal.
- Identifying these domains can help direct the focus of rehabilitation as well as inform outcome measurement practice.
- The interrelated nature of these domains suggests the need for a physical and psychosocial multi-domain approach to outcome measurement in prosthetic rehabilitation, with patient priorities at its centre.

Introduction

As the demand for healthcare increases [1] and the cost of delivering services to an aging population spiral [2], outcome measurement has been highlighted as central to understanding the value of healthcare provision [3]. The term "outcome measurement" can be better understood by breaking it down into the outcome domain being measured and the measurement tool used for the task. An outcome domain can be defined as an element of health (i.e., pain, physical function, emotional wellbeing, and social activity) that is changed by a particular intervention [4]. A measurement tool can be defined as a standardised instrument used in research and clinical practice to capture and evaluate the change [5].

Within the field of prosthetic rehabilitation, research focusing on outcome measurement appears to centre around the development and analysis of measurement tools [6–15]. For example, a review carried out by Heinemann and colleagues [16] identified 43 different tools for use following lower limb amputation. The wide range of tools available has led several authors to highlight an absence of consensus in the field regarding the use of measurement tools, i.e., which tools should be used to evaluate different domains [6,7]. A recent narrative review [17] suggests that this may be driven by a lack of understanding and consensus around which outcome domains characterise meaningful recovery following prosthetic rehabilitation.

The absence of consensus regarding both outcome domains and measurement tools is problematic for clinical and research settings. In clinical practice, consensus would enable routine measurement of agreed domains, using standardised tools, across prosthetic service providers nationally, and internationally. This information could inform the use of available resources to have

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the greatest impact on patient's lives [3]. Such an approach could also allow benchmarking to identify services where outcomes measured against agreed domains are good and use those as exemplars to raise standards across healthcare providers; reducing variation in the system.

In research, a consensus about what outcome domains are important and should be measured would enable effective comparison and synthesis of studies that evaluate the same interventions. This could contribute to a less fragmented evidence base and reduce research waste [18]. However, consensus is not a problem unique to prosthetic rehabilitation [19,20] and has led to the development of initiatives, such as Core Outcome Measurement in Effectiveness Trials (COMET) [21], and the International Consortium of Health Outcome Measurement (ICHOM) [22]. These organisations take a step back from selecting measurement tools and first seek to develop consensus around *what* outcome domains to measure, in research (COMET), or clinical settings (ICHOM). Both organisations advocate for a multi-stakeholder approach to developing outcome domain consensus, with patients at the centre of the process, as these are the individuals for whom health and rehabilitation interventions have the most impact. Understanding this perspective not only has the potential to direct meaningful outcome measurement but can also provide insight into what domains are most valued by patients and should be the focus of rehabilitation.

Qualitative approaches are increasingly used to explore meaningful outcome domains from the patient's perspective [18]. Within the field of prosthetic rehabilitation qualitative approaches have been highlighted by Murray and Forshaw as important patient centred methodologies for informing healthcare for people with limb loss [23]. A recent editorial by Dillon et al. [24] also encouraged qualitative enquiry in the field of prosthetics, championing its use in informing clinical practice and future research.

Several authors have begun to explore what people who use a prosthetic limb feel are important outcome domains using qualitative approaches. A small body of research has explored this phenomenon within the context of the International classification of functioning (ICF) [25–28]. The ICF is a classification system developed by the World Health Organisation (WHO) to provide a universal language to describe the health and functioning of individuals [29]. It describes a dynamic interaction between many different domains, which can be characterised as body impairments, activity limitations, and participation restrictions, as well as contextual factors, such as environmental conditions and personal factors [29]. The ICF is often used to categorise functional impairment following amputation [30].

Several studies have used qualitative methods to explore the views of patients and clinicians to develop a core set of concepts from the wider ICF that describe function and disability following lower limb amputation. It has been suggested that these core concepts/domains could be used to inform rehabilitation priorities and direct which outcome domains to measure [25–27].

Although large numbers of the concepts identified by patients (92%) and clinicians (82%) in these studies were matched to ICF domains [25,26], not all the concepts aligned. Both studies highlighted that important concepts, such as "socket comfort and appearance" and "acceptance following amputation", could not be matched and were therefore not included [25,26]. In addition to this, ICF core set development uses a deductive approach that follows core set development guidance [31] including questions designed to illicit responses within the ICF domains [25]. This approach may diminish the voice of the patient by limiting the depth and richness of their personal accounts, which could lead to further important domains specific to prosthetic users being misunderstood or overlooked. Although the ICF provides a useful foundation for understanding functioning and disability, exploring outcome domains of importance exclusively within this universal framework may restrict the depth and understanding of the experience of prosthetic limb users.

Two further studies have used more iterative qualitative designs to take a patient centred approach to understanding outcome domains of importance, such as balance, safety, independence, and adjustment to amputation [32,33]. McDonald and colleagues [32] used a qualitative focus group approach to explore domains related to physical function, that were important to five individuals with lower limb loss taking part in a trial of two different prosthetic feet. Schaffalitsky et al. [33,34] also explored the benefits of prosthetic prescription from a patient, clinician, and wider stakeholder viewpoint. Interestingly clinicians and patients often prioritised different domains. As clinicians are most likely to select what outcome domains are measured [32], it is possible that services may not be capturing what patients think are the domains that really matter.

These studies also focused on the outcome of a single intervention in the post-amputation rehabilitation pathway, i.e., the prescription of prosthetic componentry, and did not consider the outcome of a multidisciplinary approach to *rehabilitation* with that device, delivered in a holistic way through a variety of interventions, i.e., physiotherapy, counselling, occupational therapy, etc. Evidence-based guidance from a range of professional bodies involved in prosthetic rehabilitation recommend that recovery following lower limb amputation should be facilitated by a period of multidisciplinary rehabilitation that addresses the physical, psychological, and social needs of the patient, far beyond prescribing them with a prosthetic device [35–38].

There is currently limited research which takes an iterative patient-centred approach to understanding outcome domains that are important to prosthetic users following lower limb amputation, particularly from a holistic rehabilitation perspective. Therefore, the aim of this study was to explore important outcome domains of recovery, from the perspective of people who have undergone prosthetic rehabilitation following lower limb amputation.

Materials and methods

Research design

This research has been developed from a critical realist world view which looks to access the knowable world, in this case, the perceptions of the most important outcome domains following lower limb amputation, within a community of prosthetic users [39]. Due to the exploratory nature of this work, and limited previous research on the topic, an experiential qualitative approach was used independent of any specific theoretical and epistemological stance, such as grounded theory or phenomenology. This open approach, using reflexive thematic analysis [40], fits well with the critical realist world view, seeking to capture the complexity, and diversity of recovery following lower limb loss [39], and will explore and interpret what domains characterise a successful outcome from the perspective of the person with lower limb loss.

Patient and public involvement and engagement (PPIE)

Patient and public involvement and engagement (PPIE) in research is defined as "research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them"[41,42] and is vital to ensure research is focused on issues the public feel are important and is conducted in a participant centred way. As the notions of "outcome" or "domain" may be viewed as "research" or "clinically-focused" concepts, ensuring we were asking about them in a way that people with limb loss found accessible was an important part of our PPIE. We worked closely with a group of public research partners who were established prosthetic limb wearers. The group helped us to think about the language patients may use when talking about outcome domains, as well as practical issues, such as where patients would like to find out about the study and how they might like to take part. This crucial PPIE approach allowed us to co-design the study and study materials, such as the interview guide, to ensure a positive participant experience, maximise recruitment, and develop accessible language around the concept of outcome domains in partnership with patients.

Ethical review

The study was given ethical approval by the East Midlands Research Ethics Committee and the National Health Service (NHS) Health Research Authority (Ref: 8/EM/0259).

Participants

Participants were invited to take part in the study if they were over the age of 18 and had undergone a major lower limb amputation (i.e., an amputation occurring at or proximal to the ankle, due to the extent of the functional impact associated with higher levels of amputation [43]) within the last five years. This was to ensure the clarity with which they were able to recall their rehabilitation experiences. The inclusion criteria also stated that participants must have completed rehabilitation with a prosthetic limb, allowing them to reflect on their own recovery.

A number of recruitment approaches were used to generate a sample with a range of rehabilitation and limb loss experiences relevant to UK practice. Clinical teams (i.e., Physiotherapists, Prosthetists, and Rehabilitation Consultants) working in four English NHS prosthetic rehabilitation centres introduced the study to eligible participants as they completed their outpatient rehabilitation, or returned for follow-up reviews with their prosthetist or multidisciplinary team. Adverts were also posted on social media platforms and invitation letters were sent to limb loss supporting charitable organisations to share with their members.

Sampling was undertaken using a two-staged process using both convenience and purposive sampling that was informed by a demographic questionnaire. This approach was undertaken to build a sample with a diverse range of characteristics, views, and experiences, which are representative of people who undergo prosthetic rehabilitation. The questionnaire collated self-reported information from participants on a variety of characteristics which may influence outcome following lower limb amputation, such as age, level of amputation, presence of co-morbidities, functional status, and social support [44,45]. Convenience sampling was used in stage one and the characteristics of the sample were monitored throughout. This approach led to fewer older transfemoral participants included in the sample than are described in the UK limb loss population [46–48]. The final six participants in the study were recruited purposively. Stage two purposive sampling involved clinical teams approaching participants with the required characteristics (65 years of age or older, and a transfemoral amputation) which were verified prior to consent using the demographic questionnaire.

Procedure

As the aim of the study was to explore and understand the views and experiences of participants, focus groups and semi-structured interviews were used to collect data as these approaches enable follow up questions and contextualisation of answers [39]. The selection of *both* of these methods was on the advice of our PPIE group, to enable and promote participation in a way that individuals found most acceptable and comfortable. As we were talking about life after amputation, which is a complex and life-changing experience, it was anticipated that the choice of how to be involved would allow people to feel more at ease when sharing their experiences.

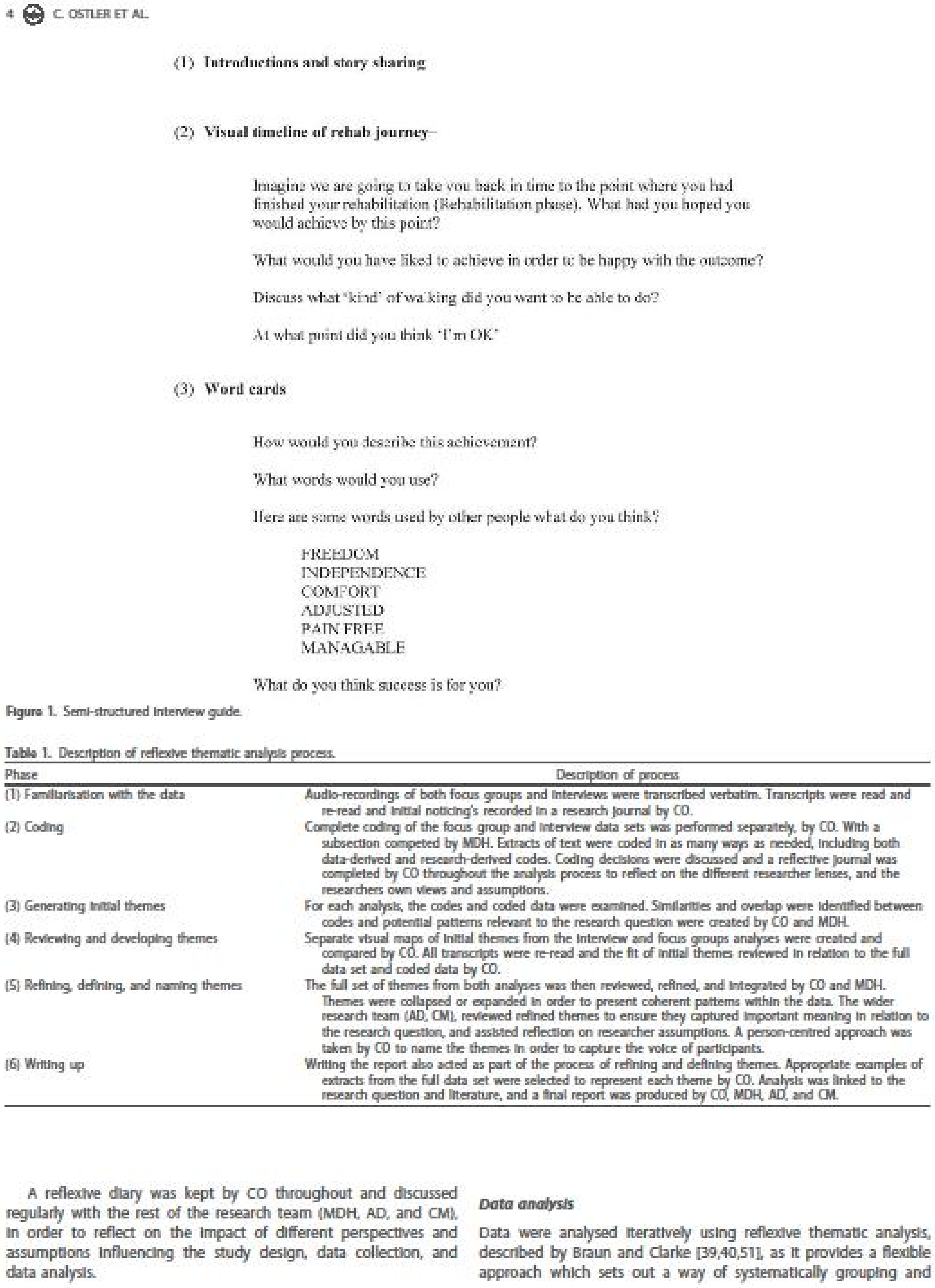
Participants self-selected how they would like to take part, and the focus groups and interviews were completed independently of each other and in parallel. This multiple-method approach allowed data source triangulation, providing different views of the same phenomenon, gathered using different methods to enhance credibility [49].

Focus groups took place in a quiet room in each of the four recruiting limb centres and lasted no more than an hour and a half. Interviews were undertaken either over the telephone or in a location of the participant's choosing and lasted up to one hour. Written informed consent was collected from all participants prior to their involvement in the study.

A semi-structured interview guide was co-produced with our PPIE group (Figure 1) and was used to collect data during both interviews and focus groups. Data were audio recorded and then transcribed verbatim to capture all verbal utterances. Transcripts were fully anonymised to remove any identifiable information and pseudonyms were used throughout to ensure the confidentiality of participants. Written consent was also obtained for using verbatim quotations.

Research team and reflexivity

Contextual information about the research team has been presented here to enable readers to assess any influence our background and experience may have had on the research [50]. All of the interviews and two of the four focus groups in the study were undertaken by the first author (CO). CO is a consultant clinical academic physiotherapist at one of the recruiting limb centres. She has over 15 years' experience in prosthetic rehabilitation clinical practice, and 10 years of experience in research. This study is being undertaken as part of CO's Ph.D., but she has undertaken several qualitative research enquiries prior to the study described here. The second author (MDH) is one of CO's Ph.D. supervisors, a health psychologist and associate professor. She has over 20 years of experience undertaking qualitative research with people following limb loss, and complimentary areas of rehabilitation. MDH conducted the other two focus groups as some of the participants were known to CO. Both CO and MDH undertook aspects of the data analysis, described below in Table 1. Involvement of a second researcher helped to refine ideas, enhance the reflexive process, and by viewing the phenomenon through a different lens, provide more comprehensive interpretive depth within the findings, therefore enhancing credibility [40].



(1) **Introductions and story sharing**

(2) **Visual timeline of rehab journey–**

Imagine we are going to take you back in time to the point where you had finished your rehabilitation (Rehabilitation phase). What had you hoped you would achieve by this point?

What would you have liked to achieve in order to be happy with the outcome?

Discuss what 'kind' of walking did you want to be able to do?

At what point did you think 'I'm OK'

(3) **Word cards**

How would you describe this achievement?

What words would you use?

Here are some words used by other people what do you think?

FREEDOM
INDEPENDENCE
COMFORT
ADJUSTED
PAIN FREE
MANAGABLE

What do you think success is for you?

Figure 1. Semi-structured interview guide.

Table 1. Description of reflexive thematic analysis process.

Phase	Description of process
(1) Familiarisation with the data	Audio-recordings of both focus groups and interviews were transcribed verbatim. Transcripts were read and re-read and initial noticing's recorded in a research journal by CO.
(2) Coding	Complete coding of the focus group and interview data sets was performed separately, by CO. With a subsection competed by MDH. Extracts of text were coded in as many ways as needed, including both data-derived and research-derived codes. Coding decisions were discussed and a reflective journal was completed by CO throughout the analysis process to reflect on the different researcher lenses, and the researchers own views and assumptions.
(3) Generating initial themes	For each analysis, the codes and coded data were examined. Similarities and overlap were identified between codes and potential patterns relevant to the research question were created by CO and MDH.
(4) Reviewing and developing themes	Separate visual maps of initial themes from the interview and focus groups analyses were created and compared by CO. All transcripts were re-read and the fit of initial themes reviewed in relation to the full data set and coded data by CO.
(5) Refining, defining, and naming themes	The full set of themes from both analyses was then reviewed, refined, and integrated by CO and MDH. Themes were collapsed or expanded in order to present coherent patterns within the data. The wider research team (AD, CM), reviewed refined themes to ensure they captured important meaning in relation to the research question, and assisted reflection on researcher assumptions. A person-centred approach was taken by CO to name the themes in order to capture the voice of participants.
(6) Writing up	Writing the report also acted as part of the process of refining and defining themes. Appropriate examples of extracts from the full data set were selected to represent each theme by CO. Analysis was linked to the research question and literature, and a final report was produced by CO, MDH, AD, and CM.

A reflexive diary was kept by CO throughout and discussed regularly with the rest of the research team (MDH, AD, and CM), in order to reflect on the impact of different perspectives and assumptions influencing the study design, data collection, and data analysis.

Data analysis

Data were analysed iteratively using reflexive thematic analysis, described by Braun and Clarke [39,40,51], as it provides a flexible approach which sets out a way of systematically grouping and

identifying meaning within the data. NVIVO software (QSR International, Melbourne, Australia) was used to manage the data. Initially, interviews and focus groups were analysed separately. Verbatim transcripts were coded in as many ways as needed, allowing lines of text to be coded more than once in order to consider different interpretation and meaning. A second researcher coded a subsection of the transcripts. Similarities and overlaps were identified between codes and potential patterns relevant to the research question were created. Visual maps of initial themes from the interview and focus group analyses were created independently of each other to compare and contrast. The full set of themes from both analyses was then reviewed, refined and integrated, in order to present coherent patterns within the data. Table 1 describes the stages of thematic analysis and by whom they were undertaken.

The characteristics of the sample were also analysed using data collected from the demographic questionnaire. Means and percentages were used to describe the full sample. To explore the potential relationship within themes, participant's characteristics were linked to all the quotations within the subthemes. Although this process of synthesis helped contextualise the findings, it was carried out cautiously as the sample was small and this was not the key aim of this qualitative approach.

Data saturation was not sought as reflexive thematic analysis does not presume that the themes emerge from the data but are interpreted during the researcher's analytical process, and on this basis further interpretations are always possible [52]. In addition, experiences following lower limb amputation can be diverse, depending on characteristics, such as age or cause of amputation, and it is unlikely any one study design would be able to capture them all [52]. Data collection was completed when close to 40 participants were recruited as this was deemed a pragmatic sample size based on the time and resources available to the research team [53].

Synthesised member checking [54] was undertaken following data analysis to offer participants the opportunity to reflect and feedback on the themes. This process enabled further triangulation of the knowledge gathered around the phenomenon of outcome domains of importance following prosthetic rehabilitation. Member checking allowed participants to assess the trustworthiness of the findings, ensuring they resonated with their experiences so the results may be credible with the wider limb loss population.

An accessible synthesised summary of the results, with space for written feedback, was sent by post to participants with an accompanying return envelope. It was not possible to send all participants a summary. Three participants had not provided an address, one participant had moved, and one participant had died. Seven summaries were returned (19%). All of the returned summaries confirmed the study findings and none of the themes were altered following feedback. Written responses were added to the data set and cross referenced with existing codes, as described in Table 1.

Results

Sample characteristics

Forty-two participants were approached during the recruitment phase of the study. One participant was ineligible, three participants dropped out due to health reasons and one participant's audio recording malfunctioned. This resulted in 37 participants' views and experiences being included in the study. Eighteen participants took part in interviews (14 *via* telephone and four face to face) and 19 participants took part in four focus groups comprising of a group of 7, a group of 5, a group of 4, and a group of 3.

Table 2. Sample characteristics.

Characteristic		$N = 37$ (%)
Age		Mean 59 years (range 33–88 years)
Gender	Male	23 (62)
	Female	14 (38)
Level of amputation	Transtibial	20 (54)
	Knee disarticulation	4 (11)
	Transfemoral	8 (21)
	Bilateral transtibial	4 (11)
	Hip disarticulation	1 (3)
Time since amputation		Mean 2.2 years (range 6 months – 5 years)
Cause of amputation	Diabetes	10 (27)
	Trauma	9 (24)
	Cancer	2 (5)
	Peripheral vascular disease	8 (22)
	Infection	4 (11)
	Other	4 (11)
Number of co-morbidities	None	9 (24)
	1	9 (24)
	2	7 (19)
	3	4 (11)
	4	2 (6)
	5	6 (16)
Social situation	Living alone	8 (22)
	Living with partner	19 (51)
	Living with family	10 (27)
Independencewith ADLs	Independent	12 (33)
	Family supporting	19 (51)
	Package of care	6 (16)
Employment status	Employed	9 (24)
	Unemployed	10 (27)
	Retired	15 (41)
	Volunteer	3 (8)
Use of walking aids	None/occasional use	12 (32)
	Sticks/crutches	21 (57)
	Walking frame	4 (11)
Community ambulatory	Yes	34 (92)
	No	3 (8)
Walking distance	50 m or less	11 (30)
	51–500 m	10 (27)
	501 m – 1 km	3 (8)
	More than 1 km	11 (30)
	Unsure	2 (5)

The sample characteristics were varied and included participants between 33 and 88 years of age, with a variety of different levels of amputation, including both knee and hip disarticulation. Time since amputation ranged between 6 months and 5 years and the cause of amputation included diabetes, peripheral vascular disease, trauma, cancer, and infection. The participants also had varied social situations, employment, self-reported level of independence with activities of daily living, and functional status. Table 2 further summarises the sample characteristics.

Themes

Five themes, with associated subthemes, were identified, which illustrate what participants felt were the important outcome domains that characterise successful prosthetic rehabilitation. The themes are summarised in Table 3 and will be explored below alongside quotes from study participants. Pseudonyms are used throughout and quotes have been contextualised with information about the participant's age and level of amputation.

Theme 1 – I am able to participate in my important activities

This theme describes outcome domains of prosthetic rehabilitation related to participation in important activities.

Appendix E Paper two study documents

Participant Introduction letter

UNIVERSITY OF Southampton

Portsmouth Hospitals NHS
NHS Trust

Dear Sir or Madam

Re: Me-AMPUTEE study - Exploring meaningful outcomes of recovery following lower limb amputation and prosthetic rehabilitation: The patient's perspective.

REC reference number: 18/EM/0259 and IRAS ID: 248850

We would like to invite you to take part in the above research project being carried out by the University of Southampton and sponsored by Portsmouth Hospitals Trust.

Before you decide if you would like to take part you need to understand why the research is being done and what it would involve for you.

Please take time to read the following information sheet carefully.

You may talk to others about the study if you wish or ask your Physio or Prosthetist at the limb centre about the project.

If you decide you would like to take part please let your clinician know and with your consent they will pass your contact details on to us. Alternatively you could contact us directly at chantel.ostler2@porthosp.nhs.uk or 07843 283147.

Thank you for reading this information and I look forward to hearing from you.

Yours sincerely

Chantel Ostler

Researcher

Participant recruitment poster

University of Southampton

Portsmouth Hospitals NHS
NHS Trust

Have you undergone a lower limb amputation in the last 5 years?

If so you may be able to take part in a research study investigating what people who have lost a limb feel are the important aspects of recovery and how the NHS should measure them.

You can take part by joining a group discussion or a one to one interview with a researcher to share your experiences.

Me-Amputee Study

You may be able to take part if:

- You are over the age of 18
- Have had a lower limb amputation in the past 5 yrs
- Have finished your initial rehabilitation with a prosthesis

If you would like to find out more or take part in the research please contact the research team Chantel.ostler2@porthosp.nhs.uk or 07843 283147

Recruitment poster – Version 2, 09/09/18 IRAS ID: 248850

Participant Information sheet

Participant Information Sheet

ME-AMPUTEE Study - Exploring meaningful outcomes of recovery following lower limb amputation and prosthetic rehabilitation: The patient's perspective.

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Feel free to talk to others about the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Within healthcare we need to measure the result of the treatments we provide so we can tell if the treatment has worked or not. We do this using tools or questionnaires called outcome measures.

There are many different outcome measures used by services who deliver amputee rehabilitation and in research projects investigating new products and treatment techniques. Nationally we are not all using the same measures and it has been difficult to agree on what we need to measure and what tools should be used.

In this study we want to find out what people who have undergone an amputation think are the important aspects of recovery. We hope this will allow us to identify what really matters to people as they undertake life with a prosthesis. We can then identify the outcome measures that capture this and make recommendations to clinicians and researchers about what are the most meaningful measures to use from a patients perspective.

Why have I been invited?

As you are someone who has undergone a lower limb amputation and prosthetic rehab we think that you are in an ideal situation to help us understand the recovery process. You do not have to take part. It is up to you to decide. We will telephone you to describe the study and go through this information sheet. We will give you time to ask any questions you may have and then if you are happy we will ask you to sign a consent form to show you have agreed to take part.

If you would like to find out more about being involved please contact the researcher directly via email at chantel.ostler2@porthosp.nhs.uk or phone 07843 283147. Or you can speak to a clinician at your limb centre, who with your consent will pass your contact details on to the researcher.

What will happen to me if I take part?

You will be able to choose how you would like to take part. You can take part in a small group discussion at one of four English limb centres in Portsmouth, Stanmore, Roehampton or Wolverhampton, £15 will be available to each participant to support their travel costs, or you can choose to speak to us on a one to one basis, either in person at a location and time convenient to you, or over the telephone.

If you choose a group discussion we will also ask you to select a 'back up' one to one option in case there are not enough people in your area to carry out a discussion group.

What will I have to do?

If you choose a group discussion - You will be part of a discussion group of 6-8 people, all who have undergone a lower limb amputation. We will ask the group questions about things like your experience of recovering from amputation. We will encourage the group to discuss the issues which arise.

If you choose a one to one interview – You will be able to do this face to face with the researcher in your own home or at a location of your choosing, or over the telephone.

In order to remember what has been discussed we will tape record the group session/interview and make notes at the time about key comments and ideas discussed. After the study has finished there is nothing further you will need to do.

What are the possible benefits of taking part?

There are no direct benefits from taking part in the study.

What are the possible harms of taking part?

There are few risks associated with taking part in the study. Sometimes talking about experiences may be upsetting. If at any point during the discussion group or interview you feel you need a break or you do not wish to continue you will be able to leave. Support is available at your local limb centre if you feel you would like to talk about any issues outside of the research project.

What will happen if I decide not to take part?

You do not have to take part in this study. If you decide not to take part your care will not be affected in any way.

What will happen if I don't want to carry on with the study?

You can withdraw at any time and your care will not be affected in any way. If you have chosen a focus group your contributions may be recorded alongside those of others during the group and it will not be possible to remove them, but if you have chosen to take part in a one to one interview we can destroy these recordings should you want us to. However once the data has been analysed we will be unable to withdraw your contribution.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to speak to someone else, you can contact the Patient Advice and Liaison service (PALS) at **Recruiting Trust name** (all contact details below). The normal NHS complaints mechanisms are also still available to you.

Will my taking part in this study be kept confidential?

Your confidentiality will be safeguarded during and after the study. All information which is collected about you during the course of the research will be kept strictly confidential.

When the tapes from the focus groups or interviews are written out you will be identified with a code. The list of codes will only be accessed by the research team and will be kept in a locked filing cabinet. Information about you will be kept for 12 months and then disposed of securely. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study we will keep limited personal information about you we have already obtained for audit purposes only. To safeguard your rights we will use the minimum personally-identifiable information possible.

Anonymised data will be seen for research purposes by the research team. All together three professionals might help with the research and read your transcript. However they will have been trained about confidentiality and you will not be personally linked to the data. Should something you have said as part of the group or interview be quoted in any publications following the research, a different name will be used to protect your identity.

Portsmouth Hospitals trust is the sponsor for this study and will act as the data controller which means we are responsible for looking after your data and using it properly. You can find out more about how we use your information by contacting us on 02392 286000 extension 6236.

What will happen to the results of the research study?

If you wish we will send you a brief summary of the findings of the full study on completion. We hope to arrange some sessions at the limb centres involved in the study to share our findings, as well as producing a short information video about the project for use on websites and via social media. The results will also be published as academic papers and we are intending to present our findings at national and international conferences. You will not be identified in any report/publication.

Who is organising and funding the research?

The research has been organised by Portsmouth Hospitals Trust and the University of Southampton.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the East Midlands Research Ethics Committee, REC reference 18/EM/0259.

Further information and contact details

For further information on this project please contact
Chantel Ostler (researcher). Tel: 07843 283147
Email: chantel.ostler2@porthosp.nhs.uk

If you are unhappy about anything to do with the study please contact
(Local trust R&D contact details and PALS details)

Appendix E

Consent form

Study Number: 248850 ID no:

UNIVERSITY OF Southampton Portsmouth Hospitals NHS NHS Trust

Trust Logo

CONSENT FORM

Title of Project: ME-AMPUTEE Study - Exploring **me**aningful outcomes of recovery following lower limb **amput**ation and prosth**e**tic r**e**habilitation: The patient's perspective. IRAS ID: 248850

Name of Researcher: Chantel Ostler

Initials

1. I confirm that I have read and understand the information sheet (Version 2, 2/10/18) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected ☐

3. I understand that data collected during the study may be looked at by individuals from the University of Southampton and Portsmouth Hospitals Trust. ☐

4. I understand that focus groups/interviews will be audio-taped. I give my consent to be audio-taped. ☐

5. I give consent for anonymised quotations to be used in academic publications and study dissemination materials. ☐

6. I give consent to receive a copy of the study's results ☐

I agree to take part in the above study

Name of participant (print): Date Signature

______________________ __________ ________________

Name of person taking consent (print): Date Signature

______________________ __________ ________________

When completed, 1 for participant and 1 for researcher site file.

Demographic questionnaire

Me-Amputee Study Questionnaire

Please could you complete the following questionnaire so we know a little bit about your background for the research project. The information in this questionnaire will not be shared outside of the research team. It will be anonymised and will only be used to describe the characteristics of the group of people who have taken part in the study.

Study ID:	Age :
What level is your amputation? i.e above the knee, below the knee etc.	
How long ago was your amputation?	
What was the cause of your amputation?	
Do you have any other health conditions? Please could you list them here	
Do you live alone or with other people? i.e. wife, family/friends etc.	
Does anyone help you with your daily activities? i.e spouse, carer etc.	
Are you currently working and if so what do you do?	
Do you use any walking aids to help you walk? i.e sticks, crutches etc	
Can you walk outside?	
How far can you walk before needing a rest?	

Thank you for completing the questionnaire

Interview guide

1. Introductions and story sharing

2. **visual timeline of rehab journey–** Imagine we are going to take you back in time to the point where you had finished your rehabilitation (Rehabilitation phase) . What had you hoped you would achieve by this point?

   What would you have liked to achieve in order to be happy with the outcome?

   Discuss what 'kind' of walking did you want to be able to do?

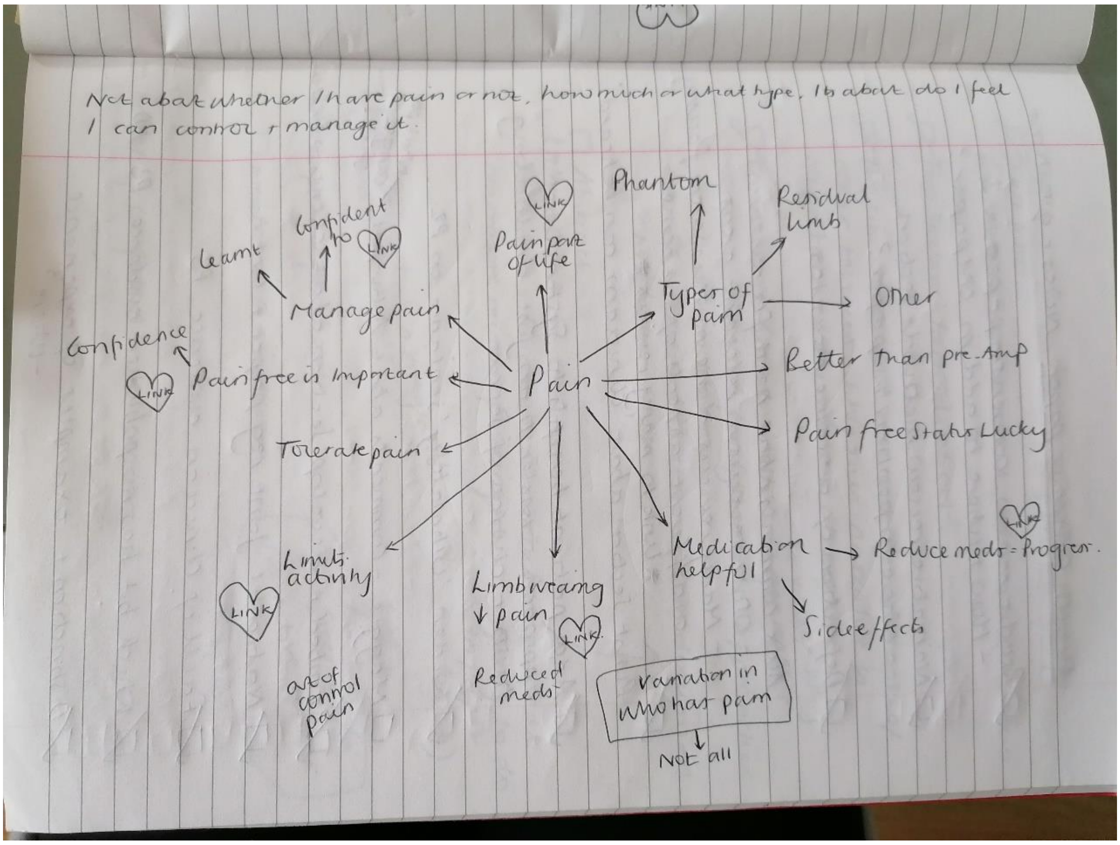
   At what point did you think 'I'm OK'

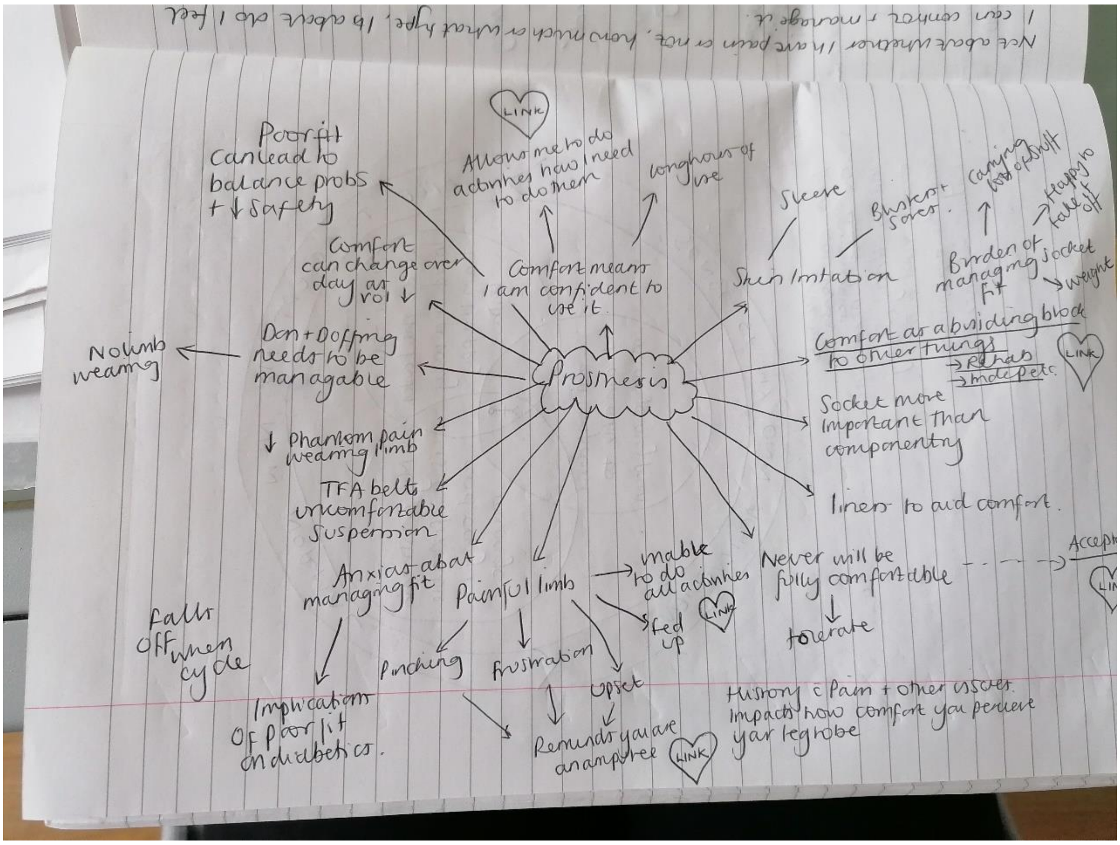
3. **Word cards –** How would you describe this achievement? What words would you use? Here are some words used by other people what do you think?

   FREEDOM, INDEPENDENCE, COMFORT, ADJUSTED, PAIN FREE, MANAGABLE

   What do you think success is for you?

Theme development diagrams





Data table for pain theme with quotations

Themes	Sub themes	Category	Code	Quotes
If I have pain I am able to manage it When I have pain it's not about how much or what type it's about whether I feel I can control and manage it	Variation in pain experiences P013 W003 P005 W005 W006 R008 R003 P003	Impact of pain status	Confidence when pain free	Yeah you know It gives you confidence, pain free, confidence. They go hand in hand. They're the same thing. P013
			Impact of co-morbidities on pain	When I've got my leg on I can't lift it up. It still hurts me. It hurts me with my back as well as I say I had two discs taken out my back and I've spent that much time lying on my back now I'm coming to sit up and use it, well I'm alright sitting but I try walking and take a few steps and the pain is unbearable. W003 I'm not pain free but still it can be horrific sometimes but that's not purely down to the um phantom pain that's just me and my condition. P005
			Important to be pain free	The only thing that would make me feel completely cured if that's the word for it is if I could get rid of the phantom pains W005 Also one big comfort is I'm not having phantom pains which is seems to be at the group three or four of them suffer really badly with phantom pain. and em Thankfully I don't. W006
			Improvement from pre-amp pain	I used to do martial arts so I always had a good balance and that's why I think my recovery was quite good because A) my pain had gone in my leg and B) I could use my leg. It was really weird, I was still waiting three days after the operation thinking the anaesthetic was still in my leg because I couldn't believe the pain wasn't there which was quite a really strange feeling waking up not knowing that I've not got pain in my leg and not having to take all these tablets all the time. R008

	P002 R003 W006 S002 S002 P003 P006 W006			Before I had my leg chopped off I was in some pain because the knee joint was awful, in a dreadful state. When it was chopped off I was delighted I had no more pain R003
			Less pain than pre-amp	It was dreadful and felt like someone was tearing my foot off, erm but now I just get, erm especially in the cold weather I find I get, it just feels like my old foot is being squashed a bit. P003 I wasn't expecting it to be pain free and it's not pain free, but I'll still take what I've got now over my previous any day of the week. P002 Yes, before I had an orthotic on my leg so that I could walk and cycle but if I was walking and suddenly the bones would shift and I'd be in awful pain and I would fall over if I wasn't careful; luckily I didn't actually fall over seriously. And I didn't have that anymore and it was lovely. R003
			Lucky not to have pain as others do	That's it, so that's one big thing because it seems to be the latest ones who have had the op don't have it. It seems to be the earlier ones, the six years and the one from 1972 and he's still getting them. It seems to be the later ones that that have had it done years ago that are suffering with the phantom pain but I'm glad I don't because that is a big comfort. W006
			Pain impacting my ability to fulfil important roles	if I do have this pain then I'm going to have to think about another career, another job, and and I'm going to have to think that this is for life. S002
			Pain limits how much I can walk	Yes. If i get that if that TMR surgery, it will work this time there's no doubt, it's going to work and that is that. But it's a life changer because at the moment I can't walk, it varies from like

				sort of 25-30 minutes to you know an hour and a half but it can be anything i mean yeah. S002
			Pain is taking over	Oh gosh, yes. That phantom pain, yes, that's wonderful. It doesn't feel like it's taking over. P003
	P015		Pain whilst walking	I personally I've suffered very little pain over this but some of the other clientele I've spoken to you know are in continuous pain when they are in motion on their prosthetics as it were. That I would find difficult to cope with personally I think. Er erm any pain that can't be abated as it were er er is a huge mental stress isn't it? P006
	R008 P009		Protective of pain free status	When I was getting better he said I've read a book on phantom pain. I said yes oh yes I've heard about that but luckily I'm not suffering. To cut a long story short he actually ordered the book for me and sent it to me. I: Oh bless him. MP: So I picked it up and I read the back and I thought I don't want to read this really. I'm not suffering and if you start reading stuff and looking into stuff it sends your mind funny. W006
	P010		Phantom pain even after years	The little monkey will play up and it's not a nice feeling that because you can't yourself organised to get to sleep because it's aggravating you. And that's after three years. When I first came round the phantom pains were really bad but they're starting to ease down. And then I thought I was clear and then the little bugger comes back again at you. P015
			Pain when I take the legs off	I have but basically if I have my legs on I could walk all day, not walk all day but I could have them on all day and see when I take them off at night time I don't know where this pain comes from but I'd never wish it on the devil. It's crazy. R008

	R008		Unrealistic to expect no pain	So I think you are always going to get some level of pain but again it's managing it and also managing your expectations of it. So if you think right I've lost my foot which has caused me so much grief and so much pain as soon as you take that off I'm going to be pain free I think you'll get disillusioned. P009
	P006 P005		Helps if people understand what pain actually feels like	I did the same with my son but the figures were a little bit higher and with my wife what was really interesting was she started off at about 4 on the box and then I ramped it up to about 15 and instantly her toes went bang like that and then she made some really funny noises and then I switched it off again. Have you seen the cat on YouTube that says no? No, no, no, no. That's the noise she made. But what was really interesting was where her toes just went bang and cramped down. I said that's what mine feel like all the time, I can lift them and then as soon as I stop they go bang back down again. So that was quite interesting the way that worked out. But it was quite a good way to demo what the phantom pain is like P010
	S005 P005		Pain limits participation in life	It's just being able to manage in a daily life without having to worry about, it's not about the 24 hours in the day it's about the amount of hours you can do and what you can do in those hours. Resting up, yes, OK, but before it was resting up all the time. And now it's more hours doing things than it was not doing things and that's the best thing about it in my, that I found personally. R008
			Upset about pain	I personally I've suffered very little pain over this but some of the other clientele I've spoken to you know are in continuous pain when they are in motion on their prosthetics as it were. That I would find difficult to cope with personally I think. Er erm any pain that can't be abated as it were er er is a huge mental stress isn't it? P006

		Types of pain	Painful residual limb	But with me things are so up and down again there's not really er a good answer for that. Pain is always going to be there until someone wants to take the neuromas away because they don't want to operate on me at the moment. P005 I get I get residual pain in my stump. Its annoying when it's cold because that makes it even worse, the cold gets into it and it starts hurting. S005
			Phantom pain	I think you've always got a good bit of phantom pain. I don't know if people don't have it anymore, if it does go away or not but that's always niggling. P005
	Managing pain P003 P008 R009 P009	Pain management	Confidence in ability to manage pain	Oh they're much better, yes. I think I manage it better. I know this will go away, I don't get myself in a pickle and as I say I think wearing the leg more seems to help me. P003 And no pain, werm ell I have phantom pain but I I I take medication for that so that's not a problem…..It's manageable, yes. I take er Gabapentin I take, as soon as you take it within seconds it works. P008 I only get phantom pain on very rare occasions and am able to live with it, so I'm very fortunate, as I know how some people suffer. R009 MC summary
	P008		Learnt to manage pain	I think pain management because I don't think pain free is the expectation. Well it's an expectation but to achieve that I think at the end of the day you've had your leg chopped off. It's not going to operate like a normal leg would do so I think you learning to cope and deal with the pain is the important bit. P009

	S005 P005		Medication helps phantom pain	It’s manageable, yes. I take er Gabapentin I take, as soon as you take it within seconds it works. P008 the amputation has brought on a totally different type of, in my case a totally different type of pain. cos I’ve got to be careful, em I've got I’ve got an exposed nerve on my scar line and there’s a couple of times I’ve caught it and I’ve almost took off the bed. as I say and Like I say when the cold gets into it that that makes it even worse and I have to put heat on it to try and sort it. So, yes, I’m pain free but I do have a lot of medication to try and keep it that way. S005
	R007 P002 P006 P008		Pain is part of my life	Well from people I’ve spoken to so far no one has ever really got rid of it but that’s again from talking to people. I’ve not met someone yet who says they are pain free. Everyone else I know or speak to have always got some sort of phantom pain or actual limb pain. P005 For me for me being pain free probably if you include discomfort as part of pain being pain free is not an option for me. R007 Not just you know I get phantom pain not that badly. I get more sensations but actually it’s everything else and there’s not, I mean I've been up all night last night, it was my fifth night in a week I’ve been up all night with pain. I wouldn’t even know what pain free was anymore. P002
	R001		Pain well managed	well I would say as long as you can make the pain manageable that’s what everybody prays for, isn’t it? you know P006 The pain is under control definitely. I’m pain free from what I used to have but it’s only there now and again and it’s mainly when I take the leg off and just sit there erm I can feel, before it

	P003			was 10 out of 10 but now it's just 2 or 3 out of 10 and I know it's not really there it's just in my mind. you know It's under control. P008
	P011		Reduce pain killers	So when I then finished here my aim was, well A) I was already feeling like no pain so my first goal was to wean myself off all medication as far as I could, see how far you could go. And I managed that so I was out here in September and by December I was off everything, which suddenly I just had my head back. R001 Probably because I wear my leg more and erm that makes me, for some reason that seems to have stopped me having phantom pain as much. So I've managed to reduce my Pregabalin, which is good. P003
	P010 P002		Side effects of medication	MP: Sorry? I pull faces? Yes. But I er you know I tolerate it because when I was in hospital I said about it, erm I can't remember whether I was..it was the time I was in QA or in Southampton, I think it was QA, and the doctor prescribed me something to help with the phantom pain. But I woke up the next day and er ....I felt disorientated, didn't know where I was, dizzy and apparently that is a side effect of that particular. I: The medication. MP: Of the medication, so I mean my reaction was well I'll put up with the pain erm rather than take those tablets because it was a horrible feeling. P011
	S002 P003		Tolerate pain	after a couple of months or so it started to lessen. Once I got walking it lessened even more so I'm now at the point where I've got a constant 2 to 3 of a buzz like I've been sat on the toilet for too long with occasional ramps up to about 10 and a few in between basically. So, yes, I can cope with that. P010

	P008			But I think if you've had pain and chronic pain you know for years no it's not pain free but I can live with what I've got. But if you are expecting it to be pain free. P002 No because I just get on with it. I mean it's more painful to do judo, and more painful to teach, but psychologically, mentally and emotionally it would be more painful not to do it. So it's likeyou know just pain. It's there all the time, just varying degrees. S002
			Wearing leg helps	Oh they're much better, yes. I think I manage it better. I know this will go away, I don't get myself in a pickle and as I say I think wearing the leg more seems to help me. P003 I've got no pain whatsoever apart from phantom pain. Phantom pain seems to only come when I erm take the leg off. erm I've had it on since 8am this morning and I'm going to take it off in a minute and sit sit down, but when I'm walking and doing things, sitting with it on it's not too bad. P008

Appendix E

Member checking summary

UNIVERSITY OF Southampton

NHS
Portsmouth Hospitals
University
NHS Trust

Dear

I am writing to thank you very much for taking part in the Me-Amputee study over the last year.

As you will remember, the aim of this study was to explore what people who have had a lower limb amputation think is a successful outcome or recovery following prosthetic rehabilitation. You may have spoken to me over the phone, met me in person or attended a focus group at your local prosthetic centre. During that session we discussed your personal experience of prosthetic rehabilitation and what things made you feel like you had, or had not recovered.

When we last spoke, I mentioned contacting you again in the future to get your thoughts on the findings and check I have understood what you shared with me. I have been working hard listening to the tapes we made and exploring all of your different experiences, pulling together a summary of the key ideas that many of you talked about. This summary is included in this letter and sets out the ideas, or themes, which include the experiences of the 37 people who took part in the study. The themes may not describe your experiences exactly but capture the essence of what it is to feel that you have recovered following your amputation and rehabilitation with a prosthesis. These themes are not the final results of the study as I would really value your feedback first.

There are two copies of the summary included with this letter. One is for you to keep and the other is for you to write your comments on and return back to me, but only if you would like to. In the summary the five themes are described in a table. After each theme there follows a box for you to add your comments. If you would like to give feedback please read the summary and add your comments. You can then send the summary pages back to me at the address above or scan them and email them to me at chantel.ostler2@porthosp.nhs.uk. If you do decide to feedback it would be really useful to have your thoughts by the 31st of December 2020.

Many thanks again for your amazing contribution to this project. It was a real honour to hear your story and I look forward to receiving your feedback on the themes so far.

Best wishes

Chantel Ostler - Me-Amputee researcher

Summary of themes from the Me-Amputee study exploring what people who have undergone rehabilitation with a prosthetic limb feel is a successful outcome or recovery.

Theme no. 1 – Physical ability to participate in important activities

I found that being able to walk again was very important to people. Walking helped people to feel more normal and allowed them to do important tasks again such as:

- Taking care of themselves i.e. washing, dressing and making hot drinks or meals
- Getting out of the house to go to the shops or for a meal, or on holiday
- To be able to do their work and hobbies such as walking a dog, exercising or socialising, or returning to the work place

When going outside people told me that being able to manage steps, uneven pavements or slopes were important skills, as well as being able to walk long enough distances to do what they needed to do.

People told me that how they were able to do these important activities was also a consideration. Relying on other people as little as possible and being independent with the things they wanted to do, was described as an important outcome.

People also talked about wanting to feel confident doing their important tasks and to feel they had mastered the activity. Using too much mental energy and concentration to plan and undertake tasks was described as very tiring.

I also heard that feeling safe and steady when walking and doing important activities was a good outcome but some people often felt afraid of falling over which limited some of the activities they were able to do.

Many people didn't want to have to rely on equipment for their important activities. Less equipment made them feel they were making more progress back to normality i.e. fewer or no walking aids was often a goal. However in some cases certain equipment really made life easier and in those cases people were much happier to use it.

Please add any comments here about whether you agree with the descriptions above:

Theme 2 – Accepting my new normal

In this theme I found people also talked about wanting to return to normal and that this was about people feeling like themselves again. Feeling like yourself again was very much linked to the first theme of being able to do important tasks, but people also described other factors such as:

- Being able to wear the clothes or shoes that they wanted to

- Being able to be spontaneous and make their own choices
- Being able to fulfil important life roles such as a wife or husband or as a parent

Many people also described a complex relationship with the outside world and wanted to appear as normal as possible to other people, such as not using equipment like sticks or wheelchairs, but that could cause problems with important benefits such as blue badges.

Adjusting and accepting the changes brought about following lower limb amputation was described as an important but challenging process which involved adjusting expectations, compromising, adapting, accepting limitations and ultimately learning to live with the new situation. People spoke of how a positive attitude and focusing on what they could do helped this process, and that acceptance often led to people feeling like they were in a better place.

Many people felt that there should be more focus on mental health following amputation and the impact the amputation has on mental health needs to be considered and measured. Using a prosthesis can help with mental health issues, as well as support from other people who have had an amputation, but that this needs to happen at the right time.

Please add any comments here about whether you agree with the descriptions above:

Theme 3 – Comfortable and manageable prosthesis

Within this theme people talked about the fact that it was important to have a well-fitting prosthesis that was easy for them to get on and off. Without this people couldn't always do their important activities, they may end up with skin problems and this had an impact on their mental health.

When the socket was uncomfortable people struggled more to cope with and adjust to wearing a prosthetic limb.

People also talked about the fact that they often didn't feel comfortable all the time in the limb. Comfort varied quite a lot. For example as the day went on, when doing different activities, if people put on weight or if the weather was very hot.

Please add any comments here about whether you agree with the descriptions above:

Theme 4 – If I have pain I am able to manage it

The people I spoke to have a wide variety of different pain experiences. Some had no pain, others had stump pain but no phantom pain, some had terrible phantom pain and others had constant pain but described it as better than before their amputation.

Despite all these different pain experiences a common thread was that people didn't necessarily expect to be pain free following their amputation, but that if they did have pain they wanted to feel like they were able to manage it themselves so they were able to live with it.

Please add any comments here about whether you agree with the descriptions above:

Theme 5 – Achieving personal goals

Being able to achieve the goals that people set for themselves following amputation was important to most people who took part in this project. Achieving goals gave people a great sense of achievement, motivation and pride.

Many people continued to set new goals for themselves as they progressed with their recovery. Some people set goals for themselves that they only intended to do once such as walking to a certain place, running a short distance, or trying without a walking aid. These goals were important so people could keep pushing and challenging themselves.

Please add any comments here about whether you agree with the descriptions above:

Appendix E

Member checking sample summary

33 lay member checking summaries were sent to the 37 participants.

It was not possible to send 4 of the summaries as 3 participants had not provided postal or email addresses as part of the study and 1 participant had moved and not provided a forwarding address.

From the 33 participants 8 summaries were returned (24% response rate)

From those 8 participants we were informed that one had passed away and therefore the member checking was undertaken by 7 participants (21%).

The demographics of the member checking group are described in the table below and compared to the full sample

Sample Characteristic	**Full sample N=37**		**Member checking sample**	**Comments**
Age	Mean 59 years Range 33-88 Years		Mean 64 Years Range 36-86 Years	Slight older sample on average
Gender	Male	23 (62%)	3 (43%)	More women
	Female	14 (38 %)	4 (57%)	
Level of amputation	TTA	20 (54%)	4 (57%)	Good range of levels of amputation
	KDA	4 (11 %)	1 (14.3%)	
	TFA	8 (21%)	1 (14.3%)	
	Bilat TTA	4 (11%)	1 (14.3%)	
	HD	1 (3%)	0 (0%)	
Time since amputation	Mean 2.2 years Range 6 months – 5 years		Mean 2.9 years Range 1-5 years	Similar lengths of time since amputation
Cause of amputation	Diabetes	10 (27%)	1 (14.3%)	Good range of cause but more participants with a cancer cause included
	Trauma	9 (24%)	2 (28.5%)	
	Cancer	2 (5%)	2 (28.5%)	
	Vascular	8 (22%)	1 (14.3%)	
	Infection	4 (11%)	0 (0%)	
	Other	4 (11%)	1 (14.3%)	
Number of co-morbidities	None	9 (24%)	2 (28.5%)	Similar numbers of co-morbidities
	1	9 (24%)	2 (28.5%)	
	2	7 (19%)	1 (14.3%)	
	3	4 (11%)	1 (14.3%)	
	4	2 (6%)	0 (0%)	
	5	6 (16%)	1 (14.3%)	
Social situation	Living alone	8 (22%)	1 (14.3%)	Similar social situations

Sample Characteristic	**Full sample N=37**		**Member checking sample**	**Comments**
	Living with partner	19 (51%)	4 (57%)	
	Living with family	10 (27%)	2 (28.6%)	
Independence with ADLs	Indep	12 (33%)	3 (43%)	No patients with carers assisting ADLs
	Family support	19 (51%)	4 (57%)	
	Carers	6 (16%)	0 (0%)	
Employment status	Employed	9 (24%)	2 (28.6%)	No unemployed participants and more retired and volunteers
	Unemployed	10 (27%)	0 (0%)	
	Retired	15 (41%)	4 (57%)	
	Volunteer	3 (8%)	1 (14.3%)	
Use of walking aids	None/ occasional	12 (32%)	4 (57%)	More participants not needing walking aids
	Sticks/ Crutches	21 (57%)	3 (43%)	
	Walking frame	4 (11%)	0 (0%)	
Community ambulatory	Yes	34 (92%)	7 (100%)	Similar levels of mobility
	No	3 (8%)	0 (0%)	
Walking distance	50m or less	11 (30%)	1 (14.3%)	More mobile sample than full sample
	51-500m	10 (27%)	1 (14.3%)	
	501-1km	3 (8%)	1 (14.3%)	
	1km+	11 (30%)	4 (57%)	
	Unsure	2 (5%)	0 (0%)	

Summary:

The member checking sample shared many similarities with the full study sample. Key differences were the inclusion of more female participants and an increased proportion of participants with cancer causing their amputation. The member checking sample also appeared to be slightly more mobile and independent than the main sample, requiring less walking aid support, able to walk further distances and with none needing formal carers to support their activities of daily living.

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Exploring the patient experience and perspectives of taking part in outcome measurement during lower limb prosthetic rehabilitation: a qualitative study

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ABSTRACT

Purpose: Outcome measurement provides clinicians, services and funders with useful information. However, little is known about the experience of participating in outcome measurement during lower limb prosthetic rehabilitation from the patient's perspective.
Materials and methods: Thirty-two participants who underwent lower limb amputation within 5 years, and had experience of taking part in outcome measurement during prosthetic rehabilitation, were recruited from UK limb fitting centers and social media. Data were collected using focus groups and interviews and analysed using reflexive thematic analysis.
Results: Four themes were identified. (1) How does participating in outcome measurement make *me* feel? (2) Do the outcome measures used in routine clinical care capture an accurate picture of my recovery? (3) Who is outcome measurement for? and (4) are prosthetic services measuring what is meaningful? These themes suggest outcome measurement is not a neutral activity for patients following lower limb amputation.
Conclusions: Harnessing the positive impacts of measuring outcomes could be used for motivation, to support adjustment and recovery, to improve communication and to support shared decision-making. This could make outcome measurement more meaningful and patient-centered. However, there may be potential for patients to respond negatively to outcome measures and clinicians should consider their impact on psychosocial factors.

> IMPLICATIONS FOR REHABILITATION

- Outcome measurement in prosthetic rehabilitation can provide clinicians, service providers and funders with important information.
- Adopting a patient-centred approach could make the process more meaningful and therefore beneficial for patients themselves.
- Measuring what is important to patients by considering a holistic approach beyond physical domains may make outcome measurement more meaningful.
- Patient centred approaches may include talking to patients about outcome measurement, using it to support motivation, goal setting and decision-making, as well as exploring outcome ranges to account for, or even capture variability.
- However, the potential for negative responses should not be overlooked, and clinicians should consider the psychosocial impact of outcome measurement on this patient group, especially when using performance-based measures.

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Background

Outcome measures are used in clinical practice to capture changes in patient status following an intervention or when monitoring patients over time [1]. This information can be shared with the patient to demonstrate progress throughout rehabilitation, and increase motivation, or can be used by the clinician to direct treatment planning or inform funding requests [2]. Aggregated outcome information can also be used to inform service improvement work and research. Measuring the outcome of health care interventions using outcome measures is especially relevant in today's increasingly evidence-based health services. When facing increasing demands on resources, as well as the expectation of a culture of continual improvement, services need to demonstrate their value and impact [3] consistently. Outcome information can provide an understanding of the effect health services have on the health and well-being of patients.

The term 'outcome measure' can be better understood by breaking it down into the outcome domain being measured and the measurement tool used for the task. An outcome domain can be defined as an element of health (i.e. pain, physical function, emotional well-being, social activity) that is changed by a particular intervention [4]. A measurement tool can be defined as a standardised instrument used in research and clinical practice to capture

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and evaluate one or more outcome domains at a single point in time or evaluate change over time [1]. Measurement tools exist in the form of observed performance measures such as the six-minute walk test [5], or the Timed up and go [6], where a clinician or independent observer rates or measures the individual's ability to complete a predefined activity [1]. Or, the patient-reported outcome measures (PROMs), which are completed by the patients themselves, often in the form of questionnaires or scales, such as the Trinity Amputation and Prosthesis Evaluation Scale (TAPES) [7] or the prosthesis evaluation Questionnaire (PEQ) [8], and reflect the patient's perspective on the outcome domain being assessed [1].

A range of outcome measurement tools have been developed for use following lower limb amputation and prosthetic rehabilitation. Heinemann et al. [9] identified 43 unique measures, and several clinical interest groups have developed recommendations for which outcome measurement tools should be used in clinical practice settings [10–12], such as the 6 min walk test [5], the Timed Up and Go test [6] and the TAPES [7]. The most recent of these is a set of recommended outcome measures from the International Society of Prosthetics and Orthotics [13]. Healthcare policy in the United Kingdom (UK) also recommends the use of outcome measures within the National Health Service (NHS) prosthetic rehabilitation services [14, 15].

Despite the availability of many different tools and recommendations, there is currently no UK outcome measurement consensus and self-reported use of outcome measures amongst clinicians is variable [16–18]. A recent narrative review exploring the current state of outcome measurement in prosthetic rehabilitation called for a focus on how outcome measures are used in clinical settings to develop a practice that ensures measuring outcomes is a meaningful and useful part of clinical care [19]. A few studies have begun to explore the experiences of clinicians using outcome measures in prosthetic rehabilitation, but only focus on the experiences of prosthetists [17, 18]. Barriers such as perceived time limitations, poor confidence with and knowledge of measurement tools which are often not covered in undergraduate education are reported [17, 18]. A lack of perceived value in using outcome measures is also described, with prosthetists reporting that tools do not produce useful information [2, 17, 18]. Experiences of outcome measurement amongst other members of the prosthetic multidisciplinary team are currently unknown.

Within prosthetic rehabilitation, the perspectives and experiences of patients taking part in outcome measurement have also yet to be considered. Their experience is particularly relevant in clinical settings where outcome measurement will likely be undertaken as part of clinical care. Patient experience of clinical care is 'the process of what receiving care feels like for the patient, their family and carers' and is an important quality indicator and area of focus for healthcare providers [20]. Improved patient experience is linked to organisational reputation, patient outcomes, the cost-effectiveness of services and staff experience [20]. Understanding how people might experience care can help design healthcare services, processes and interventions that deliver the best outcomes, but also promote positive patient experiences. All aspects of a patient's care contribute to whether someone has a positive or negative experience, including their experiences of taking part in outcome measurement.

Several systematic reviews have sought to review and summarise the evidence base concerning the experiences of patients taking part in outcome measurement in clinical settings such as primary care, renal, mental health, musculoskeletal services and cancer care [21–23]. These reviews focus on people's experiences with PROMs and describe both positive and negative aspects. The benefit of completing PROMs was highlighted as generating information about outcomes, which can promote communication and rapport with clinical teams, and improve the quality and focus of care. Concerns focused on how valuable the information collected was, and the accuracy of the questionnaires used to evaluate the impact of health conditions or healthcare interventions [21–23]. Despite the range of conditions included in these reviews, to our knowledge, no studies have yet explored the experience of people following lower limb loss and prosthetic rehabilitation, of taking part in outcome measurement. Furthermore, the systematic reviews described here only include studies exploring patient views of using PROMs. Within the field of prosthetic rehabilitation, both healthcare policy [14, 15] and specialist interest group recommendations [10–12] advocate for a mixed approach to capturing outcomes, using both observed performance measures and PROMs.

Due to the ongoing drive to use outcome measures in prosthetic settings [13], and in response to calls for a more meaningful, patient-centred approach to outcome measurement in clinical practice [19], it is vital to consider the perspectives of everyone involved. The findings presented in this article are part of a larger qualitative study that sought to explore outcome domains of importance following lower limb prosthetic rehabilitation from the patient's perspective [24]. Data were collected during the conduct of this larger qualitative study that captured patient experiences of outcome measurement during clinical care. This paper reports the analysis of this data and aims to explore experiences of outcome measurement during prosthetic rehabilitation, from the patients' perspective.

Method

Research design

The findings presented here were collected as part of a larger qualitative study that aimed to explore the patient's perspective of outcome domains of importance following lower limb prosthetic rehabilitation. The interview schedule developed for the larger study also included questions asking participants about their experience of taking part in outcome measurement during prosthetic rehabilitation. Responses to these questions were analysed separately from the rest of the data.

The entire project was developed from a critical realist (CR) world view which differentiates between the 'real' and 'observable' world and suggests the world is built from 'perspectives and experiences'. CR acknowledges there is an objective reality i.e. the 'real' world, but proposes it is never truly observable or knowable as it sits behind, and is therefore viewed through, different lenses or prisms i.e. individual human factors or cultural and organisational factors [25, 26]. In this case the lenses of community prosthetic users who have experience of taking part in outcome measurement as part of prosthetic rehabilitation. Due to the exploratory nature of this work and limited previous research on experiences of outcome measurement with this population, a generic approach to qualitative inquiry was used, rather than more defined methodologies, such as grounded theory or phenomenology. This open approach, using reflexive thematic analysis [27], fits well with the critical realist worldview, seeking to capture, explore and interpret experiences of outcome measurement following lower limb loss [28].

Patient and public involvement and engagement (PPIE)

Patient and public involvement and engagement in research is defined as "research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them" [29, 30] and is vital

to ensure research is focused on issues the public feel is important and is conducted in a participant-centred way. As outcome measurement may be viewed as a 'research' or 'clinically-focused' concept, we worked closely with a group of public research partners who were established prosthetic limb wearers to ensure we were asking about it in an accessible way. The group consisted of three members, one male with a transfemoral amputation due to trauma, and a male and female with transtibial amputations due to diabetic dysvascularity. CO and MDH met with the group on two occasions and through collective discussions they helped us consider the language used when talking about outcome measures and suggested providing examples of questionnaires and functional tests, during the interviews and focus groups, to stimulate discussion. They also considered practical issues, such as where patients would like to find out about the research and how they might like to take part. They were then able to participate in the study if they wished to. This crucial PPIE approach allowed us to co-design the study and study materials, such as the interview guide, to strive for a positive participant experience, maximise recruitment and develop accessible language around the concept of outcome measurement in partnership with patients.

Ethical review

The study was given ethical approval by the East Midlands Research Ethics Committee and the NHS Health Research Authority (Ref: 8/EM/0259).

Participants

The methods for the entire study have been reported in detail in the publication for the first analysis [24], and will be summarised here to provide context for this second set of analysis.

Individuals were invited to participate if they were over the age of 18 and had undergone a major lower limb amputation i.e. proximal to the ankle, within the last five years. Those who had experience taking part in outcome measurement with any member of the multidisciplinary team (MDT) during prosthetic rehabilitation contributed to the analysis reported here. Prosthetic rehabilitation is defined as initial MDT rehabilitation following limb loss or any ongoing MDT interventions provided as health or prosthetic needs change. People with experience in both observed and PROMs were included, as this mixed approach to capturing outcomes is reflective of current recommendations for outcome measurement practice in prosthetic rehabilitation [10–13].

Participants were recruited from four English NHS prosthetic rehabilitation centres that used outcome measures as part of routine care. Adverts were also posted on social media platforms and invitation letters were sent to limb loss supporting charitable organisations to share with their members.

A two-staged process, using both convenience and purposive sampling, was utilised to recruit a diverse sample with a range of characteristics, views and experiences, which are representative of people who undergo prosthetic rehabilitation in the UK. A demographic questionnaire was used to collate information from participants on a variety of characteristics, such as age, level and cause of amputation and presence of co-morbidities [31, 32]. This information allowed the research team to monitor the sample characteristics during the convenience sampling stage, and then employ purposive sampling later in the recruitment process to ensure harder-to-reach groups (i.e. older, transfemoral participants) were represented.

Procedure

Focus groups and semi-structured interviews were used to collect data as these approaches enable follow-up questions and contextualisation of answers [28]. The selection of both of these methods was on the advice of our PPIE group, to enable and promote participation in a way that individuals found most acceptable and comfortable. Participants self-selected how they would like to take part, i.e. focus group or interview, and the focus groups and interviews were completed independently of each other and in parallel. This allowed data source triangulation, providing different views of the same phenomenon, gathered using different methods to enhance credibility [33].

Focus groups took place in a quiet room in each of the four recruiting limb centres. Interviews were undertaken either over the telephone or in a location of the participants choosing. Questions addressing the aim of the larger study i.e. what participants felt were meaningful outcome domains following prosthetic rehabilitation were asked first. If the participant had experience of outcome measurement as part of prosthetic rehabilitation, they were then asked additional questions addressing the aims of this analysis. The interviews and focus groups for the entire study lasted no more than an hour, and an hour and a half respectively, with contributions to this analysis lasting between 15 and 30 min. Written informed consent was collected from all participants before their involvement in the study.

A semi-structured interview guide was co-produced with our PPIE group and was used to collect data during interviews and focus groups. Table 1 describes the questions related to this analysis. A selection of outcome measures from UK health policy [14, 15] and professional guidance [10–12] were described by researchers, or in the case of PROMs were available as examples to help stimulate discussion. These included the 6/2-min walk tests, timed up and go and activities balance confidence scale UK. TAPES, PEQ, locomotor capabilities index 5 and the re-integration into normal living index. During telephone interviews, all outcome measures were verbally described to participants by the researcher.

Data were audio recorded and then transcribed verbatim to capture all verbal utterances. Transcription was undertaken by a professional transcriber contracted to the University of Southampton. Audio recordings were anonymised to remove any identifiable information, and pseudonyms were used throughout the results section to ensure the confidentiality of participants. Written consent was also obtained for using verbatim quotations.

Table 1. Semi structured interview guide questions.

1. Can you tell me about your experiences completing questionnaires or any tests of your ability to do different things?
2. These are some examples of the ways your clinician may have measured how you were getting on.
   - Locomotor capabilities index 5
   - Activities balance confidence scale UK
   - Timed up and go
   - 6 min and 2 min walk tests
   - Socket comfort score
   - Prosthesis Evaluation questionnaire
   - Reintegration into normal living index
3. Do you have any thoughts about these or any other tests you took part in?
4. What do the tests or questionnaires mean to you?
5. Could they be improved and if so how?

Table 2. Summary of research team background and experience.

Researcher	Background
CO	Is a consultant clinical academic physiotherapist at one of the recruiting limb centres. She has over 15 years' experience in prosthetic rehabilitation clinical practice, and 10 years of experience in research. This study is being undertaken as part of CO's PhD, but she has undertaken several qualitative research enquiries prior to the study described here.
MDH	Is one of CO's PhD supervisors, a health psychologist and associate professor. She has over 20 years of experience undertaking qualitative research with people following limb loss, and complimentary areas of rehabilitation
AD	Is one of CO's PhD supervisors, a mechanical engineer and associate professor. He has over 15 years of experience undertaking biomechanics research, the last 8 of which relate to limb loss and prosthetics.
CM	Is one of CO's PhD supervisors, she is a professor and head of school of Healthcare Enterprise and Innovation. She has a diverse background spanning computer science, biomechanics, and health sciences with much of her work within the amputation rehabilitation and mobility sector.

Table 3. Sample characteristics.

Characteristic	*N* = 32	
Age	Mean 59 years (range 33–88 years)	
Gender	Male	20 (62.5%)
	Female	12 (37.5%)
Level of amputation	Transtibial	17 (53%)
	Knee Disarticulation	4 (13%)
	Transfemoral	7 (22%)
	Bilateral transtibial	3 (9%)
	Hip disarticulation	1 (3%)
Time since amputation	Mean 2.1 years (range 6 months–4.5 years)	
Cause of amputation	Diabetes	9 (28%)
	Trauma	7 (22%)
	Cancer	2 (6%)
	Peripheral vascular disease	7 (22%)
	Infection	4 (13%)
	Other	3 (9%)
Number of co-morbidities	None	8 (25%)
	1	8 (25%)
	2	7 (22%)
	3	4 (12.5%)
	4	1 (3%)
	5	4 (12.5%)
Recruiting location	Centre 1	15
	Centre 2	7
	Centre 3	2
	Centre 4	8

Research team and reflexivity

Contextual information about the research team has been presented in Table 2 to enable readers to assess any influence our background and experience may have had on the research [34]. CO is a practicing physiotherapist in one of the recruiting rehabilitation services. Several of the participants were aware of her role but had never been treated by her. Any participants who had a previous clinical relationship with CO were interviewed by MDH. All of the interviews and two of the four focus groups in the study were undertaken by the first author (CO). MDH conducted the other two focus groups as some of the participants were known to CO. Both CO and MDH undertook aspects of the data analysis, described below. The involvement of a second researcher helped to refine ideas, enhance the reflexive process and by viewing the phenomenon through a different lens, provide more comprehensive interpretive depth within the findings, therefore enhancing credibility [27].

A reflexive diary was kept by CO throughout and discussed regularly with the rest of the research team (MDH, AD and CM), to reflect on the impact of different perspectives and assumptions influencing the study design, data collection and data analysis.

Data analysis

Data were analysed iteratively, using reflexive thematic analysis as described by Braun and Clarke [27, 28, 35], to identify inductive themes from the transcripts which gave an understanding of the participants' experience of taking part in outcome measurement. Thematic analysis was used as it provides a flexible approach that sets out a way of systematically grouping and identifying meaning within the data. NVIVO software (QSR International, Melbourne, Australia) was used to manage the data.

Initially interview and focus group data were analysed separately. Audio-recordings of both focus groups and interviews were transcribed verbatim. Transcripts were read and re-read and initial notices were recorded in a research journal by CO. Verbatim transcripts were coded in as many ways as needed by CO, with MDH coding a subsection of the transcripts. For each analysis, the codes and coded data were examined. Similarities and overlaps were identified between codes and potential patterns relevant to the research question were created by CO and MDH. Separate tables of initial themes, codes and quotations from the interview and focus group analyses were created and compared by CO. All transcripts were re-read and the fit of initial themes was reviewed about the full data set and coded data by CO.

The full set of themes from both analyses were then reviewed, refined and integrated by CO and MDH. Themes were collapsed or expanded to present coherent patterns within the data. The wider research team (AD, CM) reviewed refined themes to ensure they captured important meaning about the research question and assisted reflection on researcher assumptions. A person-centred approach was taken by CO to name the themes to capture the voices of participants. Appropriate examples of extracts from the full data set were selected to represent each theme by CO, and a final report was produced by CO, MDH, AD and CM.

Data saturation was not sought for this study as the reflexive thematic analysis does not presume that the themes emerge from the data but are interpreted during the researcher's analytical process, and on this basis, further interpretations are always possible [36]. In addition, experiences following lower limb amputation can be diverse, depending on the rehabilitation setting and individual characteristics such as age or cause of amputation, and it is unlikely any study design would be able to capture them all [36]. Data collection was completed when close to 40 participants were recruited for the larger qualitative study as this was deemed a pragmatic sample size based on the time and resources available to the research team [37]. All participants taking part in the larger study were asked whether they had experience of outcome measurement during prosthetic rehabilitation, only those who said yes answered questions for this analysis.

Results

Thirty two out of the 37 participants who took part in the larger study reported they had experience with outcome measurement in clinical care and therefore contributed information to this analysis. Of the 32, 13 took part in interviews (nine *via* telephone and four face to face) and 19 participants took part in four focus groups comprising of seven, five, four and three. The sample characteristics were varied and included participants between 33 and 88 years of age, with a variety amputation levels (Table 3). Over half of the participants had undergone a transtibial amputation (TTA) (53%). Participants with other levels of amputation, including transfemoral (TFA) (22%), bilateral (9%) and both knee (KDA) (13%) and hip disarticulation (HDA) (3%), were also represented. Time since amputation ranged between 6 months and four and a half years and the main causes of amputation were diabetes (28%), peripheral vascular disease (22%) and trauma (22%). Participants losing their limb/s due to infection (13%) and cancer (6%) were also included.

Themes

The findings from this study have been grouped together into four themes, which describe these participants experience of taking part in outcome measurement in routine prosthetic care:

1. How does participating in outcome measurement make *me* feel?
2. Do the outcome measures used in routine clinical care capture an accurate picture of my recovery?
3. Who is outcome measurement for?
4. Are prosthetic services measuring what is meaningful?

Theme development is visualised in the coding tree in Figure 1. Each of the themes will be discussed in turn and illustrated using quotations from the study participants. Pseudonyms are used throughout, and quotes have been contextualised with information about the participant's age and level of amputation.

Theme 1: How does participating in outcome measurement make me feel?

The participants in this study spoke about their experience of taking part in outcome measurement during their rehabilitation and the impact it had on them. Many participants reflected on completing performance-based measures or filling out PROMs as a positive experience, discussing how assessing outcomes helped them to realise how far they had progressed, allowing them to see the improvements they had made.

> *I think they were very useful because it made me realise how much I'd improved. Which is easily forgotten you know. It was very affirming of the of the progress I'd made.* (Karen, 61 yrs, TFA)

This affirmation appeared to give them confidence and a sense of satisfaction with their recovery.

> *I just filled them in. I just thought to myself right I've done all that, ticked everything and I'm happy with the situation.* (Chris, 55 yrs, TTA)

Others reported that taking part in outcome measurement was motivating and encouraged them to work harder to try and beat previous scores.

> *Male participant 2: Yes. A goal. This is when I was here and how long it took me to walk around the thing and back again and how long before I could go in a certain distance.*
>
> *Male participant 1: Try and improve each time I think* (Alex, 45 yrs, TTA and Angus, 88 yrs, TTA)

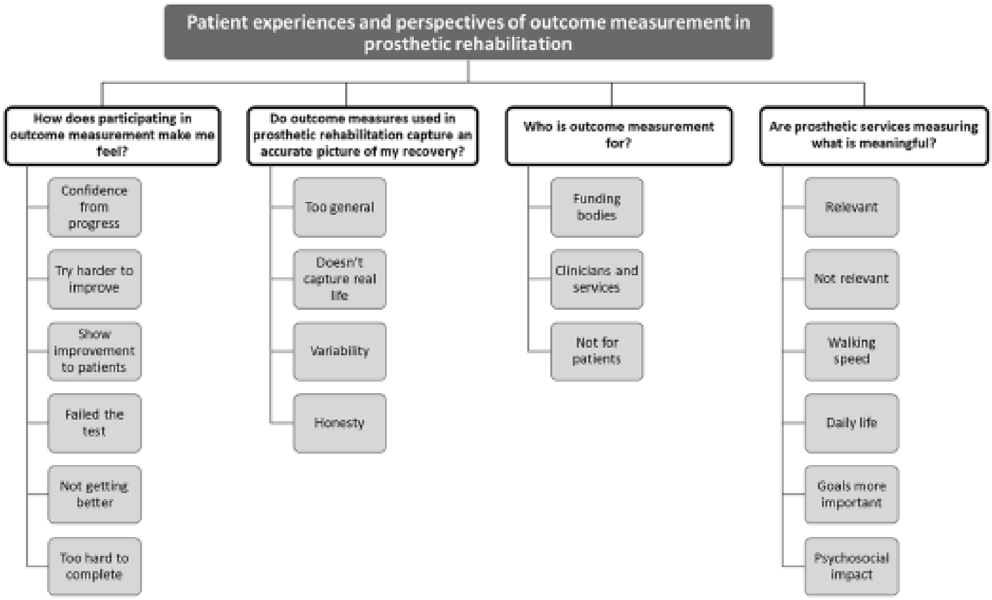


Figure 1. Coding tree describing development of study themes. Tree style diagram with branches extending from the central concept of 'Patient experiences of outcome measurement'. Each branch describes the four themes of the study, with descending branches listing the higher-level codes that make up each theme, demonstrating how the theme was developed.

> *Come on I'm going to be better. I'm going to be better.* (Erica, 39 yrs, TTA)

Participants also discussed that motivation could be harnessed by both clinicians and patients throughout the rehabilitation process to promote and consolidate achievements, as well as identify areas where greater input is required.

> *you've started to walk so they might be feeling a bit more happier or you could do something at the beginning, middle and then end to see how that patient has progressed from the beginning and at the end they could be feeling more happy about themselves than what they were at the beginning. So they can see then they've achieved ……… because there's an an amazing vibe so at the middle of their rehabilitation, see the percentage, see if it's changed and at the end see if it's got better. If it has great, if it hasn't what can be done.* (Harry, 33 yrs, KDA)

However, despite many positive comments about the experience and impact of outcome measurement, several participants perceived the process in a negative way. People who felt they had not increased scores captured on some performance-based measures, or those who's scores had deteriorated, described a very different experience. One participant described feeling disappointed he had not improved despite working hard to get better.

> *Competitiveness that you want to try and get yourself better than what you did last time and that. If you get the same sort of time or lower you are really quite disappointed.* (Alex, 45 yrs, TTA)

One participant in particular described performance-based outcome measurement as a test, which she felt she had failed.

> *Participant: The day I failed the test I had to say I felt like a failure because having achieved it once before but then having broken my leg I was just so frustrated…. because I can't do anything.*
>
> *Interviewer: So how did that make you feel when the score showed that you'd gone backwards?*
>
> *Participant: (sigh) Very frustrated…… Incapable.* (Gill, 67 yrs, TTA)

She went on to describe the impact of this perceived failure on how she felt about her rehabilitation potential and that it led to her being discharged from physiotherapy.

> *Participant: I didn't expect to be discharged…. so quickly but then I suppose if things aren't happening (sigh) it's a waste of a physios time to do things.*
>
> *Interviewer: How did that make you feel?*
>
> *Participant: Almost that I er I was a dead loss if you know what I'm trying to say because it was pointless working with me.* (Gill, 67 yrs, TTA)

One participant felt negative experiences may have been linked to the questions included in PROMs or the tasks included in performance-based measures. She highlighted that some tasks could be too hard for some patients, especially those with co-morbidities, which are highly prevalent in this population, and this could disadvantage some people.

> *So I think I think If we make outcome measures too difficult em then then it can be quite derogatory for patients and certainly some of these people who have em got all sorts of other issues going on. They've had an amputation, they've got other comorbidities, they might have back problems because of the issues they've had with their leg over the years.* (Sam, 54 yrs, TTA)

Theme 2: Do the outcome measures used in routine clinical care capture an accurate picture of my recovery?

As well as discussing the impact of being involved in outcome measurement on the experience of rehabilitation, participants also talked about whether outcome measurement can capture a real and honest picture of their recovery. One participant described the conflict of attempting to quantify the uniquely personal experience of recovery, using PROM questionnaires.

> *To sum it up the problem with these forms and all the others that says ability and mobility and everything else is that these forms are black and white, life is grey.* (Simon, 36 yrs, TTA)

Participants highlighted that day-to-day life as a prosthetic user can be highly variable, in terms of the different types and amount of activity they are able to do each day, and in some cases this can vary from hour to hour. They suggested that measuring outcome at a single point in time, such as during a clinic visit, may not capture a true reflection of the complexity of their recovery.

> *I think it depends how you feel on the day like these guys have said. One minute he's in pain and the next minute you're not in pain. So it depends when you are asked these questions as to what the answer is going to be………. you're never going to get an accurate outcome really because you might get the worst-case scenario where you are in pain or you might get the best-case scenario whereas actually I feel on top of the world today.* (Alison, 51 yrs, KDA)

It was suggested by one participant that this 'variability' is an important part of recovery following amputation and needs to be captured to comprehensively reflect the nature of recovering from amputation.

> *But it's like that's on my best day, that's on my worst day. On a normal day it's around about this. I think that would be a better way of measuring it because you'd get an understanding of not every day is the same………… The people who get this information might not appreciate and understand that. So maybe wording them ever so slightly, it's difficult because you want to get as broad amount of information as possible without overkilling it but giving someone that range, worst, average, best, what can you achieve on those days because it's going to be different for everybody.* (Jamie, 42 yrs, TTA)

Alongside the daily variation in outcomes described by these participants, there were also other concerns about whether outcome measures can truthfully capture progress through rehabilitation. Some participants felt that the clinical environment where performance-based outcome measurement takes place, with its large open spaces and smooth flat flooring, does not reflect the 'real world' in which life with a prosthesis happens.

> *See I think the thing about the tests is hospitals have magic floors so actually whether you can go really fast down the corridor doesn't really matter because what's out there is bumpy roads and pavements.* (Erica, 39 yrs, TTA)

Another concern was whether the responses, captured using PROMs are influenced by worries from patients about their benefit entitlements. Participants highlighted a conflict between demonstrating improvement through outcome measures and the consequences the results may have on financial support, suggesting this could influence self-reporting.

> *I can guarantee probably 80% of people answering these sort of questions are going 'If I put that down they might take my PIP away'. You know, nervous as hell going what if someone gets hold of that, thats my PIP* [personal independence payment] *gone…….If you say how far can you walk someone in their head is going well I'm going to lose my PIP so it's going to be zero.* (Jamie, 42 yrs TTA)

Theme 3: Who is outcome measurement for?

The participants in this study raised the question of 'why outcomes are measured' and 'who the information is collected for'.

It appeared participants viewed outcome measurement as a process not intended for their use, but about informing others, such as service providers or researchers.

> *So I think I've always just assumed it's more measurement for you guys (indicating researcher) than it is for me* (Erica, 39 yrs, TTA)

One participant perceived that outcome measurement was also used to justify funding from bodies, such as the Veterans Prosthetic Panel.

> *Yes the only problem with, it's great as a person to measure achieving goals but unfortunately like the Veterans Board want you to measure this sort of thing, don't they, running around the chair. So it's not what you want to achieve with the leg so if you do that with us then you've got to get these Boards on board as well haven't you.* (Alison, 51 yrs, KDA)

These examples provided by the participants demonstrate that they don't feel outcome measurement generates information they would use, rather it is completed to provide services or funders with information. One participant also questioned whether 'what' was being measured was important to patients, or whether it just evaluated the work done in limb centres.

> *Male Participant: The questions were important, very important. They were the right questions.*
>
> *Female Participant: I think they are in the context of the work that goes on here but it's so much more than that.* (Chris, 55 yrs, TTA and Tina, 58 yrs, Bilateral TTA)

Theme 4: Are prosthetic services measuring what is meaningful?

Many participants felt that the type of information captured during their experience of outcome measurement *was* important and often assessed their ability to do the different activities they want to do, as well as considering the impact of different environmental contexts on outcome.

> *So they were asking how long do I wear my leg inside em the house, do I wear my leg outside. So they were covering a lot of areas, so they were covering indoors, outdoors, stairs, stuff that normal ….people who aren't amputees take for granted. So all the stuff that I've had to learn how to do again, how to manage, em how to actually em walk backwards and stuff like that. So, they em yes, they were they've done, I felt that it was really comprehensive what they did.* (Adam, 38 yrs TTA)
>
> *They were all things you needed to be able to do……. So it's not like going to school and they teach you all of this stuff about Shakespeare and goodness knows and you don't need it ever again in your life you know. It's all stuff that is relevant.* (Gill, 67 yrs, TTA)

However, other individuals discussed feeling frustrated that the activities measured were not relevant to their lives or were too hard for them to do.

> *Well I've mean on this; I mean we've got no stairs.* (Mike, 74 yrs, TTA)
>
> *Interviewer: Are you looking at the balance one there that says about standing on a chair and things like that?*
>
> *Male Participant: Yes, I couldn't do that. I mean with my balance I would be straight on the floor.* (David, 74 yrs TTA)

Walking speed was highlighted as a domain that was commonly measured, using performance-based tests such as the 6 min Walk Test or the Timed Up and Go, but was suggested by many as not being a priority in their day to day lives.

> *I think they put way too much emphasis on speed because it doesn't matter whether you walk really slowly with or without a stick or whether you walk fast with or without a stick. It's what is comfortable for you, it's what is manageable for you and especially over a longer distance and you might not have been a fast walker beforehand. It doesn't matter if you can walk between now and the shops within two minutes or whether you do it in ten minutes, it's an achievement if you've done it. But I think they do put a lot of emphasis on how fast.* (Emma, 41 yrs, TTA)

Despite these useful reflections on the relevance of the domains measured in the experience of these participants, it was also suggested that some important elements of recovery are not always included. Participants suggested that the outcome measures they had experienced tended to focus on the technical aspects of recovery, such as walking and balance, and did not necessarily capture a more holistic view of their lifestyle.

> *Lifestyle is what you can and can't…. do. I mean the balance thing, yes, that's very important but there's nothing sort of about lifestyle. It's all one thing, one subject. There needs to be a bigger picture to the questions* (Harry, 33 yrs, KDA)

Many participants also felt that understanding whether people had achieved their goals was an important aspect to capture. Goal achievement was described as more important to participants than the results of measurement tools.

> *I certainly agree that that questionnaires that are subjective are very useful, but I also think em that that setting little goals and seeing if people achieve them. em so For example, walking up and down the stairs em initially was really difficult for me and by the end of it I was walking up and down the stairs holding on to one bannister instead of two.* (Sam, 54 yrs, TTA)
>
> *I think that for me, I do remember what I said for those 'what would you have liked to have done in the next six weeks' and I do remember those goals. So I think for me those questions were more important I guess than this (indicating outcome questionnaire)* (Erica, 39 yrs, TTA)

A notable domain that some participants described as overlooked during their experience of outcome measurement, was the psychosocial impact of recovering from amputation with a prosthesis.

> *think possibly er er to some of the people that are more severely injured er erm it possibly could go more into assessing er erm the mental wellbeing side of it, the psychology of it basically rather than just the physiology if you know what I mean. It was rather physically prioritised shall we say as to can you do this, can you do that? Erm there was probably a little less emphasis on the psychological side.* (Bruce, 64 yrs, TTA)

Discussion

The findings from this analysis offer an insight into the experience of taking part in outcome measurement in clinical practice as part of lower limb prosthetic rehabilitation, and include contributions from a large and diverse sample whose characteristics reflect those of the UK limb loss population [38–40]. To our knowledge, no other study has explored this aspect of prosthetic rehabilitation with people with limb loss, especially considering their experience of both performance-based outcome measures and PROMs. Although considerable qualitative literature has been published in other healthcare settings exploring the patient's perspective of using PROMs, there is a paucity of evidence available exploring the experiences of patients taking part in performance-based outcome measurement, which is highlighted in a critical review of performance-based outcome measures in occupational therapy [41]. This lack of exploration brings into question how patient-centred and meaningful performance-based outcome measures are [41]. Although we did not ask patients to distinguish between different types of outcome measurement within this study, it is hoped that this paper may provide insights that could begin to address this gap in the literature. However, future research is required to fully understand patient experiences of using performance-based outcome measures during prosthetic rehabilitation, and wider rehabilitation settings.

The first theme presented in this study highlights the impact outcome measurement can have on patients and describes how participation in the process affected them. Most participants described their experience of outcome measurement using PROMs and performance-based measures in a positive way, discussing how seeing their improvement validated their recovery and highlighted progress that was hard to see or remember. Positive experiences were also described in several systematic reviews exploring patient experiences with PROMs, where patients described outcome measurement leading to a sense of empowerment through self-reflection [22], or helping to reinforce positive changes when symptoms were on track or progress had been made [23]. Our participants also talked about how outcome measurement could be motivational and useful for goal setting. Using outcome measurement to facilitate goal setting has been described in a study using PROMs in pain management services. Both clinicians and patients found using outcome information in this way useful, resulting in more individualised care plans [41–43].

Despite many positive experiences, some participants in this analysis also described negative responses to outcome measurement, particularly related to experiences of taking part in performance-based measurement. When scores didn't improve, some participants described feeling like they had failed a test or were not progressing. Mixed responses to outcome measurement have been reported in research using the multiple sclerosis symptom and impact diary (MSSID), where participants reported both positive impacts of seeing symptoms improve, and feelings of depression if symptoms worsened [43]. A systematic review by Soldstad et al. [42] highlighted the negative impact of outcome measurement for people with mental health conditions and suggested that in this population it could be completed with clinicians for emotional support, as well as practical help. Greenhalgh [43] highlighted the need to explain the possible positive and negative impacts of outcome measurement to patients and ensure processes are in place to allow patients to cease participation if they need to. The varied emotional responses described in our analysis may suggest that patient-centred approaches to outcome measurement in prosthetic rehabilitation need to be individualised and supportive, especially in light of the well-documented struggles with psychosocial adjustment in this population [44]. Future approaches to outcome measurement should consider the individual patient's coping strategies and adjustment process and could include support and options to opt out, where required.

A further concern highlighted by participants in this study, and described in the second theme, was whether outcome measurement captures an accurate picture of recovery. For Performance-based measures, accuracy concerns focused on the testing environment, as flat hospital/clinic floors were not thought to represent the wider environment that patients with limb loss need to navigate. For PROMs, participants questioned how honestly measures would be completed, especially when people were concerned about how outcome information may affect the financial support they were receiving *via* the UK benefits system. Participants talked about not being able to show the best of what they can do during outcome measurement over fears that their benefits may be reduced.

This tension has been described previously in the limb loss and wider disability literature [45, 46]. Wadey and Day [46] reported prosthetic users need to present 'their worst day' during the benefits application process to receive the ongoing financial help needed. These concerns seem to be underpinned by a natural variation in outcome experienced by people recovering from lower limb amputation with a prosthetic limb, which was highlighted by our participants. This variation, described in other studies with limb wearers as 'good and bad' days [47], was identified as an accuracy concern, as the response or performance captured during outcome measurement may be affected by the type of day a person was having. This has been reported previously with musculoskeletal patients in primary care worrying about what type of day they were having when completing PROMs, and whether it would give their clinicians a 'representative picture' [22]. Measuring outcomes at a single point in time does not acknowledge the variation in ability that people may experience as part of recovery, as well as during lifelong prosthetic use [47]. The findings from this analysis may indicate that patient-centred approaches to outcome measurement lie in capturing this 'natural' variability, which may reflect the true nature of recovery as an outcome range. Thus, offering a more complete and meaningful picture.

The third theme described in this study focused on patients' perception of whom outcome measurement is undertaken for, highlighting that some participants perceived it as a process that does not generate information that is useful for them. They describe a lack of ownership or involvement in the wider outcome measurement process, which in their view appears to focus on providing information for clinical teams and funders. This view of measuring outcomes has also been reported in the mental health literature, with routine outcome measurement in psychological services described by patients as a bureaucratic exercise only for the benefit of service providers [42], or only used for research applications rather than patient-centred reasons [22].

Interestingly, this contrasts with the positive experiences described in the first theme which reflect the many ways outcome measurement could be of value to patients. This suggests a possible gap in how outcome measures are routinely used in clinical practice, i.e. whether results are discussed with patients, or how they are used to inform and direct prosthetic rehabilitation. Systematic reviews evaluating patient experience with PROMs report that patients identify value in outcome measurement when the information generated is used as part of their care, i.e. to improve communication between patients and clinicians, facilitate clinical assessment, for diagnosis and monitoring of problems, and to support shared decision making [22, 23]. Shared decision-making has recently been advocated for in the limb loss population with the publication of clinical decision-making tools for partial foot versus transtibial amputation [48].

Despite numerous recommendations from prosthetic rehabilitation specialist interest groups about which outcome measurement tools to use [10–13], very little information is available about *how* they should be used in clinical practice, i.e. how outcome data can be integrated with patient care and what patient-centred approaches look like. Further work is required in the field of prosthetic rehabilitation to understand how outcome measurement could be used by both patients and clinicians to add value to clinical care, as well as to understand the impact it may have on prosthetic rehabilitation outcomes and lifelong prosthetic management.

The final consideration raised by these participants was whether outcome measurement in clinical settings is capturing what is meaningful to patients. Participants discussed that some of the PROMs they had used were too hard for them to complete, or included elements that were not relevant to their lives or their recovery. Many studies have reported similar frustrations from patients using PROMs, who had difficulty answering questions that were not relevant, unclear or not specific enough [49–52]. In terms of the outcome domains being measured, some participants in this study felt the measures they experienced did capture the concepts that were important to their recovery. Whereas others felt measurement was too focused on physical recovery and did not evaluate important domains such as lifestyle or psychological response to limb loss, perhaps suggesting the need for a more holistic approach. Previous outcome measurement research has indicated that a holistic approach made patients feel that clinicians cared about them as a whole person rather than just their medical condition [23], and that outcome domains of importance following lower limb prosthetic rehabilitation extend far beyond physical capabilities, such as walking, and may need a holistic multi-domain approach [24].

The contrasting views described here regarding what was measured in the experience of different participants may be due to variability in which outcome measures are used across UK prosthetic rehabilitation settings, or variation in use by different professionals within the MDT. Within prosthetic rehabilitation, there is currently a lack of consensus over which outcome measures to use following lower limb prosthetic rehabilitation [53, 54]. A recent narrative review of outcome measurement in prosthetic clinical practice suggested this may be due to a lack of understanding, and subsequently consensus, about which outcome domains are most important to measure, especially according to prosthetic users themselves [19]. However, due to the significant variation in the extent of recovery experienced following lower limb amputation [55], which can range from using a prosthetic limb for transfers only to returning to high-impact sporting activities, it may be hard to find or develop measures that are appropriate for all patients. This may indicate the need for individualised outcome measurement tools that allow patients to identify the activities most important to them, or to select and weight issues that are of most importance, especially in situations where what is of most concern may vary [22], as may be the case following prosthetic rehabilitation.

Limitations

This analysis was part of a larger qualitative study that first asked questions about what the participants felt were outcome domains of importance following lower limb prosthetic rehabilitation. Limitations to the full study design are described further in the first analysis publication [24]. Regarding this analysis, it should be considered that prior discussions about outcome domains of importance may have influenced answers to questions about the participant's experience of taking part in outcome measurement. For example, this may have influenced the theme of 'Are prosthetic services measuring what is meaningful'.

When talking to the participants about their experiences of outcome measurement, we did not ask them to differentiate between their experiences with PROMs or performance-based measures. It is therefore possible that the findings may have been different if the study focused on one measurement type or the other. However, this mix of approaches reflects current UK practice. Future work could explore the differences in patient experience with different types of measures, especially performance-based measures considering the dearth of studies exploring perspectives of this approach across all healthcare settings.

During the interviews and focus groups we used several examples of outcome measures, as suggested by our PPIE group, to help stimulate discussion around the outcome measurement process. It is possible that the examples we used could have influenced the findings as participants may have focused on these examples rather than other measures with which they may have had experience. However, the measures we included were recommended for use in UK practice service specifications and policy [14, 15], as well as professional guidance [10–13]. We also included participants from four different UK prosthetic centres, which may have all exposed participants to a variety of different tools used within the recommendations, or others that were not included.

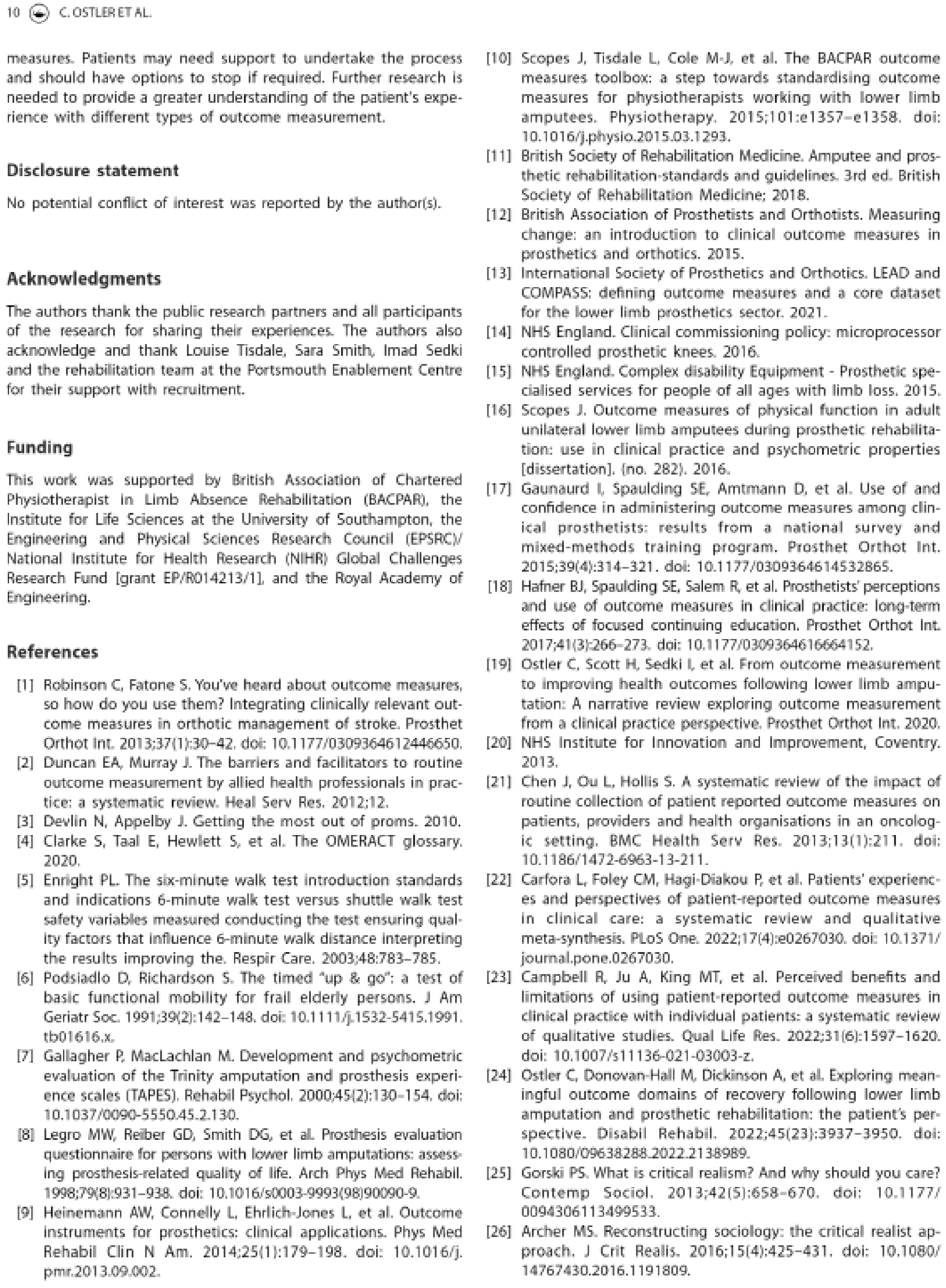
It should also be considered that nine of the participants chose to take part over the telephone, which meant they would not have seen the outcome measure examples. In these cases the researcher verbally described the measures to the participants, however this may have affected the recall of their experiences, their engagement in the discussion and the depth of their responses.

The findings from this study offer a useful insight into experiences of outcome measurement from the perspective of lower limb prosthetic users. As this is the first study to consider the patient's experience of this aspect of prosthetic rehabilitation, these findings could initiate a conversation about patient centred approaches to outcome measurement in clinical settings that may not have been considered before. However, future research is needed to broaden our understanding of this phenomenon, for example, understanding the experience of outcome measurement with different healthcare professionals, when used in different ways i.e. to evaluate the impact of a specific intervention, or when used routinely to monitor progress over time. Furthermore, this study only included participants within five years of amputation due to inclusion criteria set for the larger study, and therefore may not represent the views of more established patients. Future research with these groups could provide additional insights. Alongside in-depth qualitative approaches, as used here, quantitative approaches may be useful to establish the extent to which the experiences of outcome measurement described in this analysis, are shared by the wider population.

Conclusion

Taking part in outcome measurement may provide clinicians, service providers and funders with useful information. However, adopting a patient-centred approach could make the process more meaningful and therefore beneficial for patients themselves. Harnessing the positive impacts of measuring outcome, reported in this study, could be used for motivation, to support adjustment and recovery, improve communication and support shared decision-making. As well as a patient-centred approach it appears a holistic approach may help to capture outcome information that is meaningful to patients. Considering the variable nature of outcome following prosthetic rehabilitation may also help capture the range of recovery experienced following limb loss more accurately. Despite this initial insight into clinical outcome measurement from the patient's perspective, further work is required to understand how it could be useful to this population.

In addition, the potential for negative responses to outcome measurement should not be overlooked. Clinicians may need to consider their patient's psychological well-being when using outcome measures, perhaps more so with performance-based



measures. Patients may need support to undertake the process and should have options to stop if required. Further research is needed to provide a greater understanding of the patient's experience with different types of outcome measurement.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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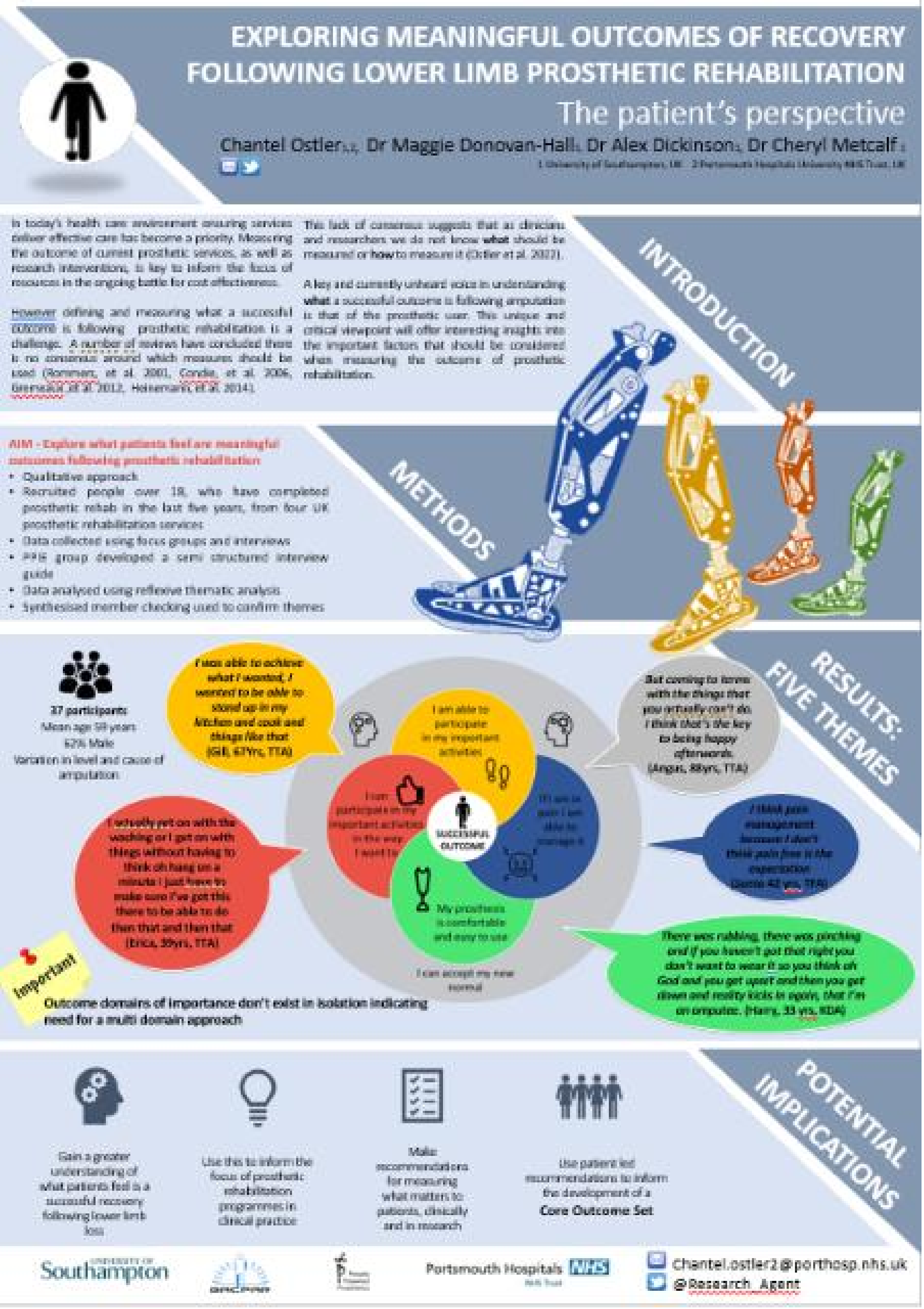
Appendix G Poster presentation of Paper 2



EXPLORING MEANINGFUL OUTCOMES OF RECOVERY FOLLOWING LOWER LIMB PROSTHETIC REHABILITATION

The patient's perspective

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INTRODUCTION

In today's health care environment ensuring services deliver effective care has become a priority. Measuring the outcome of current prosthetic services, as well as research interventions, is key to inform the focus of resources in the ongoing battle for cost effectiveness.

However defining and measuring what a successful outcome is following prosthetic rehabilitation is a challenge. A number of reviews have concluded there is no consensus around which measures should be used (Rommers, et al. 2001, Condie, et al. 2006, Gremeaux et al. 2012, Heinemann, et al. 2014).

This lack of consensus suggests that as clinicians and researchers we do not know **what** should be measured or **how** to measure it (Ostler et al. 2022).

A key and currently unheard voice in understanding **what** a successful outcome is following amputation is that of the prosthetic user. This unique and critical viewpoint will offer interesting insights into the important factors that should be considered when measuring the outcome of prosthetic rehabilitation.

METHODS

AIM - Explore what patients feel are meaningful outcomes following prosthetic rehabilitation

- Qualitative approach
- Recruited people over 18, who have completed prosthetic rehab in the last five years, from four UK prosthetic rehabilitation services
- Data collected using focus groups and interviews
- PPIE group developed a semi structured interview guide
- Data analysed using reflexive thematic analysis
- Synthesised member checking used to confirm themes

RESULTS: FIVE THEMES

37 participants
Mean age 59 years
62% Male
Variation in level and cause of amputation

I was able to achieve what I wanted, I wanted to be able to stand up in my kitchen and cook and things like that (Gill, 67Yrs, TTA)

I actually get on with the washing or I get on with things without having to think oh hang on a minute I just have to make sure I've got this there to be able to do then that and then that (Erica, 39yrs, TTA)

But coming to terms with the things that you actually can't do. I think that's the key to being happy afterwards. (Angus, 88yrs, TTA)

I think pain management because I don't think pain free is the expectation (Jamie 42 yrs, TFA)

There was rubbing, there was pinching and if you haven't got that right you don't want to wear it so you think oh God and you get upset and then you get down and reality kicks in again, that I'm an amputee. (Harry, 33 yrs, KDA)

Important

Outcome domains of importance don't exist in isolation indicating need for a multi domain approach

POTENTIAL IMPLICATIONS

- Gain a greater understanding of what patients feel is a successful recovery following lower limb loss
- Use this to inform the focus of prosthetic rehabilitation programmes in clinical practice
- Make recommendations for measuring what matters to patients, clinically and in research
- Use patient led recommendations to inform the development of a **Core Outcome Set**

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Appendix H Paper three study documents

Data table for `accuracy' theme

Themes	Code	Quotes	Notes
Accuracy of measurement *Does outcome measurement give a true picture?*	Doesn't give true picture	Just keep walking. You feel quite pressured to keep going. It's not actually your normal pace. Trying to beat your score as it were . So I could technically walk outside the bars with two sticks, technically even in terms of the outcome measures I could technically do the outcome measures um but functionally I didn't feel I could do a lot and that was a very, very, very slow process in getting there. (R007)	Measurement isn't perceived as giving a true picture of what the patient is able to do because what is measured doesn't necessarily reflect what the person is able to do in both an upwards and downwards way. The testing environment does not reflect real life The experience of being an amputee is very variable. Important things change on am hourly or daily basis and a single point in time may not capture a true reflection of what is happening. They are also unable to capture this variation. The measures were also described as being to generalist and not capturing specific tasks of activities…some of this may speak to the issues of using outcome measures to assess human activity and what problems may come out of it if you
	Outcome measures make you worry about benefits	MP2: I can guarantee probably 80% of people answering these sort of questions are going If I put that down they might take my PIP away. You know, nervous as hell going what if someone gets hold of that, thats my PIP gone, and er do I,apparently I don't er I'm not entitled to a blue badge, I got one in the end, because I don't use a walking aid. What the hell is that? P009 I think if these questions (outcome measures) were being asked by the Government in that sense. FP1: We'd all be gone. MP2: One all of us would be walking home. FP1: With no benefits. (p009 and p001)	

		If you say how far can you walk someone in their head is going well I'm going to lose my PIP so it's going to be zero. (p009) Where I've put how far can you walk and I've said (on the outcome measure) well quite comfortably without any issues I can walk a mile and a half without having to think about putting another sock on or anything like that. But if I'm filling out a form for. I2: You put worst case scenario don't you. MP2: Yes, I'd put the very worst. And that's what I've put on there my best I can go all day as long as I've got enough socks to keep changing to boost my socket up. (p9 and p10)	get it wrong. i.e. pt denied componentry, reduced funding for services etc. OM makes patients worry about the impact on their benefits. They need to consider the tension between wanting to do well on the measure and loosing financial support. They also need to consider that they may not always be that good and some days they may be a lot worse. What impact does this have on being able to accurately measure OM in a health care setting. Does our benefit system have an impact on rehab outcomes Also outcome measures are often a single point in time and this doesn't reflect real lifes up and downs.
	OM don't focus on the real environment	I found even to be honest the measures that they did to prove that my balance was good enough for the MPK I found some of them a bit weird and arbitrary because they are things that I wouldn't, I can see why I'd need to pick something up off the floor for example um because that is something you would do but then there was other stuff where you are thinking, I can't even remember what they were now, there were a couple of things on the tests we did that I thought that's got nothing to do with, that's just thats just a trick that you learn rather than something that actually measures anything meaningful. (R007) See I think the thing about the tests is hospitals have magic floors so actually whether you can go really fast down the corridor doesn't really matter because what's out there is bumpy roads and pavements. (R001)	

		Well I only did a walking test I think and erm and then perhaps sitting down on a chair and getting up again. And walking test is fine isn't it in the gym, it's fantastic in the gym, you can walk really well. But I'm just looking at my house here with my em steps and wobbly paving steps and things and garden level it's always different, isn't it. Yeah (S003)	
	OMs don't capture the variation in life	To sum it up the problem with these forms and all the others that says ability and mobility and everything else is that these forms are black and white, life is grey. (p010)	
	OMs vary depending on when you ask the patient	Going back to these questionnaires I think personally for me some of the questions need to be a little bit more specific and also I think it depends how you feel on the day like these guys have said. One minute he's in pain and the next minute you're not in pain. So it depends when you are asked these questions as to what the answer is going to be, so you are not going to get an accurate answer from somebody with a prosthetic because it's just so varying how you feel on that day. I don't know if you've felt the weight of this leg, it can be very tiring as well. I just think these need to be more specific and I think for an amputee it just varies on what day you ask them……Yes, you're never going to get an accurate outcome really because you might get the worst-case scenario where you are in pain or you might get the best-case scenario whereas actually I feel on top of the world today.(P001)	
	Outcomes can vary depending on the day	someone like me who wants to shout about how brilliant life is I can do 20 miles it's fine. But it's like that's on my best day, that's on my worst day. On a	

		normal day it's around about this. I think that would be a better way of measuring it because you'd get an understanding of not every day is the same………..The people who get this information might not appreciate and understand that. So maybe wording them ever so slightly, it's difficult because you want to get as broad amount of information as possible without overkilling it but giving someone that range worst, average, best what can you achieve on those days because it's going to be different for everybody. (p009)	
	Outcome measures too generalistic	It's too generalist. It's like when I was doing this very recently, it's like step on the sidewalk kerb. Now that depends how high the kerb is as well and it depends on if you are walking up a slope, walking down a slope because it does vary because walking down a slope I hate it and I'm sure a lot of amputees hate going down slopes. But going up a slope I'm fine. (P001)	

Appendix I Paper four publication in PLOS ONE

PLOS ONE

RESEARCH ARTICLE

Development of the ECLIPSE model of meaningful outcome domains following lower limb amputation and prosthetic rehabilitation, through systematic review and best fit framework synthesis

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Abstract

Background

Little is known about which outcome domains characterise meaningful recovery following prosthetic rehabilitation and should be measured. Our previous qualitative work developed a conceptual model of outcome domains which are meaningful to patients. This qualitative synthesis aims to develop that model by exploring views and experiences of recovery captured in the limb loss literature, and use these to produce a second iteration of the model describing outcome domains of importance following prosthetic rehabilitation from the patient's perspective.

Methods

Systematic searches were conducted using CINAHL, PsychInfo and Web of Science from 2011 to early 2023. Studies with a qualitative design focusing on views and experiences of lower limb prosthetic users were eligible for inclusion. Quality was assessed using the CASP tool. 'Best Fit' framework synthesis was used to synthesise the evidence and develop the conceptual model.

Results

40 studies were included, describing the experiences of 539 participants. Data supported the pre-existing conceptual model and led to development of four of the five domains. The newly named ECLIPSE model describes meaningful outcome domains as 1) Being able to participate in important activities and roles, 2) Participating in the way I want to, 3) My prosthesis works for me, 4) If I am in pain, I can manage it, and 5) I am able to accept my new normal. Studies came from 15 countries showing good coverage of high-income settings. Few participants from low-and-middle-income countries were included, it is unclear if the ECLIPSE model describes outcome domains of importance in these settings.

Data Availability Statement: All relevant data are within the manuscript and its Supporting Information files.

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Competing interests: The authors have declared that no competing interests exist.

Conclusions

This synthesis provides a rigorous foundation for understanding outcome domains of importance following lower limb prosthetic rehabilitation from the patient's perspective. The ECLIPSE model is an accessible representation of recovery which could direct rehabilitation programmes, as well as inform the evaluation of prosthetic care through the selection of outcome measures.

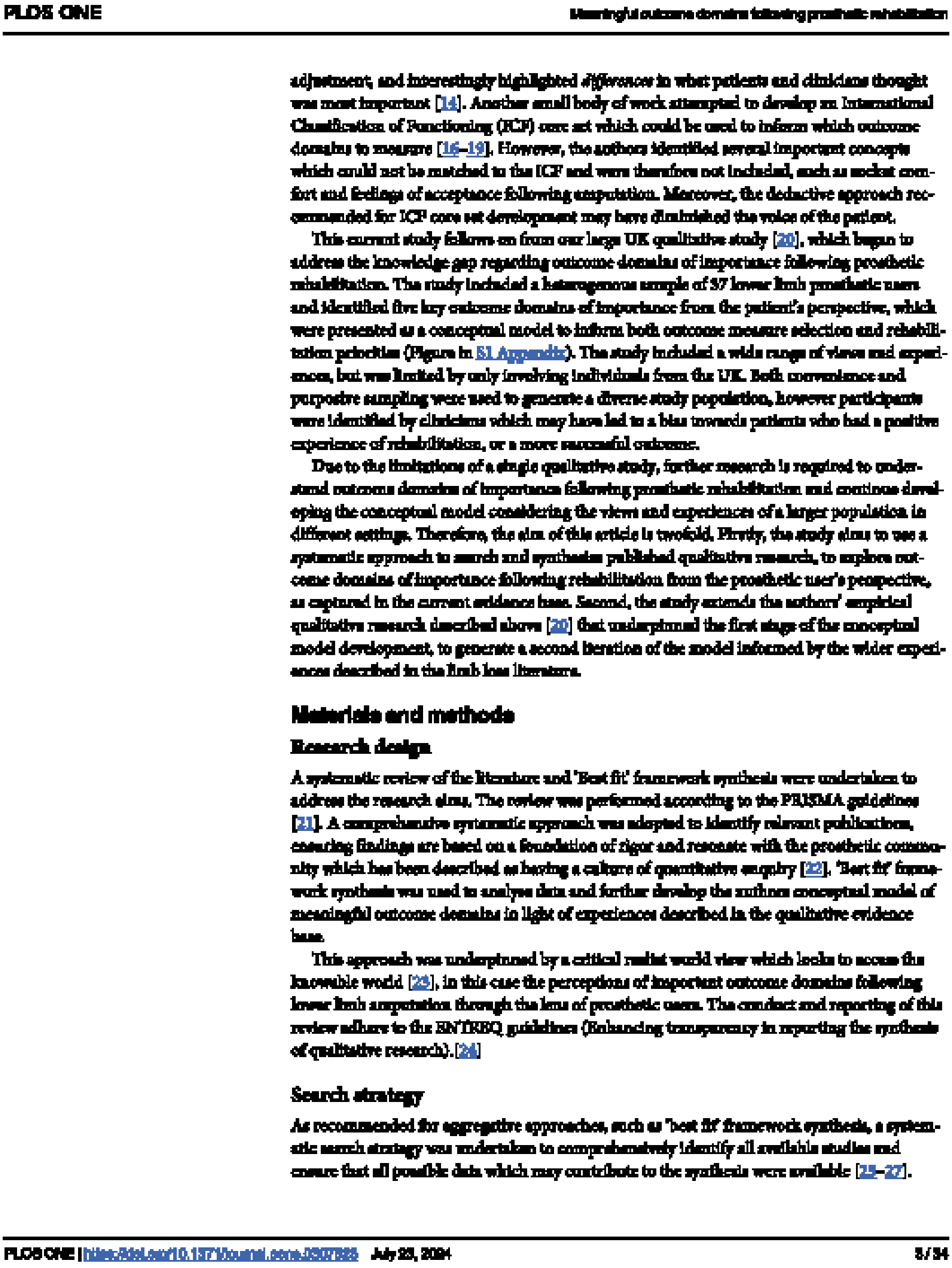
Background

Outcome measurement is increasingly important in clinical practice, assisting clinicians to understand the impact of their interventions and the effectiveness of the services they provide [1]. The term outcome measurement can be better understood by breaking it down into i) the outcome domain being measured and ii) the measurement tool. An outcome domain can be defined as an element of health (i.e. pain, physical function, emotional wellbeing) that is changed by a particular intervention [2]. A measurement tool can be defined as a standardised instrument used in research and clinical practice to capture and evaluate change [3].

Despite its potential value, outcome measurement is still not routinely used in clinical practice [4]. Within prosthetic rehabilitation several clinical interest groups, such as the British Association of Physiotherapists in Limb Absence Rehabilitation (BACPAR) and the International Society of Prosthetics and Orthotics (ISPO), have attempted to increase health care professional engagement by publishing recommended outcome measures for use in clinical settings [5–8]. However, numerous outcome measures are included in the recommendations, with different measures proposed by different professional groups. The recommendations also include many outcome measures capturing the same outcome domain (i.e., mobility via measures such as the Six Minute Walk test, Timed Up and Go, or the Amputee Mobility Predictor). A recent narrative review highlighted the absence of outcome measure consensus in the field of prosthetic rehabilitation, and suggested it may be driven by a lack of understanding around which outcome domains characterise a meaningful recovery following prosthetic rehabilitation, and should therefore be measured [9].

Gaining consensus regarding outcome domains of importance is crucial to allow effective comparison of research findings and clinical data. Consensus is advocated for by organisations such as Core Outcome Measurement in Effectiveness Trials (COMET) [10], and the International Consortium of Health Outcome Measurement (ICHOM) [11], who recommend domain consensus in research and clinical settings, respectively. Both groups promote a multi-stakeholder approach, including patients, to ensure domains are relevant to those for whom health and rehabilitation interventions have the most impact. However, a recent review of patient participation in core outcome set development questioned how patient-centred the process is [12]. The review found health care professionals tended to dominate prioritisation exercises, and few studies employed qualitative methods that may give patients more opportunity to contribute in a meaningful way [12].

Within prosthetic rehabilitation several authors have begun to explore which outcome domains are important to people who use a prosthetic limb, using qualitative approaches. McDonald et al. and Sheffaliusky et al. [13,14] both explored outcome domains of importance following the prescription of a prosthesis, focusing on the impact of componentry rather than the wider, holistic impacts of prosthetic rehabilitation recommended by professional groups [9,15]. These authors identified domains of importance such as balance, independence and



adjustment, and interestingly highlighted *differences* in what patients and clinicians thought was most important [14]. Another small body of work attempted to develop an International Classification of Functioning (ICF) core set which could be used to inform which outcome domains to measure [16–19]. However, the authors identified several important concepts which could not be matched to the ICF and were therefore not included, such as socket comfort and feelings of acceptance following amputation. Moreover, the deductive approach recommended for ICF core set development may have diminished the voice of the patient.

This current study follows on from our large UK qualitative study [20], which began to address the knowledge gap regarding outcome domains of importance following prosthetic rehabilitation. The study included a heterogeneous sample of 37 lower limb prosthetic users and identified five key outcome domains of importance from the patient's perspective, which were presented as a conceptual model to inform both outcome measure selection and rehabilitation priorities (Figure in S1 Appendix). The study included a wide range of views and experiences, but was limited by only involving individuals from the UK. Both convenience and purposive sampling were used to generate a diverse study population, however participants were identified by clinicians which may have led to a bias towards patients who had a positive experience of rehabilitation, or a more successful outcome.

Due to the limitations of a single qualitative study, further research is required to understand outcome domains of importance following prosthetic rehabilitation and continue developing the conceptual model considering the views and experiences of a larger population in different settings. Therefore, the aim of this article is twofold. Firstly, the study aims to use a systematic approach to search and synthesise published qualitative research, to explore outcome domains of importance following rehabilitation from the prosthetic user's perspective, as captured in the current evidence base. Second, the study extends the authors' empirical qualitative research described above [20] that underpinned the first stage of the conceptual model development, to generate a second iteration of the model informed by the wider experiences described in the limb loss literature.

Materials and methods

Research design

A systematic review of the literature and 'Best fit' framework synthesis were undertaken to address the research aims. The review was performed according to the PRISMA guidelines [21]. A comprehensive systematic approach was adopted to identify relevant publications, ensuring findings are based on a foundation of rigor and resonate with the prosthetic community which has been described as having a culture of quantitative enquiry [22]. 'Best fit' framework synthesis was used to analyse data and further develop the authors conceptual model of meaningful outcome domains in light of experiences described in the qualitative evidence base.

This approach was underpinned by a critical realist world view which looks to access the knowable world [23], in this case the perceptions of important outcome domains following lower limb amputation through the lens of prosthetic users. The conduct and reporting of this review adhere to the ENTREQ guidelines (Enhancing transparency in reporting the synthesis of qualitative research).[24]

Search strategy

As recommended for aggregative approaches, such as 'best fit' framework synthesis, a systematic search strategy was undertaken to comprehensively identify all available studies and ensure that all possible data which may contribute to the synthesis were available [25–27].

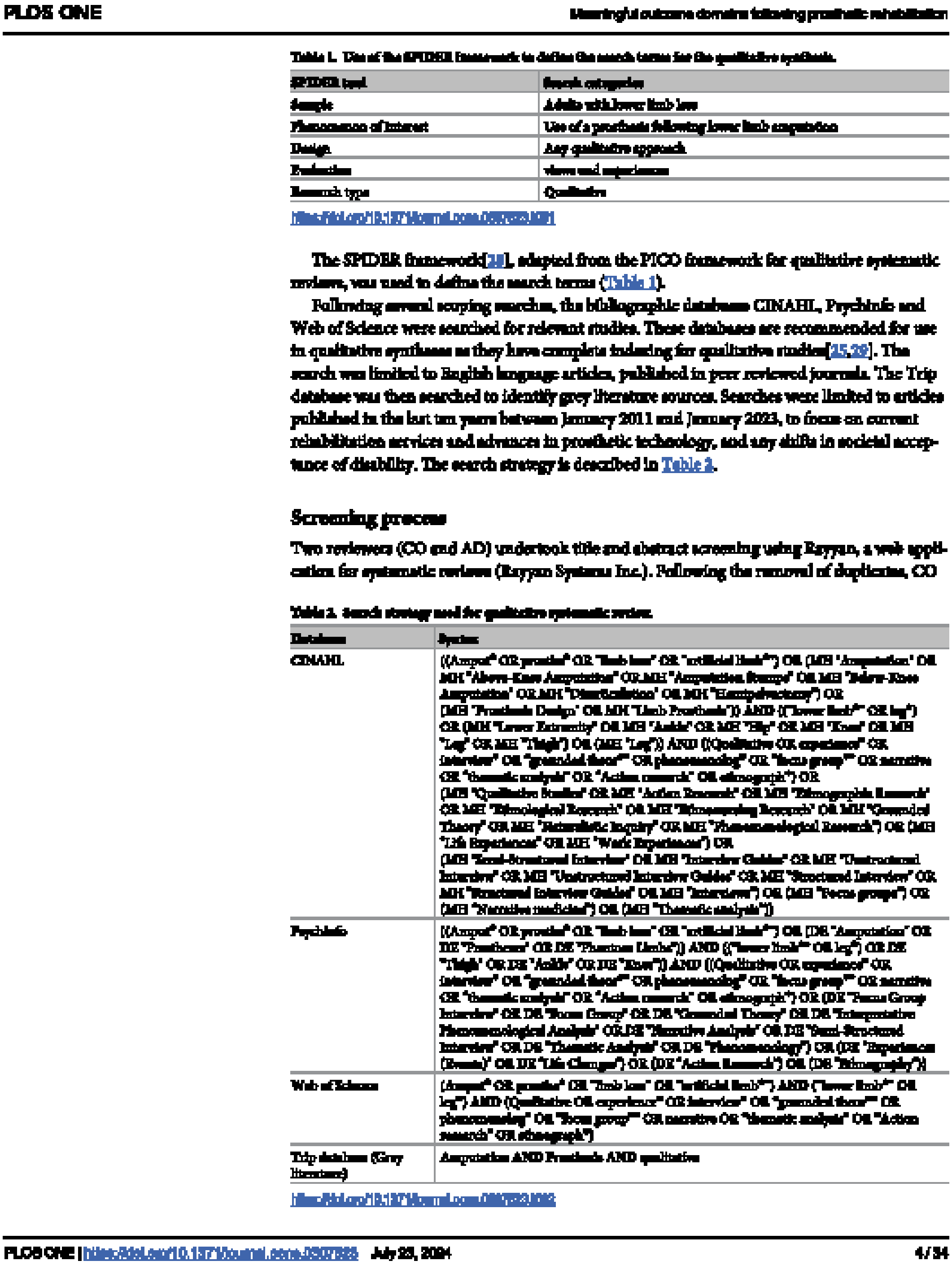


Table 1. Use of the SPIDER framework to define the search terms for the qualitative synthesis.

SPIDER tool	Search categories
Sample	Adults with lower limb loss
Phenomenon of Interest	Use of a prosthesis following lower limb amputation
Design	Any qualitative approach
Evaluation	views and experiences
Research type	Qualitative

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The SPIDER framework[28], adapted from the PICO framework for qualitative systematic reviews, was used to define the search terms (Table 1).

Following several scoping searches, the bibliographic databases CINAHL, PsychInfo and Web of Science were searched for relevant studies. These databases are recommended for use in qualitative syntheses as they have complete indexing for qualitative studies[25,29]. The search was limited to English language articles, published in peer reviewed journals. The Trip database was then searched to identify grey literature sources. Searches were limited to articles published in the last ten years between January 2011 and January 2023, to focus on current rehabilitation services and advances in prosthetic technology, and any shifts in societal acceptance of disability. The search strategy is described in Table 2.

Screening process

Two reviewers (CO and AD) undertook title and abstract screening using Rayyan, a web application for systematic reviews (Rayyan Systems Inc.). Following the removal of duplicates, CO

Table 2. Search strategy used for qualitative systematic review.

Database	Syntax
CINAHL	((Amput* OR prosthe* OR "limb loss" OR "artificial limb*") OR (MH "Amputation" OR MH "Above-Knee Amputation" OR MH "Amputation Stumps" OR MH "Below-Knee Amputation" OR MH "Disarticulation" OR MH "Hemipelvectomy") OR (MH "Prosthesis Design" OR MH "Limb Prosthesis")) AND (("lower limb*" OR leg*) OR (MH "Lower Extremity" OR MH "Ankle" OR MH "Hip" OR MH "Knee" OR MH "Leg" OR MH "Thigh") OR (MH "Leg")) AND ((Qualitative OR experience* OR interview* OR "grounded theor*" OR phenomenolog* OR "focus group*" OR narrative OR "thematic analysis" OR "Action research" OR ethnograph*) OR (MH "Qualitative Studies" OR MH "Action Research" OR MH "Ethnographic Research" OR MH "Ethnological Research" OR MH "Ethnonursing Research" OR MH "Grounded Theory" OR MH "Naturalistic Inquiry" OR MH "Phenomenological Research") OR (MH "Life Experiences" OR MH "Work Experiences") OR (MH "Semi-Structured Interview" OR MH "Interview Guides" OR MH "Unstructured Interview" OR MH "Unstructured Interview Guides" OR MH "Structured Interview" OR MH "Structured Interview Guides" OR MH "Interviews") OR (MH "Focus groups") OR (MH "Narrative medicine") OR (MH "Thematic analysis"))
PsychInfo	((Amput* OR prosthe* OR "limb loss" OR "artificial limb*") OR (DE "Amputation" OR DE "Prostheses" OR DE "Phantom Limbs")) AND (("lower limb*" OR leg*) OR DE "Thigh" OR DE "Ankle" OR DE "Knee")) AND ((Qualitative OR experience* OR interview* OR "grounded theor*" OR phenomenolog* OR "focus group*" OR narrative OR "thematic analysis" OR "Action research" OR ethnograph*) OR (DE "Focus Group Interview" OR DE "Focus Group" OR DE "Grounded Theory" OR DE "Interpretative Phenomenological Analysis" OR DE "Narrative Analysis" OR DE "Semi-Structured Interview" OR DE "Thematic Analysis" OR DE "Phenomenology") OR (DE "Experiences (Events)" OR DE "Life Changes") OR (DE "Action Research") OR (DE "Ethnography"))
Web of Science	(Amput* OR prosthe* OR "limb loss" OR "artificial limb*") AND ("lower limb*" OR leg*) AND (Qualitative OR experience* OR interview* OR "grounded theor*" OR phenomenolog* OR "focus group*" OR narrative OR "thematic analysis" OR "Action research" OR ethnograph*)
Trip database (Grey literature)	Amputation AND Prosthesis AND qualitative

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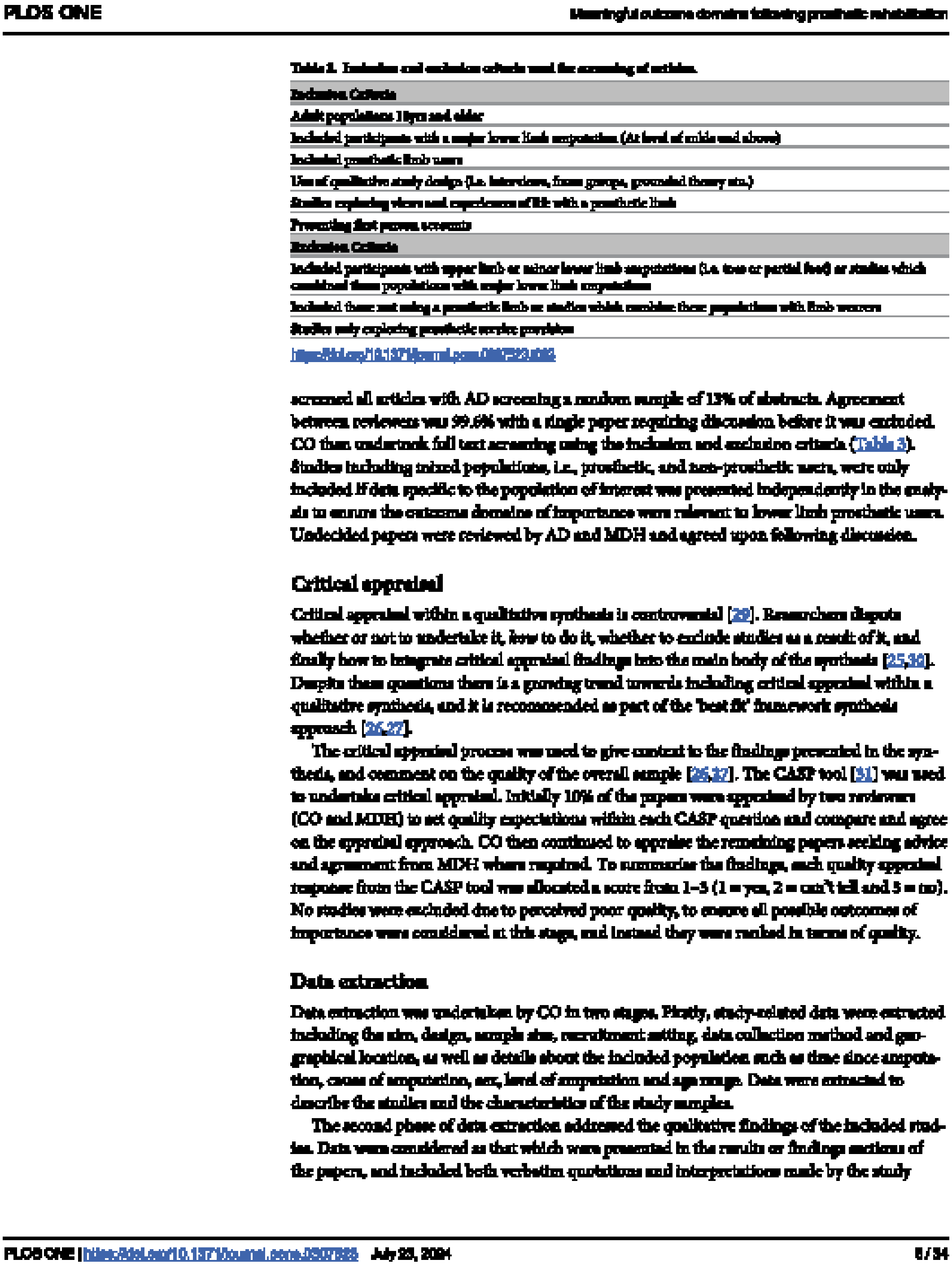

Table 3. Inclusion and exclusion criteria used for screening of articles.

Inclusion Criteria
Adult populations 18yrs and older
Included participants with a major lower limb amputation (At level of ankle and above)
Included prosthetic limb users
Use of qualitative study design (i.e. interviews, focus groups, grounded theory etc.)
Studies exploring views and experiences of life with a prosthetic limb
Presenting first person accounts
Exclusion Criteria
Included participants with upper limb or minor lower limb amputations (i.e. toes or partial foot) or studies which combined these populations with major lower limb amputations
Included those not using a prosthetic limb or studies which combine these populations with limb wearers
Studies only exploring prosthetic service provision

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screened all articles with AD screening a random sample of 13% of abstracts. Agreement between reviewers was 99.6% with a single paper requiring discussion before it was excluded. CO then undertook full text screening using the inclusion and exclusion criteria (Table 3). Studies including mixed populations, i.e., prosthetic, and non-prosthetic users, were only included if data specific to the population of interest was presented independently in the analysis to ensure the outcome domains of importance were relevant to lower limb prosthetic users. Undecided papers were reviewed by AD and MDH and agreed upon following discussion.

Critical appraisal

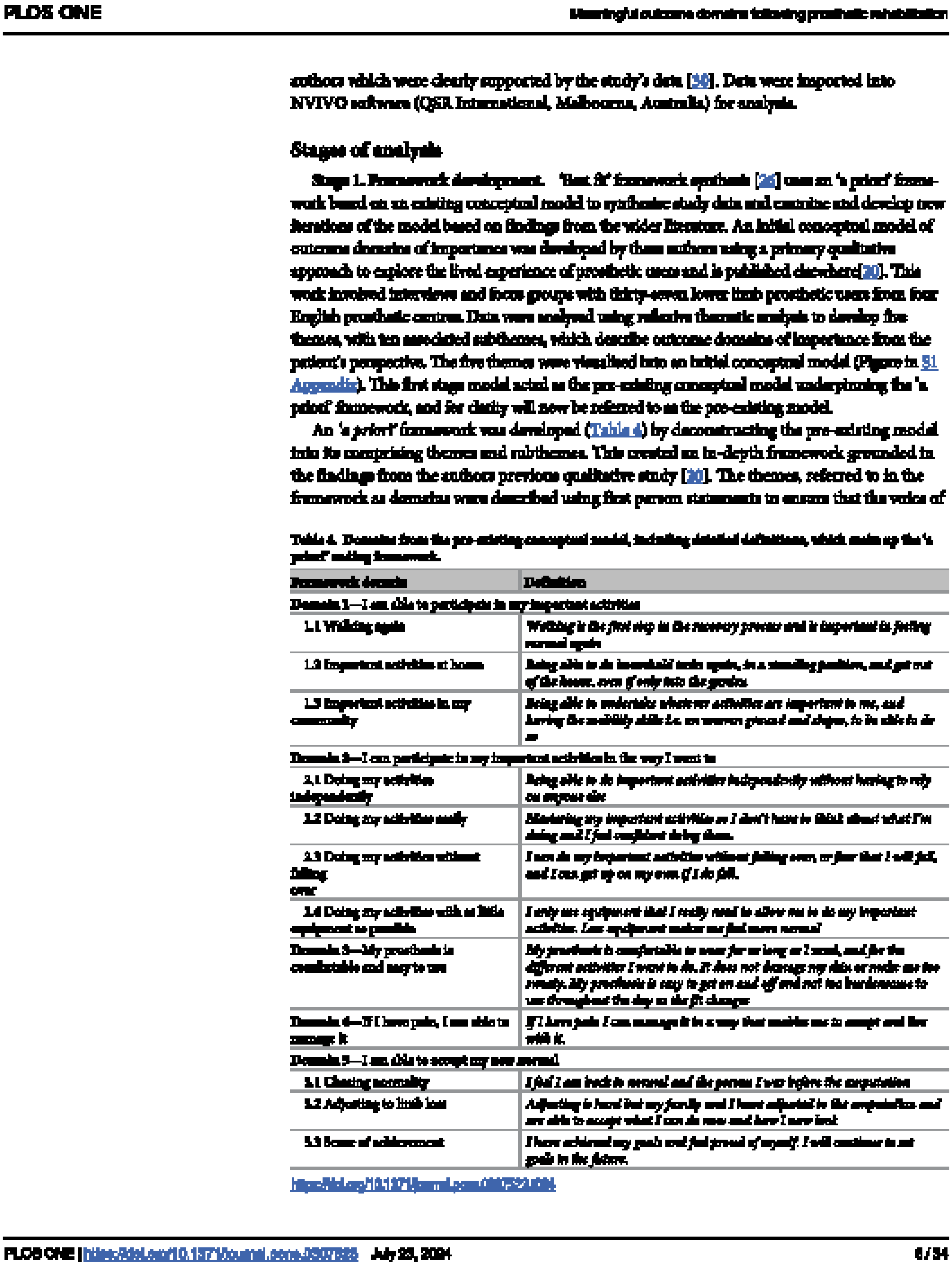
Critical appraisal within a qualitative synthesis is controversial [29]. Researchers dispute whether or not to undertake it, how to do it, whether to exclude studies as a result of it, and finally how to integrate critical appraisal findings into the main body of the synthesis [25,30]. Despite these questions there is a growing trend towards including critical appraisal within a qualitative synthesis, and it is recommended as part of the 'best fit' framework synthesis approach [26,27].

The critical appraisal process was used to give context to the findings presented in the synthesis, and comment on the quality of the overall sample [26,27]. The CASP tool [31] was used to undertake critical appraisal. Initially 10% of the papers were appraised by two reviewers (CO and MDH) to set quality expectations within each CASP question and compare and agree on the appraisal approach. CO then continued to appraise the remaining papers seeking advice and agreement from MDH where required. To summarise the findings, each quality appraisal response from the CASP tool was allocated a score from 1–3 (1 = yes, 2 = can't tell and 3 = no). No studies were excluded due to perceived poor quality, to ensure all possible outcomes of importance were considered at this stage, and instead they were ranked in terms of quality.

Data extraction

Data extraction was undertaken by CO in two stages. Firstly, study-related data were extracted including the aim, design, sample size, recruitment setting, data collection method and geographical location, as well as details about the included population such as time since amputation, cause of amputation, sex, level of amputation and age range. Data were extracted to describe the studies and the characteristics of the study samples.

The second phase of data extraction addressed the qualitative findings of the included studies. Data were considered as that which were presented in the results or findings sections of the papers, and included both verbatim quotations and interpretations made by the study



authors which were clearly supported by the study's data [30]. Data were imported into NVIVO software (QSR International, Melbourne, Australia) for analysis.

Stages of analysis

Stage 1. Framework development. 'Best fit' framework synthesis [26] uses an 'a priori' framework based on an existing conceptual model to synthesise study data and examine and develop new iterations of the model based on findings from the wider literature. An initial conceptual model of outcome domains of importance was developed by these authors using a primary qualitative approach to explore the lived experience of prosthetic users and is published elsewhere[20]. This work involved interviews and focus groups with thirty-seven lower limb prosthetic users from four English prosthetic centres. Data were analysed using reflexive thematic analysis to develop five themes, with ten associated subthemes, which describe outcome domains of importance from the patient's perspective. The five themes were visualised into an initial conceptual model (Figure in S1 Appendix). This first stage model acted as the pre-existing conceptual model underpinning the 'a priori' framework, and for clarity will now be referred to as the pre-existing model.

An '*a priori*' framework was developed (Table 4) by deconstructing the pre-existing model into its comprising themes and subthemes. This created an in-depth framework grounded in the findings from the authors previous qualitative study [20]. The themes, referred to in the framework as domains were described using first person statements to ensure that the voice of

Table 4. Domains from the pre-existing conceptual model, including detailed definitions, which make up the 'a priori' coding framework.

Framework domain	Definition
Domain 1—I am able to participate in my important activities	
1.1 Walking again	*Walking is the first step in the recovery process and is important in feeling normal again*
1.2 Important activities at home	*Being able to do household tasks again, in a standing position, and get out of the house, even if only into the garden*
1.3 Important activities in my community	*Being able to undertake whatever activities are important to me, and having the mobility skills i.e. on uneven ground and slopes, to be able to do so*
Domain 2—I can participate in my important activities in the way I want to	
2.1 Doing my activities independently	*Being able to do important activities independently without having to rely on anyone else*
2.2 Doing my activities easily	*Mastering my important activities so I don't have to think about what I'm doing and I feel confident doing them.*
2.3 Doing my activities without falling over	*I can do my important activities without falling over, or fear that I will fall, and I can get up on my own if I do fall.*
2.4 Doing my activities with as little equipment as possible	*I only use equipment that I really need to allow me to do my important activities. Less equipment makes me feel more normal*
Domain 3—My prosthesis is comfortable and easy to use	*My prosthesis is comfortable to wear for as long as I need, and for the different activities I want to do. It does not damage my skin or make me too sweaty. My prosthesis is easy to get on and off and not too burdensome to use throughout the day as the fit changes*
Domain 4—If I have pain, I am able to manage it	*If I have pain I can manage it in a way that enables me to accept and live with it.*
Domain 5—I am able to accept my new normal	
5.1 Chasing normality	*I feel I am back to normal and the person I was before the amputation*
5.2 Adjusting to limb loss	*Adjusting is hard but my family and I have adjusted to the amputation and are able to accept what I can do now and how I now look*
5.3 Sense of achievement	*I have achieved my goals and feel proud of myself. I will continue to set goals in the future.*

https://doi.org/10.1371/journal.pone.0307523.t004

the prosthetic user was not lost during the synthesis process. Each framework domain was also accompanied by an in-depth description to aid consistency of coding [26,27].

Stage 2: Analysis. Data describing the included studies and their samples were analysed using descriptive statistics to give context about the qualitative approaches taken and the overall review population.

Data synthesis from the 'findings' sections of the included articles was undertaken in two steps. Step one involved open line by line coding of the data, codes were then mapped onto the domains and subthemes described in the '*a priori*' framework (Table 4).

Codes that did not fit easily into the framework were collated separately in NVIVO and analysed in a second step, independent of the framework synthesis, using thematic analysis as described by Braun and Clarke [32–34]. This dual approach using inductive thematic analysis in addition to the more deductive framework synthesis (Table 5) allowed previously unidentified concepts related to outcome domains of importance to arise from the data.

Stage 3: Conceptual model development. The findings from the framework synthesis were reviewed by the research team to understand where the review data supported pre-existing domains and where they did not. Newly identified themes were reviewed against the pre-existing conceptual model and through discussion and reflection, were added or used to refine the model until consensus was reached on a second iteration.

Results

Summary of included studies

Searches identified 1709 records, which were filtered down to 101 potentially relevant articles following removal of duplicates and screening of titles and abstracts. Thirty-nine of

Table 5. Description of 'Best fit' framework synthesis and accompanying thematic analysis.

Phase	Description of process
(1) Familiarisation with the data	The results sections of the included studies were read and reread to increase familiarity with the data (CO).
(2) Coding	Open, line by line coding of the data was performed separately by the lead author (CO). Extracts of text were coded in as many ways as needed. A reflective journal was completed throughout the analysis process to encourage awareness of the researcher's own views and assumptions (CO).
(3) Coding into the framework	Codes were reviewed and mapped onto the domains and subthemes described in the 'a priori' framework by two researchers (CO and MDH). Data which did not map easily into the framework were collated separately.
(4) Reviewing left over codes	For codes not easily represented by domains set out in the framework a thematic analysis was undertaken. Left over codes and coded data were examined (CO and MDH), similarities and overlap were identified between codes and potential patterns relevant to the research question were created (CO and MDH)
(5) Generating and developing new themes	A visual map of initial themes not represented in the framework was created and compared (CO and MDH). All results sections were re-read and the fit of initial themes reviewed in relation to the full data set, coded data and the framework (CO). This process was then repeated by members of the research team (MDH).
(6) Refining, defining and naming new themes	The full set of concepts from both the framework and the additional thematic analysis were then reviewed and refined. Themes were collapsed or expanded in order to present coherent patterns within the data (CO). The research team reviewed newly developed concepts and subthemes to ensure they captured important new meaning in relation to the research question, and to assist reflection on researcher assumptions (CO, AD, CM, MDH). A person-centred approach was taken to naming new domains and subthemes in order to capture the voice of participants (CO).

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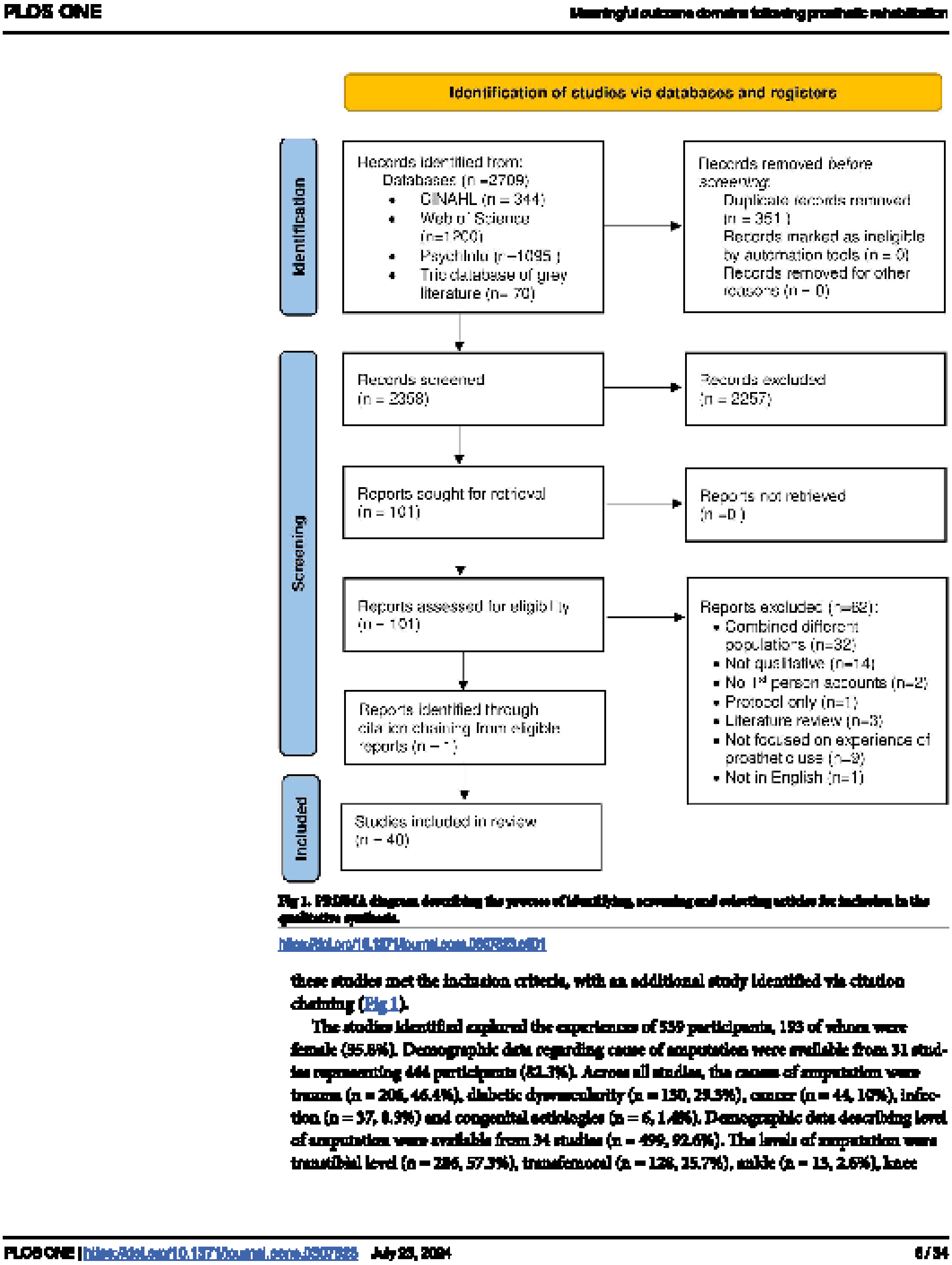
Appendix I



PLOS ONE

Meaningful outcome domains following prosthetic rehabilitation

Fig 1. PRISMA diagram describing the process of identifying, screening and selecting articles for inclusion in the qualitative synthesis.

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these studies met the inclusion criteria, with an additional study identified via citation chaining (Fig 1).

The studies identified explored the experiences of 539 participants, 193 of whom were female (35.8%). Demographic data regarding cause of amputation were available from 31 studies representing 444 participants (82.3%). Across all studies, the causes of amputation were trauma (n = 206, 46.4%), diabetic dysvascularity (n = 130, 29.3%), cancer (n = 44, 10%), infection (n = 37, 8.3%) and congenital aetiologies (n = 6, 1.4%). Demographic data describing level of amputation were available from 34 studies (n = 499, 92.6%). The levels of amputation were transtibial level (n = 286, 57.3%), transfemoral (n = 128, 25.7%), ankle (n = 13, 2.6%), knee

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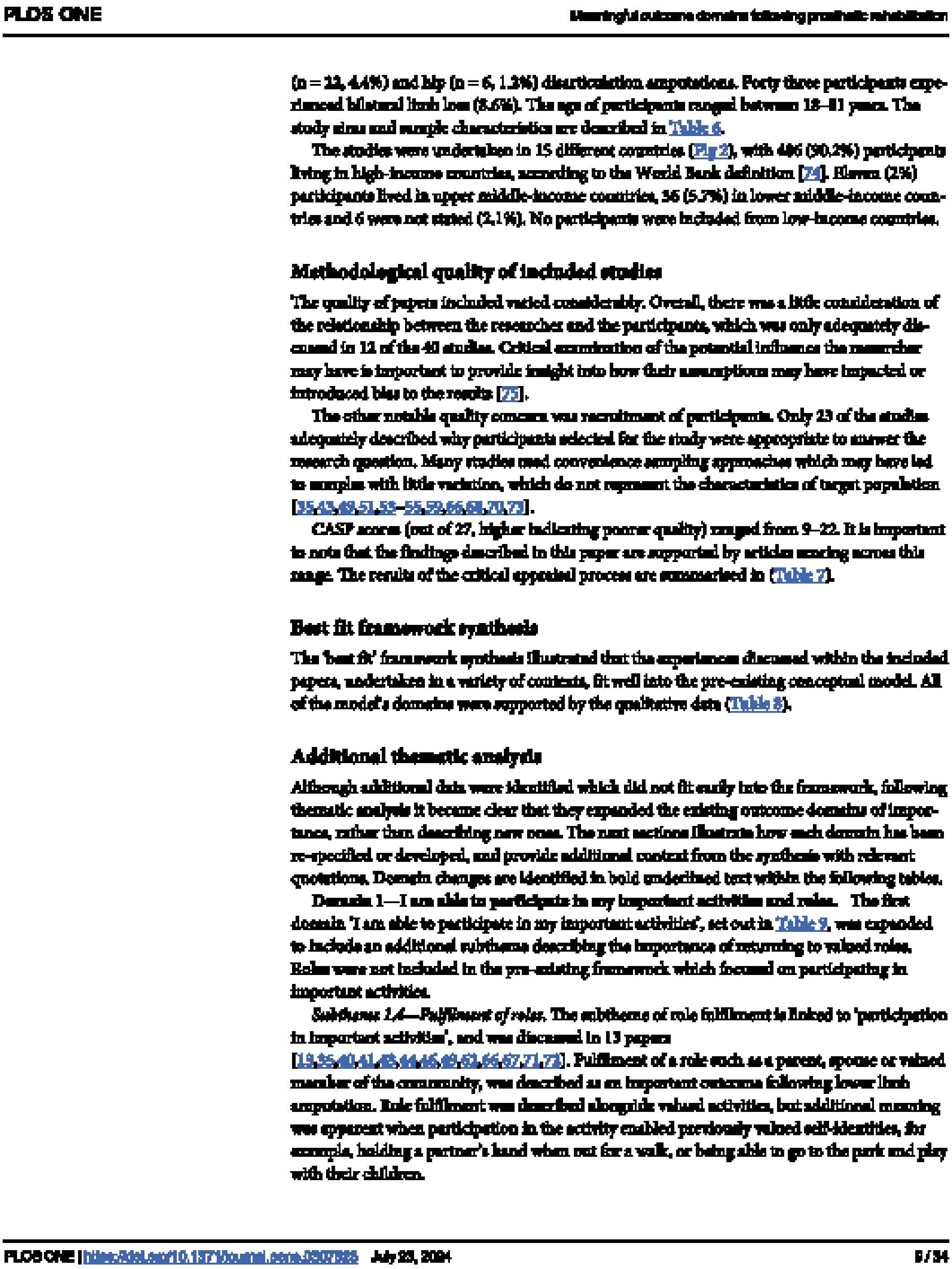

(n = 22, 4.4%) and hip (n = 6, 1.2%) disarticulation amputations. Forty three participants experienced bilateral limb loss (8.6%). The age of participants ranged between 18–81 years. The study aims and sample characteristics are described in Table 6.

The studies were undertaken in 15 different countries (Fig 2), with 486 (90.2%) participants living in high-income countries, according to the World Bank definition [74]. Eleven (2%) participants lived in upper middle-income countries, 36 (5.7%) in lower middle-income countries and 6 were not stated (2.1%). No participants were included from low-income countries.

Methodological quality of included studies

The quality of papers included varied considerably. Overall, there was a little consideration of the relationship between the researcher and the participants, which was only adequately discussed in 12 of the 40 studies. Critical examination of the potential influence the researcher may have is important to provide insight into how their assumptions may have impacted or introduced bias to the results [75].

The other notable quality concern was recruitment of participants. Only 23 of the studies adequately described why participants selected for the study were appropriate to answer the research question. Many studies used convenience sampling approaches which may have led to samples with little variation, which do not represent the characteristics of target population [35,43,49,51,53–55,59,66,68,70,73].

CASP scores (out of 27, higher indicating poorer quality) ranged from 9–22. It is important to note that the findings described in this paper are supported by articles scoring across this range. The results of the critical appraisal process are summarised in (Table 7).

Best fit framework synthesis

The 'best fit' framework synthesis illustrated that the experiences discussed within the included papers, undertaken in a variety of contexts, fit well into the pre-existing conceptual model. All of the model's domains were supported by the qualitative data (Table 8).

Additional thematic analysis

Although additional data were identified which did not fit easily into the framework, following thematic analysis it became clear that they expanded the existing outcome domains of importance, rather than describing new ones. The next sections illustrate how each domain has been re-specified or developed, and provide additional context from the synthesis with relevant quotations. Domain changes are identified in bold underlined text within the following tables.

Domain 1—I am able to participate in my important activities and roles. The first domain 'I am able to participate in my important activities', set out in Table 9, was expanded to include an additional subtheme describing the importance of returning to valued roles. Roles were not included in the pre-existing framework which focused on participating in important activities.

Subtheme 1.4—Fulfilment of roles. The subtheme of role fulfilment is linked to 'participation in important activities', and was discussed in 13 papers [19,35,40,41,43,44,46,49,51,66,67,71,73]. Fulfilment of a role such as a parent, spouse or valued member of the community, was described as an important outcome following lower limb amputation. Role fulfilment was described alongside valued activities, but additional meaning was apparent when participation in the activity enabled previously valued self-identities, for example, holding a partner's hand when out for a walk, or being able to go to the park and play with their children.

Table 4. Summary of study aim and sample characteristics from papers included in the qualitative synthesis.

Study	Aim	Location	Sample size (n)	Sample characteristics
Abouammoh et al. (2021) [35]	Explore the adjustment experiences of amputees in Saudi Arabia and their needs before and after amputation.	Saudi Arabia	9	4 females. Level: 1 symes, 8 TTA, 9 TFA, 6 bilat. Age range 26–71 yrs. Time since amp 4–15 yrs
Batten et al. (2020) [36]	Investigate barriers and enablers to community walking among people with lower limb amputation who have returned to live in a community setting	Australia	14	5 females. Cause: 1 trauma, 9 diabetic dysvascular, 2 infection, 1 cancer, 1 other. Level: 13 TTA, 1 TFA, 2 bilat. Median age 58 yrs. Age range 49–82 yrs. Time since amp 4–24 months
Bragaru et al. (2013) [37]	Identify personal barriers and facilitators that influence participation in sports of individuals with LLA	Netherlands	26	7 females. Cause: 7 trauma, 15 diabetic dysvascular, 4 tumour. Level: 1 symes, 9 TTA, 7 KDA, 7 TFA, 2 HAD, 2 bilat. Age range 21–77 yrs. Time since amp 2–39 years.
Camacho et al. (2021) [38]	Explore the lived experience of support group participants who are survivors of LLA living with PLP and understand the adaptation process postoperatively	USA	10	4 females. Cause: 2 trauma, 5 diabetic dysvascular, 1 infection, 1 tumour, 1 congenital. Level: 4 TTA, 5 TFA, 1 HAD, 1 bilat. Age range 22–70 yrs. Time since amp 1–55 yrs.
Christensen et al. (2018) [39]	Increase understanding of the military identity influence on the organisation of rehabilitation and investigate factors of importance for successful rehabilitation services	Denmark	6	All male. Level: 5 TTA, 1 TFA. Mean age 32 yrs. Age range 26–46 yrs. Time since amp 2–17 yrs
Crawford et al. (2016) [40]	Investigate barriers and facilitators to Physical Activity participation for men with transtibial osteomyoplastic amputation	USA	9	All male. Level: all TTA. Age range 31–56 yrs. Time since amp 2–33 yrs
Day et al. (2019) [41]	Explore the everyday experiences of people with an amputation using a good day/bad day approach	UK	32	14 females. Cause: 9 Trauma, 3 diabetic dysvascular, 5 infection, 4 tumour, 1 congenital. Level: 19 TTA, 4 TFA, 4 bilat. Mean age 42 yrs. Age range 23–81. Time since amp 1–37 yrs
Devan et al. (2015) [42]	Explore the perceptions of adults with lower limb amputation and LBP as to the factors contributing to and affecting their LBP.	New Zealand	11	3 female. Cause: 8 trauma, 1 tumour, 1 congenital, 1 other. Level: 8 TTA, 3 TFA. Age range 18–70 yrs. Time since amp 3–44 years
Ennion and Manig (2019) [43]	Explore the experiences of current lower limb prosthetic users in relation prosthetic service delivery and the value of their prosthesis in a rural setting	South Africa	9	1 female. Cause: 8 trauma, 1 infection. Level: 3 TTA, 6 TFA. Mean age 44 yrs. Age range 33–64 yrs. Time since amp 3–34 yrs
Hafner et al. (2016) [44]	Explore how prosthetic limb users conceptualize mobility with a prosthetic limb, construct a conceptual model of prosthetic mobility meaningful to people with lower limb loss, confirm key definitions, and inform development of items for the Prosthetic Limb Users Survey of Mobility (PLUS-M)	USA	37	11 females. Cause: 13 trauma, 3 diabetic dysvascular, 11 infection, 2 tumour, 8 other. Level: 20 TTA, 1 KDA, 11 TFA, 1 HDA, 5 bilat. Mean age 50.4 yrs. Age range 23–71 yrs. Time since amp 0.5–49 yrs
Hanson and Duquette (2021) [45]	Understand more about the reproductive experiences of amputee women who are living with amputation	Global	6	All female.
Hansen et al. (2019) [46]	Examine the process of becoming a user of a transfemoral osseointegrated prosthesis, from the beginning of rehabilitation (after second stage surgery) and forward, as seen from the user's perspective.	Denmark	7	2 females. Cause: 4 trauma, 3 tumour; Level: All TFA. Age range 37–70 yrs
Heavey 2018 [47]	Use a case study approach for analysing space as a narrative resource in stories about illness and recovery	UK	1	All Female, Cause: Diabetic dysvascular. Level: TFA. Age 68 yrs, Time since amp 50 yrs
Henry and Paul (2019) [48]	Understand the subjective experiences with chronic amputation pain and responses from family members, friends, and health care providers	USA	11	4 females. Mean age 60.82 yrs
[illegible] et al. (2018) [49]	Explore experiences of persons in Nepal using lower-limb prostheses	Nepal	16	6 females. Cause: 11 trauma, 2 infection, 2 tumour, 1 other. Level: 11 TTA, 1 KDA, 4 TFA. Mean age 38 yrs. Age range 21–67 yrs. Time since amp mean 10 yrs
Jeppsen et al. (2019) [50]	To better understand the resilience among Veterans who experienced combat-related amputations.	USA	6	Cause: 6 trauma

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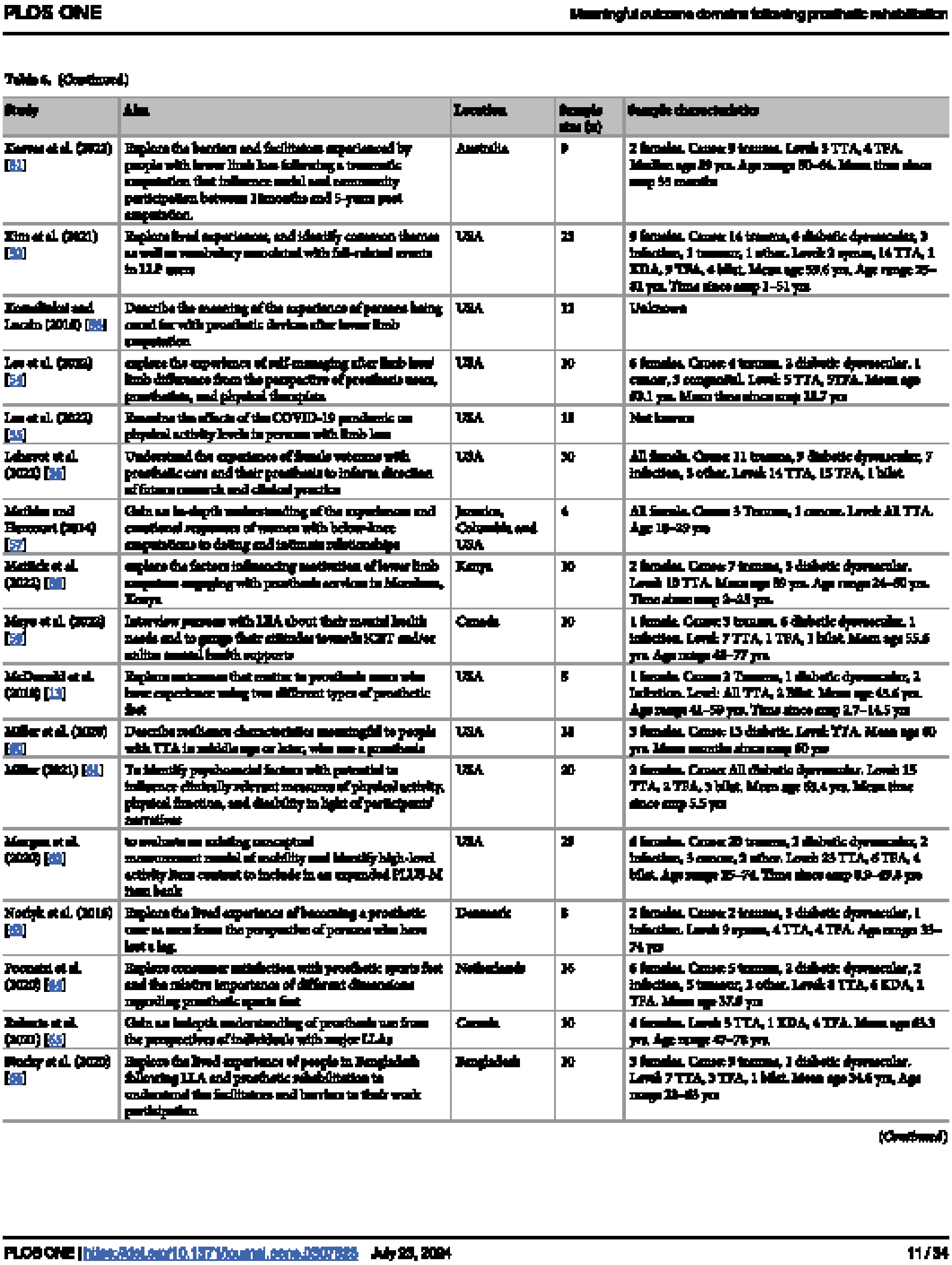

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Meaningful outcome domains following prosthetic rehabilitation

Table 6. (Continued)

Study	Aim	Location	Sample size (n)	Sample characteristics
Keeves et al. (2022) [51]	Explore the barriers and facilitators experienced by people with lower limb loss following a traumatic amputation that influence social and community participation between 1 months and 5-years post amputation.	Australia	9	2 females. Cause: 9 trauma. Level: 5 TTA, 4 TFA. Median age 39 yrs. Age range [illegible]–64. Mean time since amp 35 months
Kim et al. (2021) [52]	Explore lived experiences, and identify common themes as well as vocabulary associated with fall-related events in LLP users	USA	23	9 females. Cause: 14 trauma, 4 diabetic dysvascular, 3 infection, 1 tumour, 1 other. Level: 2 symes, 14 TTA, 1 KDA, 9 TFA, 4 bilat. Mean age 59.6 yrs. Age range 35–81 yrs. Time since amp 1–51 yrs
[illegible] and Lucas (2018) [53]	Describe the meaning of the experience of persons being cared for with prosthetic devices after lower limb amputation.	USA	12	Unknown
Lee et al. (2022) [54]	explore the experience of self-managing after limb loss/ limb difference from the perspective of prosthesis users, prosthetists, and physical therapists.	USA	10	6 females. Cause: 4 trauma. 2 diabetic dysvascular. 1 cancer, 3 congenital. Level: 5 TTA, 5TFA. Mean age 49.1 yrs. Mean time since amp 18.7 yrs
Lee et al. (2022) [55]	Examine the effects of the COVID-19 pandemic on physical activity levels in persons with limb loss	USA	18	Not known
Lehavot et al. (2022) [56]	Understand the experience of female veterans with prosthetic care and their prosthesis to inform direction of future research and clinical practice	USA	30	All female. Cause: 11 trauma, 9 diabetic dysvascular, 7 infection, 3 other. Level: 14 TTA, 15 TFA, 1 bilat.
Mathias and Harcourt (2014) [57]	Gain an in-depth understanding of the experiences and emotional responses of women with below-knee amputations to dating and intimate relationships	Jamaica, Colombia, and USA	4	All female. Cause: 3 Trauma, 1 cancer. Level: All TTA. Age 18–29 yrs
Mattick et al. (2022) [58]	explore the factors influencing motivation of lower limb amputees engaging with prosthesis services in Mombasa, Kenya.	Kenya	10	2 females. Cause: 7 trauma, 3 diabetic dysvascular. Level: 10 TTA. Mean age 39 yrs. Age range 24–60 yrs. Time since amp 2–25 yrs.
Mayo et al. (2022) [59]	Interview persons with LLA about their mental health needs and to gauge their attitudes towards CBT and/or online mental health supports	Canada	10	1 female. Cause: 3 trauma. 6 diabetic dysvascular. 1 infection. Level: 7 TTA, 1 TFA, 2 bilat. Mean age 55.6 yrs. Age range 48–77 yrs.
McDonald et al. (2018) [13]	Explore outcomes that matter to prosthesis users who have experience using two different types of prosthetic feet	USA	5	1 female. Cause: 2 Trauma, 1 diabetic dysvascular, 2 Infection. Level: All TTA, 2 Bilat. Mean age 48.6 yrs. Age range 41–59 yrs. Time since amp 2.7–14.5 yrs
Miller et al. (2020) [60]	Describe resilience characteristics meaningful to people with TTA in middle age or later, who use a prosthesis	USA	13	3 females. Cause: 13 diabetic. Level: TTA. Mean age 60 yrs. Mean months since amp 60 yrs
Miller (2021) [61]	To identify psychosocial factors with potential to influence clinically relevant measures of physical activity, physical function, and disability in light of participants' narratives	USA	20	3 females. Cause: All diabetic dysvascular. Level: 15 TTA, 2 TFA, 3 bilat. Mean age 61.4 yrs. Mean time since amp 5.5 yrs
Morgan et al. (2020) [62]	to evaluate an existing conceptual measurement model of mobility and identify high-level activity item content to include in an expanded PLUS-M item bank	USA	29	4 females. Cause: 20 trauma, 2 diabetic dysvascular, 2 infection, 3 cancer, 2 other. Level: 23 TTA, 6 TFA, 4 bilat. Age range 25–74. Time since amp [illegible]–49.8 yrs
Nørlyk et al. (2016) [63]	Explore the lived experience of becoming a prosthetic user as seen from the perspective of persons who have lost a leg.	Denmark	8	2 females. Cause: 2 trauma, 3 diabetic dysvascular, 1 infection. Level: [illegible] symes, 4 TTA, 4 TFA. Age range 33–74 yrs
Poonsiri et al. (2020) [64]	Explore consumer satisfaction with prosthetic sports feet and the relative importance of different dimensions regarding prosthetic sports feet	Netherlands	16	6 females. Cause: 5 trauma, 2 diabetic dysvascular, 2 infection, 5 tumour, 2 other. Level: 8 TTA, 6 KDA, 1 TFA. Mean age 37.8 yrs
Roberts et al. (2021) [65]	Gain an in-depth understanding of prosthesis use from the perspectives of individuals with major LLAs	Canada	10	4 females. Level: 5 TTA, 1 KDA, 4 TFA. Mean age 63.3 yrs. Age range 47–78 yrs.
[illegible] et al. (2020) [66]	Explore the lived experience of people in Bangladesh following LLA and prosthetic rehabilitation to understand the facilitators and barriers to their work participation	Bangladesh	10	3 females. Cause: 9 trauma, 1 diabetic dysvascular. Level: 7 TTA, 3 TFA, 1 bilat. Mean age 34.6 yrs, Age range 23–48 yrs

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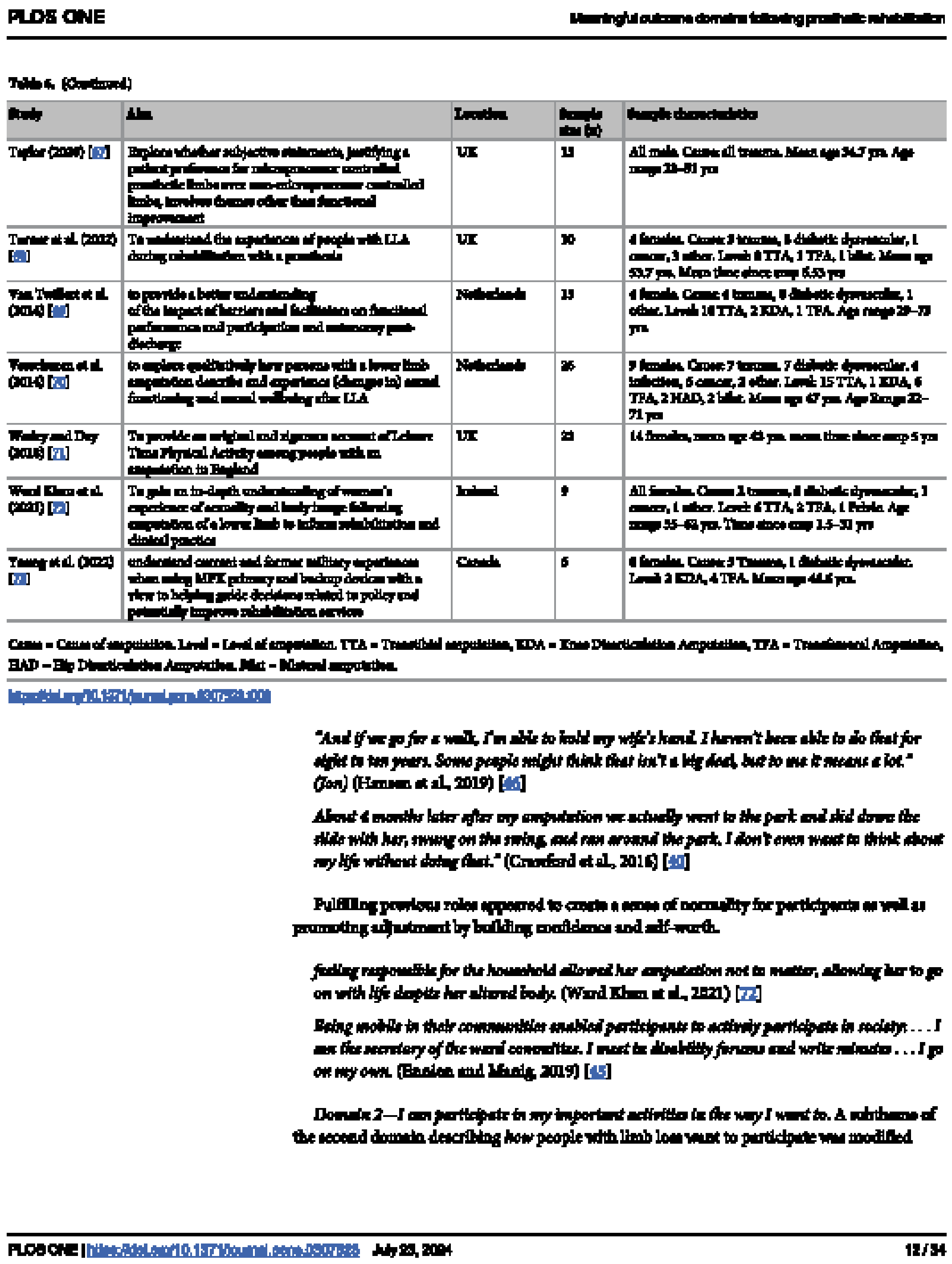

Table 6. (Continued)

Study	Aim	Location	Sample size (n)	Sample characteristics
Taylor (2020) [67]	Explores whether subjective statements, justifying a patient preference for microprocessor controlled prosthetic limbs over non-microprocessor controlled limbs, involves themes other than functional improvement	UK	13	All male. Cause: all trauma. Mean age 34.7 yrs. Age range 23–51 yrs
Turner et al. (2022) [68]	To understand the experiences of people with LLA during rehabilitation with a prosthesis	UK	10	4 females. Cause: 3 trauma, 3 diabetic dysvascular, 1 cancer, 3 other. Level: 8 TTA, 1 TFA, 1 bilat. Mean age 53.7 yrs. Mean time since amp 6.53 yrs
Van Twillert et al. (2014) [69]	to provide a better understanding of the impact of barriers and facilitators on functional performance and participation and autonomy post-discharge	Netherlands	13	4 female. Cause: 4 trauma, 8 diabetic dysvascular, 1 other. Level: 10 TTA, 2 KDA, 1 TFA. Age range 29–73 yrs
Verschuren et al. (2016) [70]	to explore qualitatively how persons with a lower limb amputation describe and experience (changes in) sexual functioning and sexual wellbeing after LLA	Netherlands	26	9 females. Cause: 7 trauma, 7 diabetic dysvascular, 4 infection, 6 cancer, 2 other. Level: 15 TTA, 1 KDA, 6 TFA, 2 HAD, 2 bilat. Mean age 47 yrs. Age Range 22–71 yrs
Wadey and Day (2018) [71]	To provide an original and rigorous account of Leisure Time Physical Activity among people with an amputation in England	UK	23	14 females, mean age 42 yrs. mean time since amp 5 yrs
Ward Khan et al. (2021) [72]	To gain an in-depth understanding of women's experience of sexuality and body image following amputation of a lower limb to inform rehabilitation and clinical practice	Ireland	9	All female. Cause: 1 trauma, 6 diabetic dysvascular, 1 cancer, 1 other. Level: 6 TTA, 2 TFA, 1 Pelvic. Age range 55–68 yrs. Time since amp 1.5–30 yrs
Young et al. (2022) [73]	understand current and former military experiences when using MPK primary and backup devices with a view to helping guide decisions related to policy and potentially improve rehabilitation services	Canada	6	0 females. Cause: 5 Trauma, 1 diabetic dysvascular. Level: 2 KDA, 4 TFA. Mean age 46.6 yrs.

Cause = Cause of amputation. Level = Level of amputation. TTA = Transtibial amputation, KDA = Knee Disarticulation Amputation, TFA = Transfemoral Amputation, HAD = Hip Disarticulation Amputation. Bilat = Bilateral amputation.

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> *"And if we go for a walk, I'm able to hold my wife's hand. I haven't been able to do that for eight to ten years. Some people might think that isn't a big deal, but to me it means a lot." (Jon)* (Hansen et al., 2019) [46]
>
> *About 4 months later after my amputation we actually went to the park and slid down the slide with her, swung on the swing, and ran around the park. I don't even want to think about my life without doing that."* (Crawford et al., 2016) [40]

Fulfilling previous roles appeared to create a sense of normality for participants as well as promoting adjustment by building confidence and self-worth.

> *feeling responsible for the household allowed her amputation not to matter, allowing her to go on with life despite her altered body.* (Ward Khan et al., 2021) [72]
>
> *Being mobile in their communities enabled participants to actively participate in society: . . . I am the secretary of the ward committee. I meet in disability forums and write minutes . . . I go on my own.* (Basson and Marais, 2019) [45]

Domain 2—I can participate in my important activities in the way I want to. A subtheme of the second domain describing *how* people with limb loss want to participate was modified

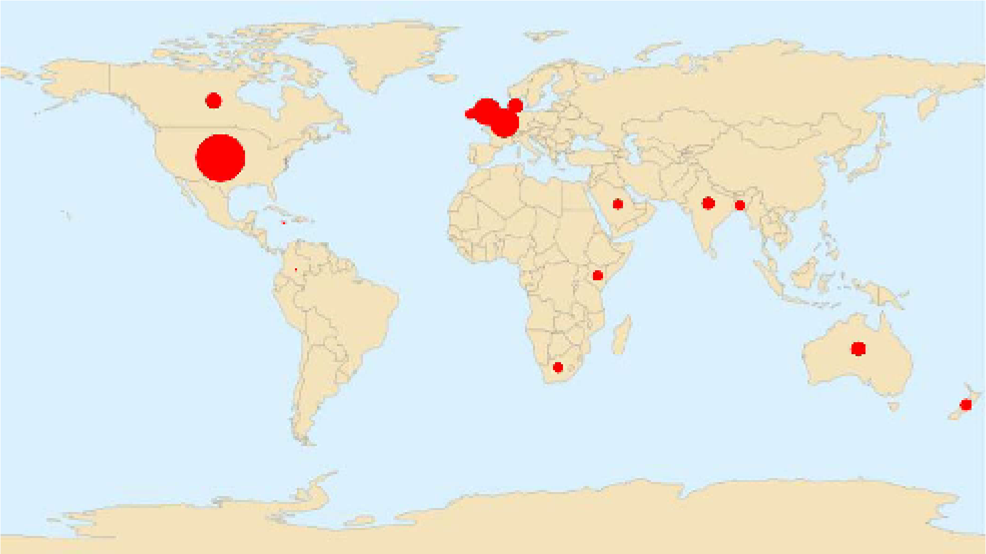

Fig 2. Map of the world illustrating the geographical spread of participants involved in the included studies.

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from 'being able to do my activities easily' to reflect being able to do activities 'easily and well' (Table 10).

Subtheme 2.2—Doing my activities easily and well. Data describing participation in sport [13,37,64] raised the issue of doing an activity well. Participants described the need to perform well during sport to be competitive, not performing well could lead to reduced participation.

> *Now, if I swim, the speed is gone and you always have a disadvantage. . . swimming is not what it used to be, all elderly swim faster than me. . . . . I stopped with it. . ."* (Bragaru et al., 2013) [37]

Domain 3 –My prosthesis works for me. Originally domain three described the need for a prosthesis that is comfortable and easy to use. This domain was well supported by the data (Table 9); however additional data went beyond describing the comfort and ease of use i.e., burdensomeness of the weight, fit and suspension of the prosthesis, and also described the importance of the functionality of prosthetic componentry, i.e., prosthetic knees and feet, in enabling valued activities. This led to the domain being restructured into three subthemes (Table 11). The first two subthemes describe the original domain of 'comfort and ease of use' but have been presented separately as 'My prosthesis is Comfortable' and 'My prosthesis is easy to use' to reflect the importance of these individual aspects of the prosthesis, as described in the data. An additional third subtheme has been developed describing the importance of prosthetic componentry which enables participation.

Subtheme 3.3—My prosthesis enables me to participate. The function of prosthetic components and how they enable people to participate was described in 18 studies [13,36,61–

Table 7. Study design and critical appraisal of study quality using the CASP qualitative appraisal tool (Yes – Light grey (1), Can't Tell – Dark Grey (2), No – Black(3)).

Author	Methodology	Data Collection approach	Analysis approach	CASP tool Section A						CASP tool Section B			Total Score
				Was there a clear statement of the aims of the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	
Day et al. (2019) [illegible]	Qualitative exploratory	FG	Inductive TA	░	░	░	░	░	░	░	░	░	9
Hansen et al. (2019) [illegible]	Descriptive phenomenology	In depth interview	RLW guiding principles	░	░	░	░	░	░	░	░	░	9
Mathias and Harcourt (2014) [illegible]	IPA	On-line SSI	IPA	░	░	░	░	░	░	░	░	░	9
McDonald et al. (2018) [illegible]	IPA	FG	IPA and adapted GT	░	░	░	░	░	░	░	░	░	9
Morgan et al. (2020) [illegible]	Not stated	FG	TA	░	░	░	░	░	░	░	░	░	9
Wadey and Day (2018) [illegible]	Longitudinal qualitative	FG, files, unstructured and SSI	Inductive TA	░	░	░	░	░	░	░	░	░	9
Mattick et al. (2021) [illegible]	Qualitative	SSI	TA	░	░	░	░	░	░	░	░	░	9
Norlyk et al. (2016) [illegible]	Phenomenology RLA	Longitudinal interviews	Thematic RLR	░	░	░	░	░	▓	░	░	░	10
Batten et al. (2020) [illegible]	Not stated	FG	Content / TA	░	░	░	░	░	▓	░	░	░	10
Devan et al. (2015) [illegible]	Qualitative	FG	General inductive approach	░	░	░	░	░	▓	░	░	░	10
Kim et al. (2021) [illegible]	Qualitative	FG	Adapted GT	░	░	▓	░	░	░	░	░	░	10
Ward Khan et al. (2021) [illegible]	IPA	SSI	IPA	░	░	░	░	░	░	▓	░	░	10
Stuckey et al. (2020) [illegible]	Not stated	SSI	TA	░	░	░	▓	░	▓	░	░	░	11
Bragaru et al. (2013) [illegible]	Phenomenology	SSI	Thematic codebook	░	░	░	░	░	█	░	░	░	11
[illegible] et al. (2021) [illegible]	Phenomenology	SSI	TA	░	░	░	░	░	▓	░	▓	░	11
Hanna and Donetto (2021) [illegible]	Qualitative exploratory	Online posts	TA	░	░	░	░	░	█	░	░	░	11

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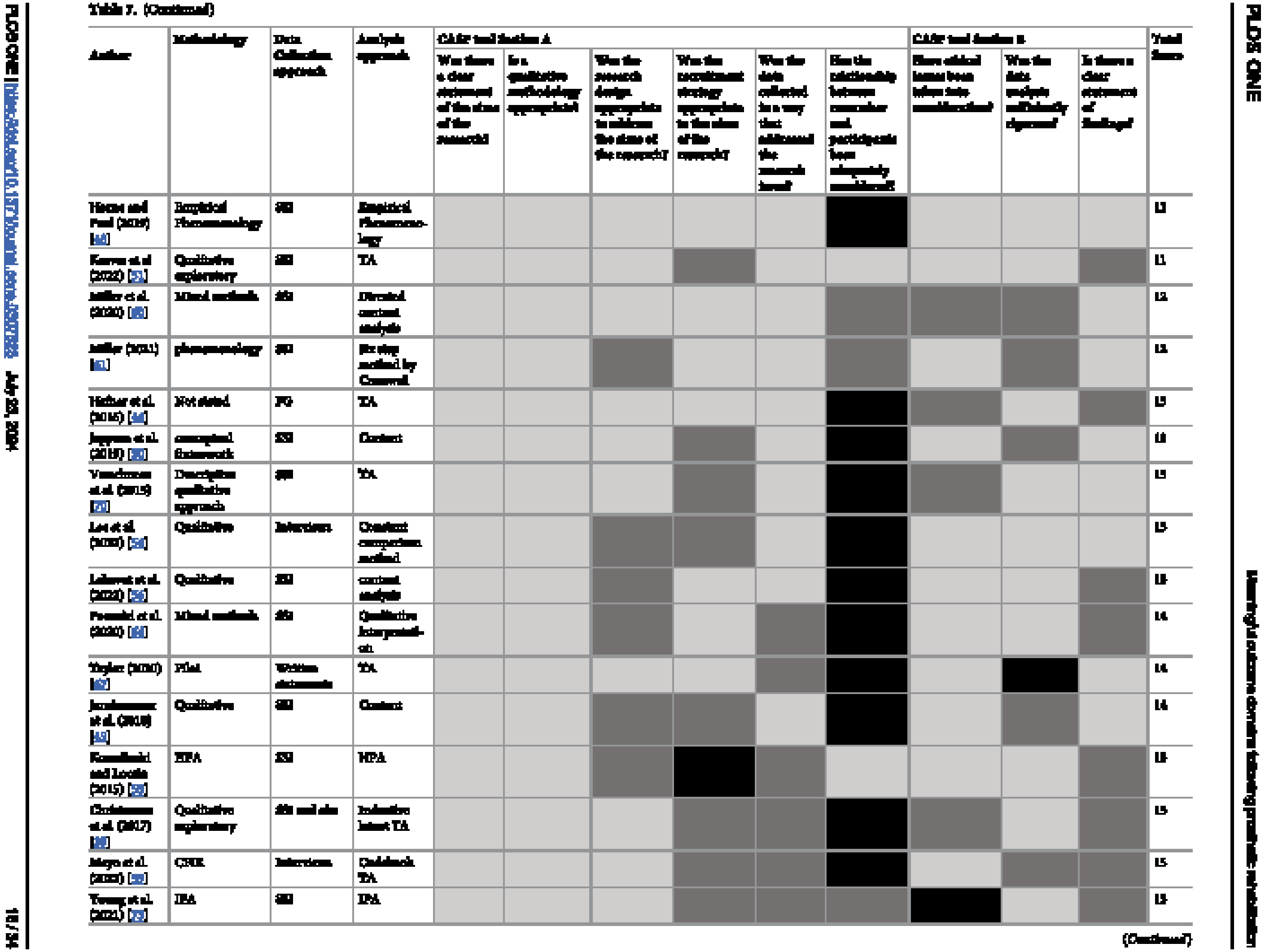

Table 7. (Continued)

Author	Methodology	Data Collection approach	Analysis approach	CASP tool Section A						CASP tool Section B			Total Score
				Was there a clear statement of the aims of the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	
Hearn and Paul (2019) [illegible]	Empirical Phenomenology	SSI	Empirical Phenomeno-logy	░	░	░	░	░	█	░	░	░	13
Karvo et al (2022) [illegible]	Qualitative exploratory	SSI	TA	░	░	░	▓	░	░	░	░	▓	11
Miller et al. (2020) [illegible]	Mixed methods	SSI	Directed content analysis	░	░	░	░	░	▓	▓	▓	░	12
Miller (2021) [illegible]	phenomenology	SSI	Six step method by Creswell	░	░	▓	░	░	▓	░	▓	░	12
Hafner et al. (2015) [illegible]	Not stated	FG	TA	░	░	░	░	░	█	▓	░	▓	13
Jeppsen et al. (2018) [illegible]	conceptual framework	SSI	Content	░	░	░	▓	░	█	░	▓	░	13
Vandamme et al. (2019) [illegible]	Descriptive qualitative approach	SSI	TA	░	░	░	▓	░	█	▓	░	░	13
Lee et al. (2020) [illegible]	Qualitative	Interviews	Constant comparison method	░	░	▓	▓	░	█	░	░	░	13
Lehavot et al. (2022) [illegible]	Qualitative	SSI	content analysis	░	░	▓	░	░	█	░	░	▓	13
[illegible] et al. (2020) [illegible]	Mixed methods	SSI	Qualitative interpretati-on	░	░	▓	░	▓	█	░	░	▓	14
Taylor (2020) [illegible]	Pilot	Written statements	TA	░	░	░	░	▓	█	░	█	░	14
Jacobsen et al. (2018) [illegible]	Qualitative	SSI	Content	░	░	▓	▓	░	█	░	▓	░	14
[illegible] and Loucks (2015) [illegible]	IPA	SSI	IPA	░	░	▓	█	▓	░	░	░	▓	14
Christensen et al. (2017) [illegible]	Qualitative exploratory	SSI and obs	Inductive latent TA	░	░	░	▓	▓	█	▓	░	▓	15
Mayo et al. (2020) [illegible]	[illegible]	Interviews	[illegible] TA	░	░	░	▓	▓	█	░	▓	▓	15
Young et al. (2021) [illegible]	IPA	SSI	IPA	░	░	░	▓	▓	▓	█	░	▓	15

(Continued)

Table 7. (Continued)

Author	Methodology	Data Collection approach	Analysis approach	CASP tool Section A						CASP tool Section B			Total Score
				Was there a clear statement of the aims of the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	
Benton and Murray (2019) [46]	Qualitative exploratory	SSI	TA	░	░	▓	▓	▓	■	░	▓	▓	16
Henry (2018) [47]	Narrative	In depth interview	Unknown	▓	░	░	▓	░	░	■	■	▓	16
Van Twillert et al. (2014) [illegible]	Mixed methods	SSI	Framework analysis using ICF	░	░	▓	░	▓	■	▓	■	░	16
Abouammoh et al. (2021) [illegible]	Phenomenology	FG and SSI	TA	░	░	░	■	▓	■	▓	▓	▓	17
Roberts et al. (2021) [35]	Qualitative descriptive	SSI	TA	░	░	░	▓	▓	■	▓	■	▓	17
Crawford et al. (2016) [40]	Observational qualitative	SSI	TA	░	░	▓	■	▓	▓	▓	▓	■	18
Lee et al. (2022) [illegible]	Mixed methods	SSI	Constant comparison method	▓	░	▓	■	■	■	■	■	▓	22
Turner et al. (2023) [illegible]	Mixed methods	SSI	TA	▓	░	■	▓	■	■	■	■	▓	22

IPA–Interpretive phenomenological approach, RLW- Reflective life world research, GT–Grounded theory, TA- Thematic analysis, HPA–Hermeneutic phenomenological approach, CFIR—Consolidated Framework for Implementation Research, SSI–Semi structured Interview, FG–Focus Group, Obs–Observations.

https://doi.org/10.1371/journal.pone.0307523.t007

Table 6. Examples of how data from the qualitative synthesis support the pre-existing framework domains.

Pre-existing framework domains and subthemes	Examples from qualitative synthesis data
Domain 1—I am able to participate in my important activities	
Subtheme 1.1 - Walking again (10 papers—[illegible])	*I just wanted to get prosthesis and be able to walk again, there were my expectations, I had been told that there are false legs that one can get and they help one to be able to walk. (Jama)* (Mattick et al., 2022 [illegible]) *I would be tempted to add something to (a definition of mobility) about the ability to accomplish wanted or needed tasks.PT2.4* (Hafner et al., 2016 [illegible])
1.2—Important activities at home (11 papers—[illegible])	*This leg [prosthesis] has managed to help me a lot, because of this leg [prosthesis] I'm able to do work, go to the toilet and carry things around my house, and I can travel and walk. (Female 31, living in urban area)* (Ennion and Manig et al., 2019 [illegible]) *For most participants, the prosthesis was actively used to complete activities of daily living such as cooking, cleaning, and laundry. One individual explained, "Well, because it's a pain in the ass trying to cook it all from your wheelchair, especially in front of the stove. Right, because I'm terrified of something like the pot tipping over, whatever and scalding me." (Participant 06)* (Roberts et al., 2021 [illegible])
1.3—Important activities in my community (24 papers [illegible])	*Expanded mobility, perhaps the most important and commonly reported outcome for study participants, was experienced in a unique way for each individual person and his or her lifestyle.* (McDonald et al., 2018 [illegible]) *Another participant expressed immense satisfaction that her prosthesis allowed her to engage in physical activity with her family, "We do a lot of swimming, we do badminton, we played as a team outside of the house, I play volleyball. . ." (Participant 14)* (Roberts et al., 2021 [illegible]) *One example was characteristics of the terrain, such as sand or uneven terrain: "I cried the first time I was on sand. I thought I would never be able to walk on sand again. I had to leave the beach" (PT1.3).* (Morgan et al., 2020 [illegible]) *Another participant had changed work roles as she was unable to walk the distances required to be a professional cleaner. One participant was unable to walk the required distance to public transport for work.* (Batten et al., 2020 [illegible])
Domain 2—I can participate in my important activities in the way I want to	
2.1—Doing my activities independently (14 papers [illegible])	*Since receiving the prosthesis, he had opened his own barber shop and how he could now "depend on myself." He was not alone; others spoke significantly about reduced dependency: I can take myself to the shop without any help, unlike there before when I used to depend on people to help me, I can go by myself to the toilet without asking for help (Mohamed)* (Mattick et al., 2022 [illegible]) *There was a reluctance to ask for support from their spouse or extended family—so not to be a burden particularly given that failure to fulfil an expected role left some women feeling their spouse may leave: If I ask someone (to help) it might be hard for them too. It becomes very difficult for my mother and sister-in-law when I go home. When I am dependent on them, this actually increases their workload.—Fatima (F, 23)* (Stuckey et al., 2020 [illegible])

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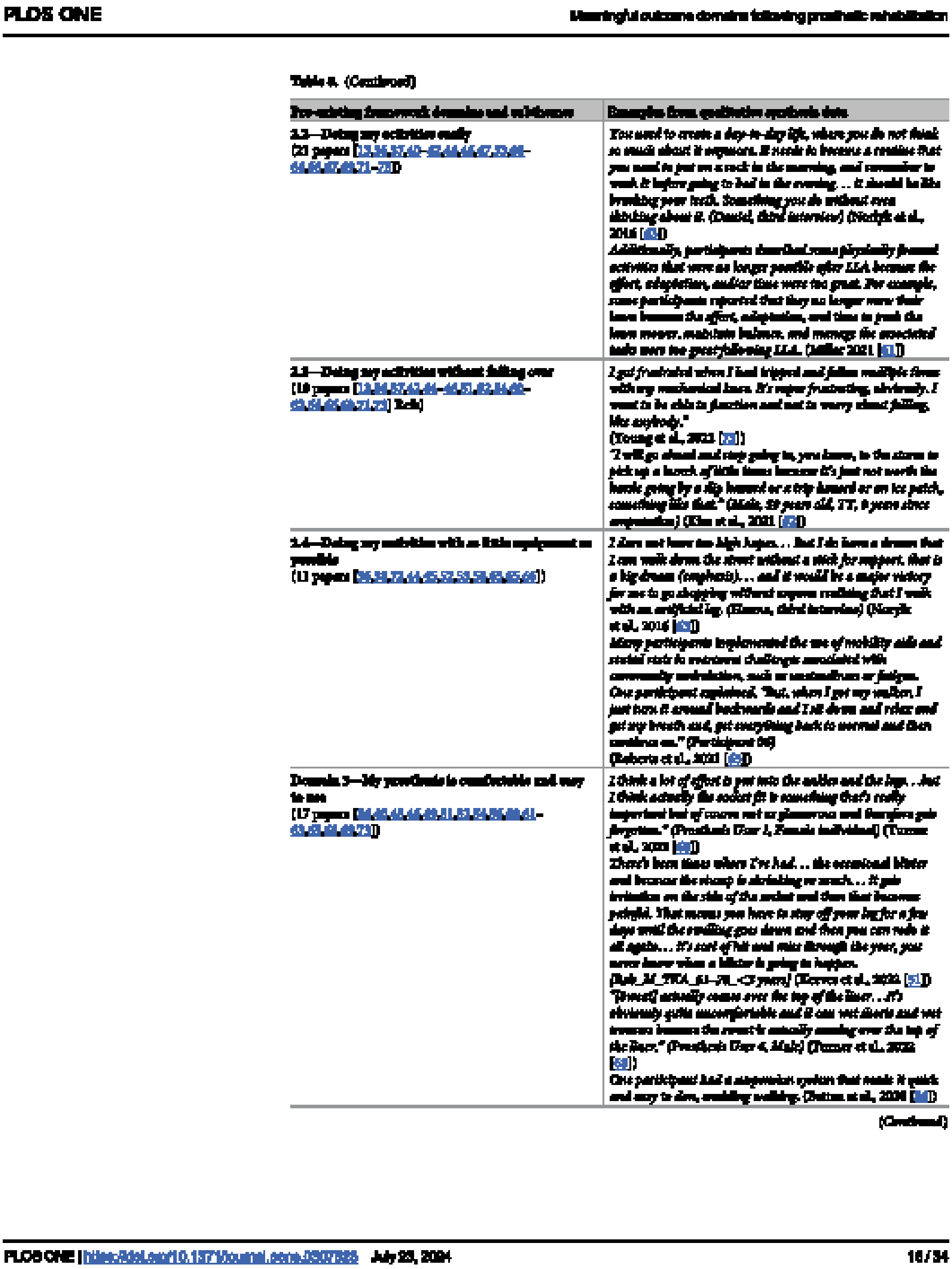

Table 4. (Continued)

Pre-existing framework domains and subthemes	Examples from qualitative synthesis data
2.2—Doing my activities easily (21 papers [[illegible]])	*You need to create a day-to-day life, where you do not think so much about it anymore. It needs to become a routine that you need to put on a sock in the morning, and remember to wash it before going to bed in the evening. … it should be like brushing your teeth. Something you do without even thinking about it. (Daniel, third interview)* (Norlyk et al., 2016 [63]) *Additionally, participants described some physically demanding activities that were no longer possible after LLA because the effort, adaptation, and/or time were too great. For example, some participants reported that they no longer mow their lawn because the effort, adaptation, and time to push the lawn mower, maintain balance, and manage the associated tasks were too great following LLA.* (Miller 2021 [61])
2.3—Doing my activities without falling over (19 papers [[illegible]] Refs)	*I get frustrated when I had tripped and fallen multiple times with my mechanical knee. It's super frustrating, obviously. I want to be able to function and not to worry about falling, like anybody."* (Young et al., 2022 [73]) *"I will go ahead and stop going to, you know, to the store to pick up a bunch of little items because it's just not worth the hassle going by a slip hazard or a trip hazard or an ice patch, something like that." (Male, 59 years old, TT, 8 years since amputation)* (Kim et al., 2021 [52])
2.4—Doing my activities with as little equipment as possible (11 papers [[illegible]])	*I dare not have too high hopes… But I do have a dream that I can walk down the street without a stick for support, that is a big dream (emphasis)… and it would be a major victory for me to go shopping without anyone realising that I walk with an artificial leg. (Emma, third interview)* (Norlyk et al., 2016 [63]) *Many participants implemented the use of mobility aids and seated rests to overcome challenges associated with community ambulation, such as unsteadiness or fatigue. One participant explained, "But, when I get my walker, I just turn it around backwards and I sit down and relax and get my breath and, get everything back to normal and then continue on." (Participant 06)* (Roberts et al., 2021 [69])
Domain 3—My prosthesis is comfortable and easy to use (17 papers [[illegible]])	*I think a lot of effort is put into the ankles and the legs…but I think actually the socket fit is something that's really important but of course not as glamorous and therefore gets forgotten." (Prosthesis User 1, Female individual)* (Turner et al., 2022 [68]) *There's been times where I've had… the occasional blister and because the stump is shrinking so much… it gets irritation on the side of the socket and then that becomes painful. That means you have to stay off your leg for a few days until the swelling goes down and then you can redo it all again… It's sort of hit and miss through the year, you never know when a blister is going to happen.* *[Sub_M_TWA_61–70_<5 years]* (Kerver et al., 2020 [51]) *"[Sweat] actually comes over the top of the liner…It's obviously quite uncomfortable and it can wet shorts and wet trousers because the sweat is actually coming over the top of the liner." (Prosthesis User 4, Male)* (Turner et al., 2022 [68]) *One participant had a suspension system that made it quick and easy to don, enabling walking.* (Batten et al., 2020 [[illegible]])

(Continued)

Table 4. (Continued)

Pre-existing framework domains and subthemes	Examples from qualitative synthesis data
Domains 4—If I have pain, I am able to manage it (7 Papers [[illegible]])	*While some participants reported that a pain-free day was possible, for most a good day involved better management of pain, allowing them to engage in activities that they wanted to do.* (Day et al., 2019 [41]) *For some participants, pain was a reason for non use of the prosthesis, "Some days I don't even put it on, don't even tell me to put it on, because I'll get mad at you. There's nothing worse than having a pain you can't control. You know, and the only way I can control it is to stay off both my feet."* (Participant 02) (Turner et al., 2022 [[illegible]]) *You know like part of the package when you get a limb you are going to get pain here and there. . .Ah it is it can be really uncomfortable yeah. but you just got to sort of carry on through it. . .* (Jack, Int 2) (Devan et al., 2015 [43])
Domains 5—I am able to accept my new normal	
5.1—Claiming normality (14 papers [[illegible]])	*You're making me think. I don't know. It's a deep question. I haven't addressed it, even though I think I have. I haven't addressed the fact that I'm disabled. I've come to terms with it, I get on, but I probably haven't properly. I don't really like that word. What does it mean? I don't like it. It makes me different. I don't want to be different. I just want to be the same as everyone else. I just want to just fit in. To just be.* (Wadey and Day, 2018 [71]) *Depending on the degree of regained mobility the participants strived to re-conquer a daily life that resembled their previous lives.* ([illegible] et al. 2016 [[illegible]]) *A good day is when I just feel like everybody else. [Gloria] Moving away from the amputation.* (Day et al., 2019 [41])
5.2—Adjusting to limb loss (32 papers [[illegible]])	*"I know that life is worth living and there is still that out there, but it's hard to come back to that."* ([illegible] et al., 2019 [[illegible]]) *Everybody's looking to the past, how they used to be. Uh. . . So for me, you go to wedding and you see someone is dancing all night. I was that guy. Can I dance again all night? I had a tree at my cottage. A poplar. It was 40–50 feet tall. I climbed way over there with a chainsaw in my hands so I chop it down. Can I do that again?* (ID#17, Male amputation, 51, traumatic aetiology) (Mayo et al., 2022 [[illegible]]) *"It doesn't matter how you do it because everybody has something, then you feel more at home and less stared at . . . . . you feel less different. . ..and then you accept it"* ([illegible] et al., 2015 [[illegible]]) *For example, a participant stated he could not squat or be down on one knee to change a car tire and, "That's a limitation that I've adapted to. So, I just put a stool down and then sit on the stool, and then do what I gotta do. So, you just have to take the limitations and then adapt to do things that way."* (49 years old; 2.5 years post-TTA). (Miller et al., 2020 [[illegible]]) *"Only the strong survive baby! If you don't adapt to the circumstances, my gosh, you are going to have a miserable life."* (Camacho et al., 2021 [[illegible]])

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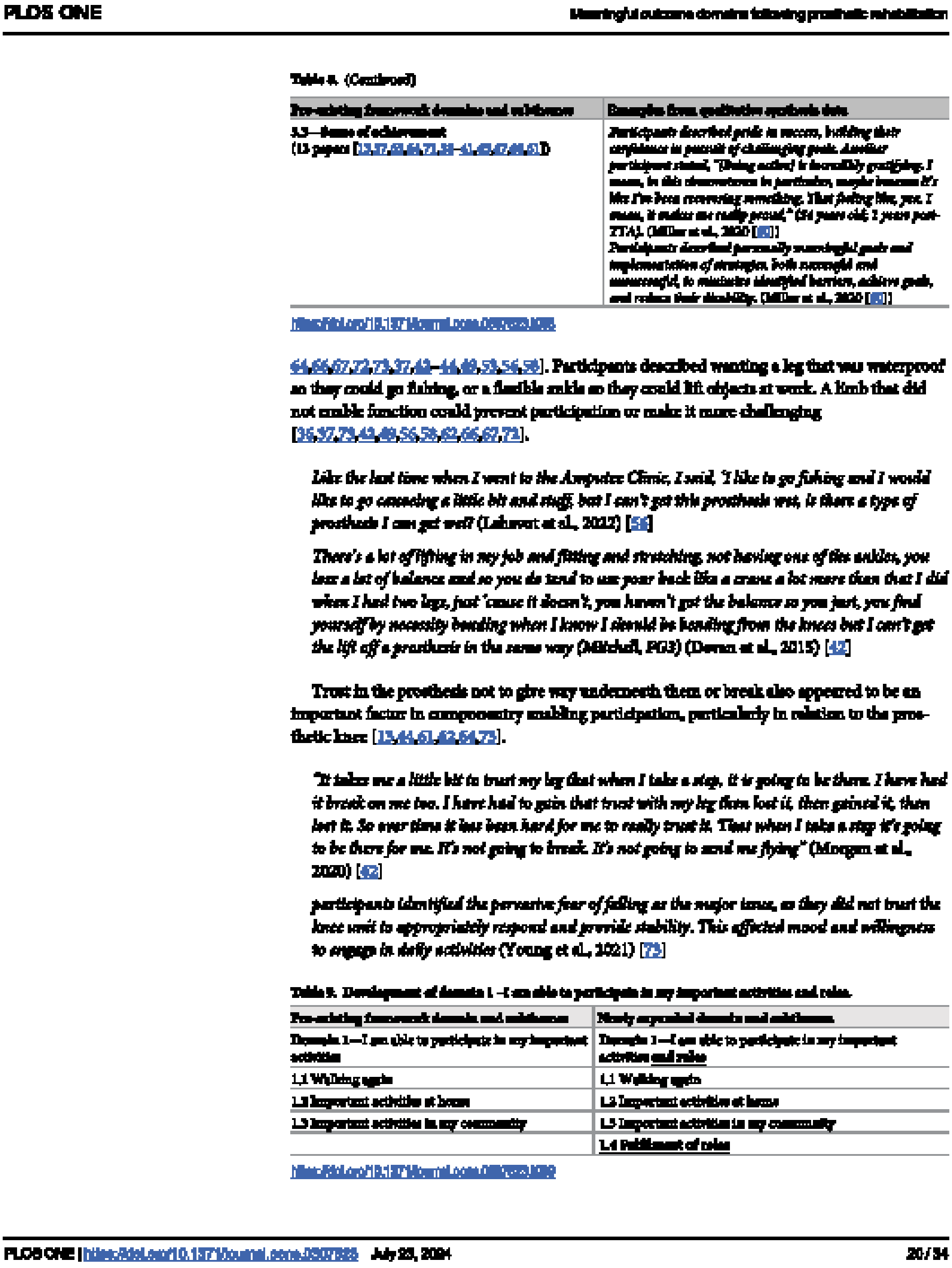

Table 8. (Continued)

Pre-existing framework domains and subthemes	Examples from qualitative synthesis data
3.3—Sense of achievement (13 papers [13,37,60,64,71,38–41,45,47,48,61])	*Participants described pride in success, building their confidence in pursuit of challenging goals. Another participant stated, "[Being active] is incredibly gratifying. I mean, in this circumstance in particular, maybe because it's like I've been recovering something. That feeling like, yes. I mean, it makes me really proud."* (34 years old; 1 years post-TTA). (Miller et al., 2020 [60]) *Participants described personally meaningful goals and implementation of strategies, both successful and unsuccessful, to minimize identified barriers, achieve goals, and reduce their disability.* (Miller et al., 2020 [60])

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64,66,67,72,73,37,42–44,49,53,56,58]. Participants described wanting a leg that was waterproof so they could go fishing, or a flexible ankle so they could lift objects at work. A limb that did not enable function could prevent participation or make it more challenging [36,37,73,42,49,56,58,62,66,67,72].

> *Like the last time when I went to the Amputee Clinic, I said, 'I like to go fishing and I would like to go canoeing a little bit and stuff, but I can't get this prosthesis wet, is there a type of prosthesis I can get wet?* (Lehavot et al., 2022) [58]
>
> *There's a lot of lifting in my job and fitting and stretching, not having one of the ankles, you lose a lot of balance and so you do tend to use your back like a crane a lot more than that I did when I had two legs, just 'cause it doesn't, you haven't got the balance so you just, you find yourself by necessity bending when I know I should be bending from the knees but I can't get the lift off a prosthesis in the same way* (Mitchell, PG3) (Devan et al., 2015) [42]

Trust in the prosthesis not to give way underneath them or break also appeared to be an important factor in componentry enabling participation, particularly in relation to the prosthetic knee [13,44,61,42,64,73].

> *"It takes me a little bit to trust my leg that when I take a step, it is going to be there. I have had it break on me too. I have had to gain that trust with my leg then lost it, then gained it, then lost it. So over time it has been hard for me to really trust it. That when I take a step it's going to be there for me. It's not going to break. It's not going to send me flying"* (Morgan et al., 2020) [42]
>
> *participants identified the pervasive fear of falling as the major issue, as they did not trust the knee unit to appropriately respond and provide stability. This affected mood and willingness to engage in daily activities* (Young et al., 2021) [73]

Table 9. Development of domain 1 –I am able to participate in my important activities and roles.

Pre-existing framework domain and subthemes	Newly expanded domain and subthemes
Domain 1—I am able to participate in my important activities	Domain 1—I am able to participate in my important activities and roles
1.1 Walking again	1.1 Walking again
1.2 Important activities at home	1.2 Important activities at home
1.3 Important activities in my community	1.3 Important activities in my community
	1.4 Fulfilment of roles

https://doi.org/10.1371/journal.pone.0307523.t009

Table 10. Development of domain 2 –I can participate in my important activities in the way I want to.

Pre-existing framework domain and subthemes	Newly expanded domain and subthemes
Domain 2—I can participate in my important activities in the way I want to	Domain 2—I can participate in my important activities in the way I want to
2.1 Doing my activities independently	2.1 Doing my activities independently
2.2 Doing my activities easily	2.2 Doing my activities easily and well
2.3 Doing my activities without falling over	2.3 Doing my activities without falling over
2.4 Doing my activities with as little equipment as possible	2.4 Doing my activities with as little equipment as possible

https://doi.org/10.1371/journal.pone.0307523.t010

Insufficient trust in prosthetic componentry was shown to prevent participation in important activities or require adaptation. Conversely trust appeared to inspire confidence in the limb, as well as individual capabilities.

> *If I feel like I can trust the leg or socket, then as far as being mobile, I feel like I can do... anything."* (Hafner et al., 2016) [44]

Domain 4 –If I have pain, I can manage it. The analysis did not reveal any new information relevant to this domain.

Domain 5 –I am able to accept my new normal. Large amounts of the data from the included studies were mapped onto this domain which has been expanded and renamed in parts (Table 12). The subtheme 'Chasing normality' was renamed to 'Feeling a sense of normality' to better capture the domain as described by people with limb loss. The subtheme 'adjusting to limb loss' was expanded and is now presented in two subthemes highlighting the importance of 'adapting and accepting my limitations' and 'accepting my appearance'. An additional fifth subtheme was also identified describing lifelong health and wellbeing.

Subtheme 5.2—Adapting and accepting my limitations. Data from 14 studies supported this subtheme [36,38,45,47,48,51,58,62,63,65,66,69–71]. Participants discussed the need to adjust to the changes they had experienced by adapting how they did their daily tasks.

> *For example, a participant stated he could not squat or be down on one knee to change a car tire and, "That's a limitation that I've adapted to. So, I just put a stool down and then sit on the stool, and then do what I gotta do. So, you just have to take the limitations, and then adapt to do things that way." (69 years old; 2.5 years post-TTA).* (Miller et al., 2020) [69]

Some participants described these adaptations as frustrating and indicative of the lives they had lost.

> *It's hard I guess you have to think about things a little bit differently. How you do things, takes a bit longer to do... and that sort of thing which is a bit frustrating... you know what*

Table 11. Development of domain 3 –My prosthesis works for me.

Pre-existing framework domain and subthemes	Newly expanded domain and subthemes
Domain 3—My prosthesis is comfortable and easy to use	Domain 3—My prosthesis works for me
	3.1 My prosthesis is comfortable
	3.2 My prosthesis is easy to use
	3.3 My prosthesis enables me to participate

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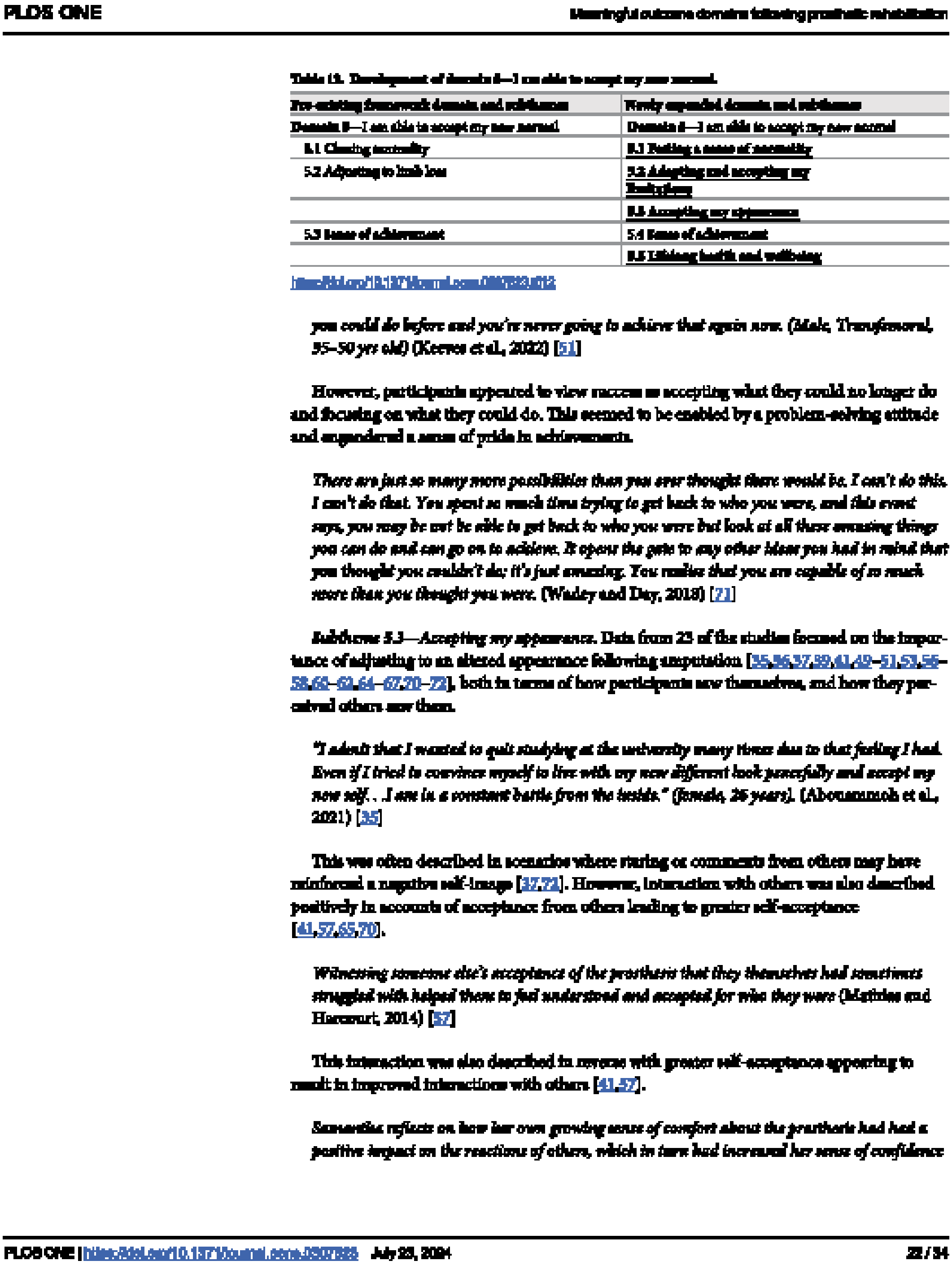

Table 12. Development of domain 5—I am able to accept my new normal.

Pre-existing framework domain and subthemes	Newly expanded domain and subthemes
Domain 5—I am able to accept my new normal	Domain 5—I am able to accept my new normal
5.1 Chasing normality	5.1 Feeling a sense of normality
5.2 Adjusting to limb loss	5.2 Adapting and accepting my limitations
	5.3 Accepting my appearance
5.3 Sense of achievement	5.4 Sense of achievement
	5.5 Lifelong health and wellbeing

https://doi.org/10.1371/journal.pone.[illegible].t012

> *you could do before and you're never going to achieve that again now. (Male, Transfemoral, 35–50 yrs old)* (Keeves et al., 2022) [51]

However, participants appeared to view success as accepting what they could no longer do and focusing on what they could do. This seemed to be enabled by a problem-solving attitude and engendered a sense of pride in achievements.

> *There are just so many more possibilities than you ever thought there would be. I can't do this. I can't do that. You spent so much time trying to get back to who you were, and this event says, you may be not be able to get back to who you were but look at all these amazing things you can do and can go on to achieve. It opens the gate to any other ideas you had in mind that you thought you couldn't do; it's just amazing. You realise that you are capable of so much more than you thought you were.* (Wadey and Day, 2018) [71]

Subtheme 5.3—Accepting my appearance. Data from 23 of the studies focused on the importance of adjusting to an altered appearance following amputation [35,36,37,39,41,49–51,53,55–58,60–62,64–67,70–72], both in terms of how participants saw themselves, and how they perceived others saw them.

> *"I admit that I wanted to quit studying at the university many times due to that feeling I had. Even if I tried to convince myself to live with my new different look peacefully and accept my new self. . .I am in a constant battle from the inside." (female, 26 years).* (Abouammoh et al., 2021) [35]

This was often described in scenarios where staring or comments from others may have reinforced a negative self-image [37,71]. However, interaction with others was also described positively in accounts of acceptance from others leading to greater self-acceptance [41,57,65,70].

> *Witnessing someone else's acceptance of the prosthesis that they themselves had sometimes struggled with helped them to feel understood and accepted for who they were* (Mathias and Harcourt, 2014) [57]

This interaction was also described in reverse with greater self-acceptance appearing to result in improved interactions with others [41,57].

> *Samantha reflects on how her own growing sense of comfort about the prosthesis had had a positive impact on the reactions of others, which in turn had increased her sense of confidence*

> *further: Once I was comfortable with it, everyone around seemed to be. . .. (Samantha)* (Mathias and Harcourt, 2014) [57]

Ultimately these experiences of acceptance were viewed positively and indicate the importance of being able to address issues of appearance during rehabilitation and recovery. Some participants described using clothing for concealment purposes to manage concerns about appearance. However, clothing also appeared to contribute to concerns, especially in certain social situations [46,61,62,75,77].

> *I suppose it's a female thing but if you are invited somewhere and it's a posh do and you're getting dressed up and then you look down at your shoes. And then it's like bloody hell, from here [head] to here [knee] I look ok, and then I have a pair of trainers on my feet.* (Carly) (Day et al., 2019) [41]

Other facilitators of acceptance, concerning both appearance and function, were described as a positive problem-solving attitude [13,41,49,53,55,56,58,62,63,65,66,70,74], being able to participate in important activities and roles [42,44–46,51,64,70,71,76], time since amputation [62], spirituality [49,53,63,71] and peer support [13,40–42,44–46,50,54,58,67,76,77].

> *"It doesn't matter how you do it because everybody [peers] has something, then you feel more at home and less stared at . . . . . . you feel less different. . ..and then you accept it* (Bragaru et al., 2013) [37]

Subtheme 5.5—Lifelong health and wellbeing. Participants in 9 of the included studies highlighted concerns about the impact amputation and prosthesis use would have on their health and wellbeing throughout their life course [37,40,42,48,57,61,62,71,72]. Participants described concerns about the impact of amputation on their remaining joints [62], the need to remain physically active to avoid health issues later in life, and to manage weight gain [37,40,57].

> *I think just talking about hopping. I have an example of what happens to you 20 years later. I had really bad arthritis in my knee. I have torn my ACL and if I had not [hopped on one leg] growing up, it probably would be better.* (Morgan et al., 2020) [62]
>
> *For the ones who stated that they cannot live without it, "sport is more a necessity" and, even if it was "not perceived as a fun activity", the individual still participated in sports because otherwise he or she had the feeling that it would have negative consequences for his or her health.* (Bragaru et al., 2013) [37]

Interconnected nature of outcome domains. Data from the qualitative synthesis demonstrated that outcome domains of importance are interconnected, which was first introduced in our qualitative paper developing the original conceptual model [20]. Many examples were presented of how the different domains interacted, for example, how socket comfort issues prevented participation which in turn impacted adjustment and mental wellbeing, or how a lack of trust in the prosthesis caused a fear of falling, which led to reduced community participation. This analysis concurs that a successful outcome appears to be multi-faceted and requires a multi-domain measurement approach, if the outcomes of prosthetic rehabilitation is to be captured in a holistic, meaningful way. Fig 3 visualises the expanded 'ECLIPSE' model, and the interconnected nature of the domains of importance.

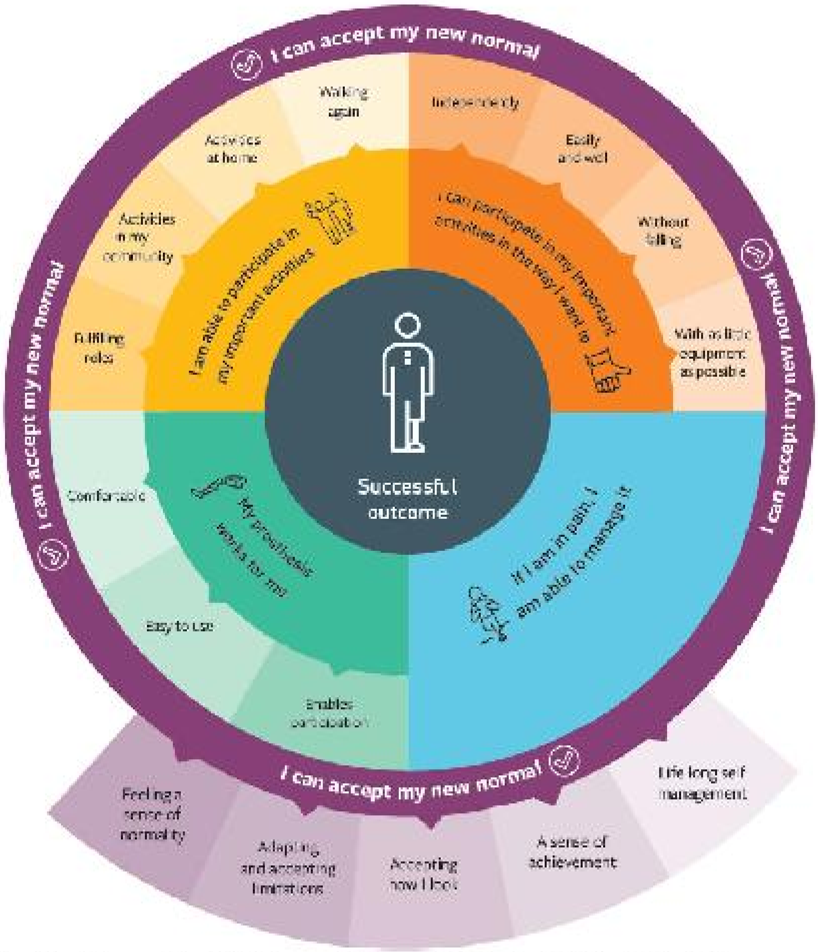

Fig 3. Expanded conceptual model–the [illegible] model of meaningful outcome domains of lower limb prosthetic rehabilitation.

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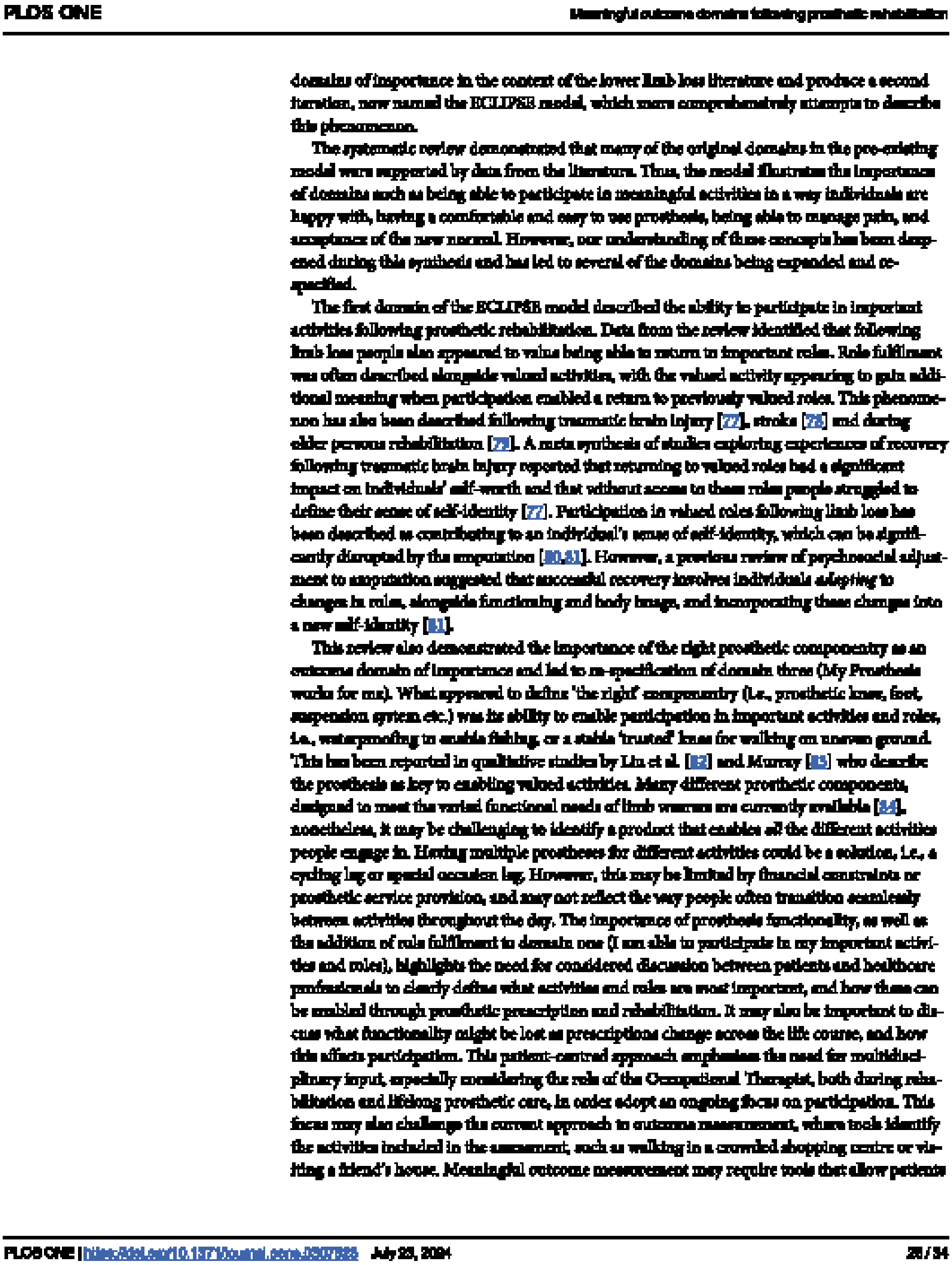
Discussion

This review presents a modified and enhanced conceptual model of outcome domains of importance following lower limb prosthetic rehabilitation from the perspective of people with limb loss. Having been initially developed during a primary qualitative inquiry with 37 prosthetic users [20], it has now been rigorously examined in this systematic review using data from 42 papers describing the experiences of 539 lower limb prosthetic users from a variety of settings. The application of 'best fit' framework synthesis allowed us to re-examine and review



domains of importance in the context of the lower limb loss literature and produce a second iteration, now named the ECLIPSE model, which more comprehensively attempts to describe this phenomenon.

The systematic review demonstrated that many of the original domains in the pre-existing model were supported by data from the literature. Thus, the model illustrates the importance of domains such as being able to participate in meaningful activities in a way individuals are happy with, having a comfortable and easy to use prosthesis, being able to manage pain, and acceptance of the new normal. However, our understanding of these concepts has been deepened during this synthesis and has led to several of the domains being expanded and re-specified.

The first domain of the ECLIPSE model described the ability to participate in important activities following prosthetic rehabilitation. Data from the review identified that following limb loss people also appeared to value being able to return to important roles. Role fulfilment was often described alongside valued activities, with the valued activity appearing to gain additional meaning when participation enabled a return to previously valued roles. This phenomenon has also been described following traumatic brain injury [77], stroke [78] and during older persons rehabilitation [79]. A meta synthesis of studies exploring experiences of recovery following traumatic brain injury reported that returning to valued roles had a significant impact on individuals' self-worth and that without access to these roles people struggled to define their sense of self-identity [77]. Participation in valued roles following limb loss has been described as contributing to an individual's sense of self-identity, which can be significantly disrupted by the amputation [80,81]. However, a previous review of psychosocial adjustment to amputation suggested that successful recovery involves individuals *adapting* to changes in roles, alongside functioning and body image, and incorporating these changes into a new self-identity [81].

This review also demonstrated the importance of the right prosthetic componentry as an outcome domain of importance and led to re-specification of domain three (My Prosthesis works for me). What appeared to define 'the right' componentry (i.e., prosthetic knee, foot, suspension system etc.) was its ability to enable participation in important activities and roles, i.e., waterproofing to enable fishing, or a stable 'trusted' knee for walking on uneven ground. This has been reported in qualitative studies by Liu et al. [82] and Murray [83] who describe the prosthesis as key to enabling valued activities. Many different prosthetic components, designed to meet the varied functional needs of limb wearers are currently available [84], nonetheless, it may be challenging to identify a product that enables all the different activities people engage in. Having multiple prostheses for different activities could be a solution, i.e., a cycling leg or special occasion leg. However, this may be limited by financial constraints or prosthetic service provision, and may not reflect the way people often transition seamlessly between activities throughout the day. The importance of prosthesis functionality, as well as the addition of role fulfilment to domain one (I am able to participate in my important activities and roles), highlights the need for considered discussion between patients and healthcare professionals to clearly define what activities and roles are most important, and how these can be enabled through prosthetic prescription and rehabilitation. It may also be important to discuss what functionality might be lost as prescriptions change across the life course, and how this affects participation. This patient-centred approach emphasises the need for multidisciplinary input, especially considering the role of the Occupational Therapist, both during rehabilitation and lifelong prosthetic care, in order adopt an ongoing focus on participation. This focus may also challenge the current approach to outcome measurement, where tools identify the activities included in the assessment, such as walking in a crowded shopping centre or visiting a friend's house. Meaningful outcome measurement may require tools that allow patients to define what activities are most important to them as an individual, and therefore should be captured as a measure of success.

Domain five of the ECLIPSE model, 'I am able to accept my new normal', was revised most significantly during this review, with three new subthemes created. This may be due to the nature of qualitative research which focuses on views and experiences and is often used to explore adjustment following amputation. The first new subtheme, 'being able to adapt to and accept my limitations' appears to be a common theme described in the rehabilitation literature characterising recovery from trauma or the management of long term conditions, i.e., anterior cruciate reconstruction [85], Parkinson's Disease [86] and traumatic brain injury [87]. A study by Rosengren et al., [86] exploring the experiences of patients with Parkinson's disease found that greater life satisfaction is achievable as people adapt to their new life situation, which involves a process of transition often based on acceptance.

This review also highlighted the need to adjust to an altered appearance following amputation. The wealth of literature describing this outcome led to its creation as a new subtheme and appeared to suggest that individuals need to adjust to how they see themselves, as well as their perception of how others see them, and that these experiences are intricately linked. This is supported by Cooley's 'Looking-Glass self theory [88] which describes how individuals base their sense of self on how they perceive others view them. The importance of adjusting to an altered appearance following limb loss is described in several studies included in a qualitative meta synthesis by Murray and Forshaw [89]. They describe the importance of using the prosthesis to moderate the reaction of others and conceal limb loss. They also highlight that adjustment to changes in self-image appear to occur over extended periods of time as people learn to accept the limitations of the prosthesis.

Both of the subthemes, 'adjusting and accepting my limitations' and 'accepting my appearance', as well as the final subtheme describing lifelong health and wellbeing, indicate the importance of both physical and psychosocial recovery following lower limb amputation. Rehabilitation programmes may need to address both aspects in an integrated way to provide holistic patient-centred care. However, it is clear interventions may not only be required in the immediate post amputation period, and that ongoing physical and psychosocial support may be crucial to address changing lifelong needs.

The interconnected nature of outcome domains of importance, first documented in the authors' primary qualitative work [20] and supported by this review, suggests the need for a multidomain approach to outcome measurement in prosthetic rehabilitation. Many examples of how domains may influence each other were described in this analysis, for example socket comfort issues leading to reduced participation in important activities. Although the findings presented here, and visualised in the ECLIPSE model (Fig 3), recognise the interconnected nature of domains of importance and the need to measure them in a holistic way to capture meaningful success, further research is needed to understand the nature of the relationships between domains.

The ECLIPSE model presents a patient-centred representation of outcome domains of importance following lower limb prosthetic rehabilitation. The model could be used to direct the course of rehabilitation and highlights the need for physical and psychosocial interventions. Although several professional networks have published prosthetic rehabilitation guidelines [5,15,90,91], none include the views of patients, and no guidance is available to inform psychosocial management. Despite many papers describing the psychosocial impact of amputation [89], little research has been undertaken to evidence treatment options. Future work may be needed in order to understand how the domain of 'accepting my new normal' might be addressed during prosthetic rehabilitation.

The ECLIPSE model also provides guidance for which domains may be most important to measure following prosthetic rehabilitation, or in research, and could underpin a future Core Outcome Set. However, given the previously described challenges of meaningful patient involvement in COS development [12], care needs to be taken that the contribution of wider stakeholders in the COS process does not diminish the voice of prosthetic users themselves. The OMERACT initiative [92] which develop COS' for Rheumatoid arthritis have acknowledged this concern and developed a patient COS which explicitly acknowledges that what is important to patients may be different and in need of specific consideration [93]. The ECLISPSE model could represent a patient Core Outcome Set, informing measurement in both research and clinical practice, and ensuring a person-centred focus. Future work is required to identify outcome measurement tools which capture these domains.

The design and quality of studies included in this review varied considerably. Critical appraisal using the CASP tool was undertaken to summarise key quality issues and provide some context to the overall findings of the review but was not used to exclude studies or indicate strength of findings. The usefulness of critical appraisal is debated in the literature due to the variation in appraisal decisions between reviewers experienced in qualitative research reported when using the same and different appraisal tools, or solely based on their independent judgement [94]. The impact of including or excluding low quality studies on the findings of a review has also been found to have little impact [95] and this is why no studies were excluded based on quality alone in this review.

Within this review the key quality issue identified in 28 of the 40 studies was undue consideration of the influence of the researcher on the research process, which could impact the dependability and confirmability of this reviews findings [96], and is considered an area of concern for qualitative research in the field of prosthetic rehabilitation. In light of this, data included consisted only of first-person quotations, or interpretations that were directly supported by first-person quotations, in an attempt to ground the findings in the experiences of participants [97].

A further quality issue in 17 studies was insufficient information about whether recruited participants were best placed to answer the research question. However, data describing the study sample characteristics was presented in 34 of the studies allowing transferability to be considered. This review captures the experiences of a large sample (n = 539) of lower limb prosthetic users living in 15 different countries. Views and experiences from participants with different levels of amputation, a variety of causes and a wide age range were included, representing a varied sample capturing many different voices. However, despite the range of study settings, 90.2% of participants live in high-income countries. Far fewer qualitative studies have been undertaken exploring the lived experiences of lower limb prosthetic users living in low- and middle-income countries (LMICs). Due to limited representation of these individuals, it is unclear whether these findings are transferable and whether the ECLIPSE model describes outcome domains of importance with a prosthesis in LMICs. Further research is required to identify and understand important domains in different social and culture settings, as well as exploring how they vary between countries. This is of particular importance as it is estimated that 80% of the world's population living with a disability live in LMICs [98], and the Global Burden of Disease study 2019 indicates an increasing international amputation prevalence of 176 million [99]. Previous outcome measure consensus work in prosthetics, undertaken by ISPO, also highlighted that many of the measurement tools for use following amputation have been developed in high income countries and call for development of measures suited to LMICs [8]. However, without first understanding which domains are most important to measure in these settings, outcome measure developers may struggle to capture what is meaningful to patients.

Limitations

When considering the findings of this review it is important to understand that the domains identified in the analysis have been generated from studies with a range of quality scores. Due to previously described issues with critical appraisal as part of systematic reviews of qualitative literature [25,28,30,100], no studies were excluded but were scored and ranked. Although this a common approach used in qualitative syntheses, it is not how the CASP tool was intended for use and should be viewed with caution.

A further limitation of the review is the potential for confirmation bias within the analysis as the authors pre-existing conceptual model was used to inform the '*a priori*' framework. Steps were taken to minimise the risk of shoehorning data into the framework by carrying out open line by line coding as the first step in the analysis process and undertaking a separate thematic analysis on data which did not fit easily into the framework, which was then used to further develop the model. A reflexive journal was also kept throughout by the lead author to critically consider methodological and analytical decisions.

The inclusion of only peer reviewed publications written in English led to a single relevant paper being excluded which may have contributed to the findings. The decision was taken not to use translation software as this may have altered the meaning of quotations.

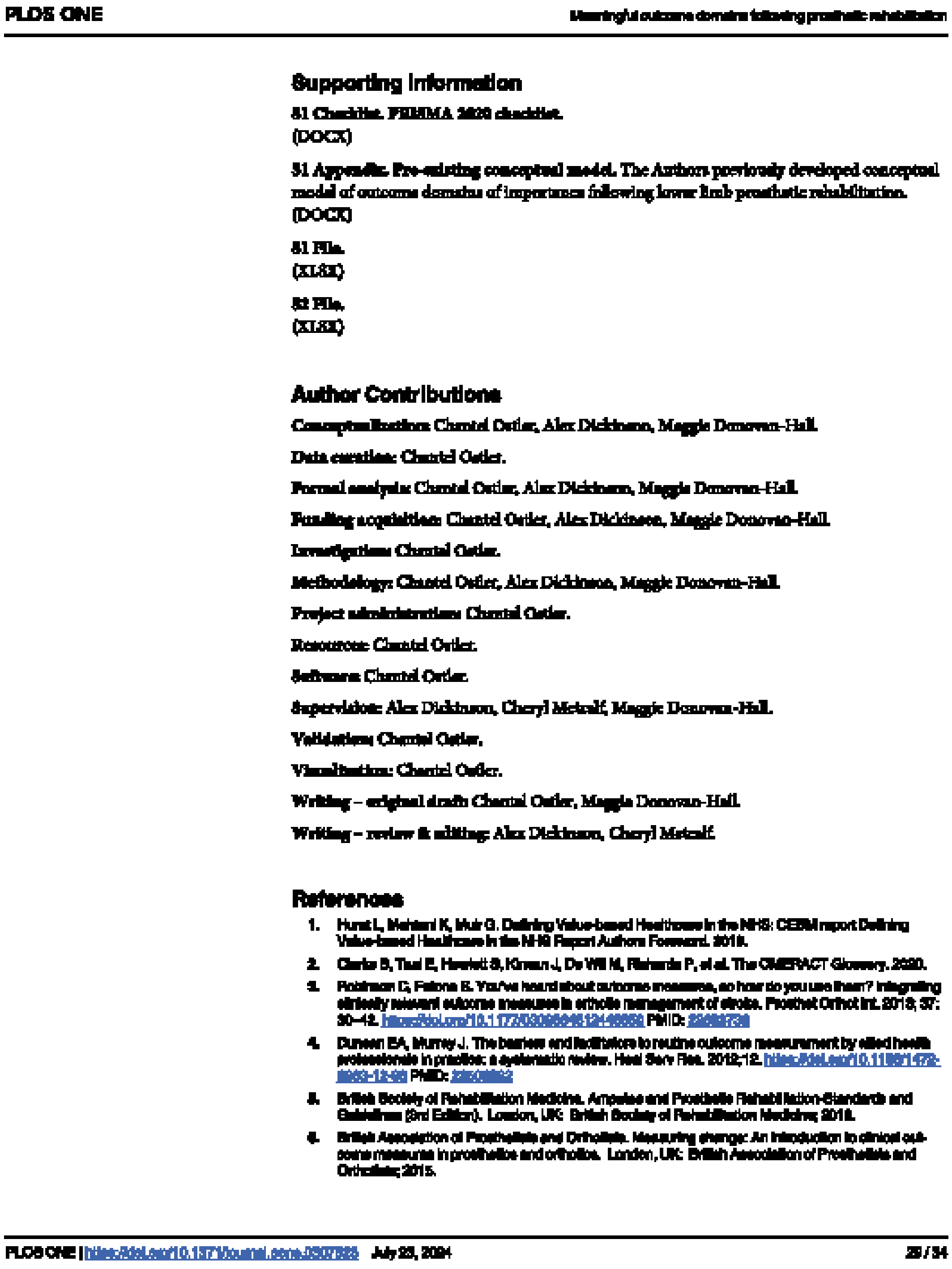
The review also took a broad approach to the search strategy, identifying studies which explored the experiences of lower limb prosthetic users, as few studies were available describing outcome domains of importance. This resulted in inclusion of studies exploring a wide variety of phenomena. It is possible that domains of importance may have been overlooked as none of the studies set out to explore meaningful recovery following prosthetic rehabilitation. However, this wide focus ensured comprehensive inclusion of the available evidence using the research question as a compass rather than an anchor [101]. This facilitated an exploratory approach to understanding outcomes of importance, which is more aligned to primary qualitative methods. Nonetheless it should be considered that researcher judgement was required to identify data presented in the included studies which were relevant to the research question, and required researchers to view the data through a different lens than was originally intended, potentially reinterpreting its meaning.

Conclusion

This synthesis of qualitative findings from 40 studies representing the views of nearly 600 people provides a rigorous foundation for understanding outcome domains of importance following lower limb prosthetic rehabilitation. By focusing on the patients perspective, the ECLIPSE model attempts to portray a meaningful recovery in the lives of those with limb loss, particularly in high income settings.

The ECLIPSE model is an accessible patient-centred view of recovery and could be used by clinicians to shape and direct the focus of rehabilitation programmes and inform goal setting, as well as direct the evaluation of their impact through the selection of outcome measures. The apparent interconnected nature of outcome domains of importance also highlights the need for a holistic approach to outcome measurement, capturing success in all aspects of the patient's life.

The domains which comprise the ECLIPSE model could also inform the selection of outcomes within research. They could underpin a future core outcome set (COS) or represent a standalone patient COS, which may be more appropriate for rehabilitation settings where the aim is to enable return to previous lives. Future work is needed to understand how well current outcome measures capture the domains described in the model and whether new measures need to be developed.



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Supporting information

S1 Checklist. PRISMA 2020 checklist.
(DOCX)

S1 Appendix. Pre-existing conceptual model. The Authors previously developed conceptual model of outcome domains of importance following lower limb prosthetic rehabilitation.
(DOCX)

S1 File.
(XLSX)

S2 File.
(XLSX)

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Formal analysis: Chantel Ostler, Alex Dickinson, Maggie Donovan-Hall.

Funding acquisition: Chantel Ostler, Alex Dickinson, Maggie Donovan-Hall.

Investigation: Chantel Ostler.

Methodology: Chantel Ostler, Alex Dickinson, Maggie Donovan-Hall.

Project administration: Chantel Ostler.

Resources: Chantel Ostler.

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Validation: Chantel Ostler.

Visualization: Chantel Ostler.

Writing – original draft: Chantel Ostler, Maggie Donovan-Hall.

Writing – review & editing: Alex Dickinson, Cheryl Metcalf.

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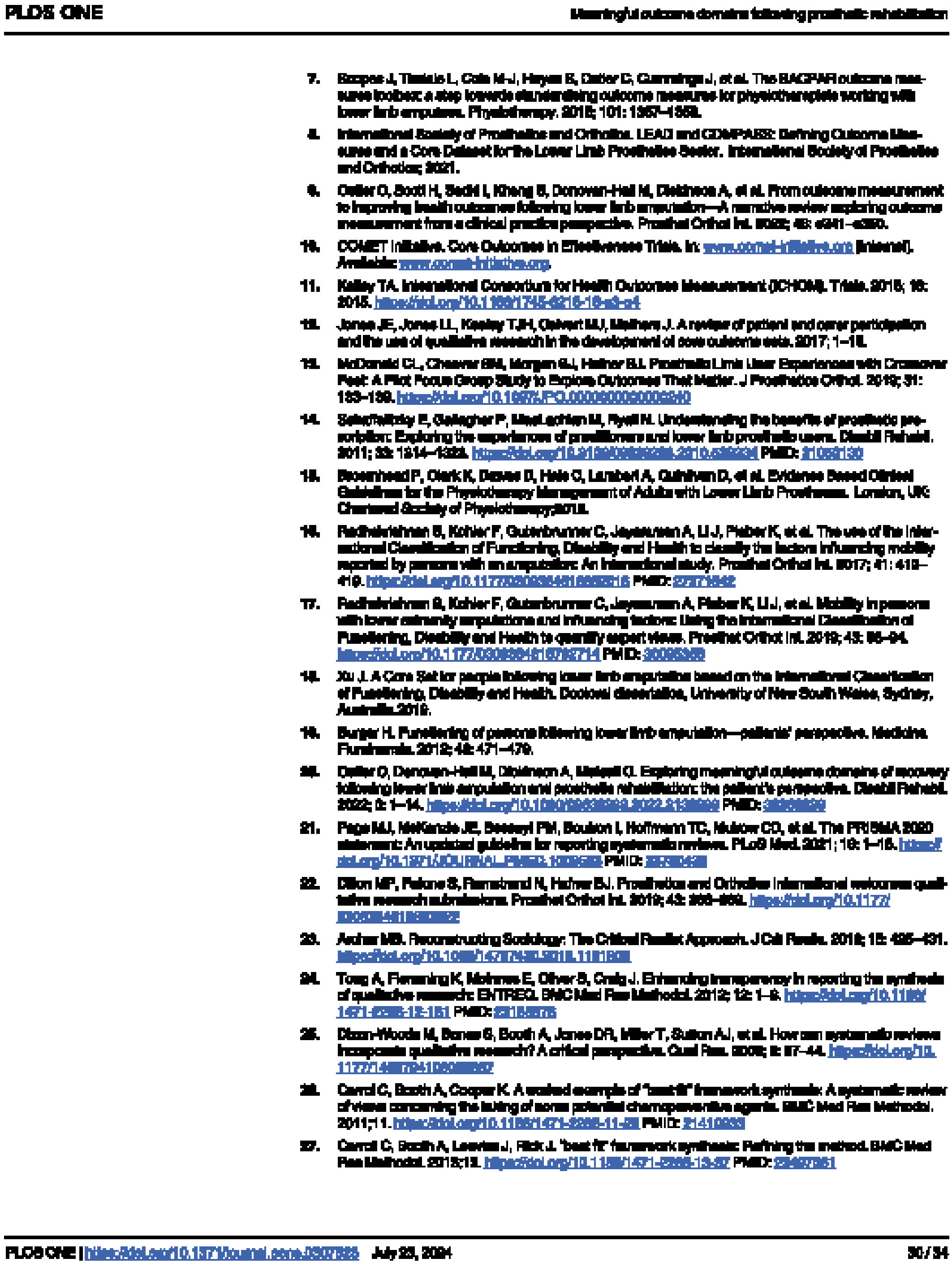

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Appendix J First reflective account example

W Focus Group - May 2019

8 Participants

I undertook this focus group and it was the first one I have facilitated as a researcher. I have undertaken a number of groups outside of research, i.e. for service improvement etc, and I was very familiar with the interview guide as I had done a number of 1:1 interviews between the first group in Dec 2018 and this, which was the second.

More participants took part than I was expecting as I thought that some would not attend. Therefore the group was quite large and took longer than the allotted hour. The participants all seemed happy for the group to run over and all appeared to have a lot to contribute and enjoyed sharing their experiences.

It was quite challenging to facilitate such a large group. Things that were difficult were stopping side conversations from happening, but we set this out as a ground rule from the start and I commented quickly during the group if conversations started using the reason that the tape might miss important information they had to contribute.

The other thing that was very hard to manage was that one participant was very chatty and kept wanting to contribute, however he tended to take the discussion off on a tangent. Once he got started it was very difficult to get him back to discussing the area we had been focusing on and I had to interrupt him a number of times. He did not seem to pick up on this and modify his behaviour, so this continued throughout the session. None of the other participants appeared concerned about this and all listened intently to each others' experiences.

MDH was present and this was very useful for me to hear how she reframed some of the questions I had asked if participants were struggling to answer the questions. This helped me to make think about how I composed some of the follow up questions and helped to develop my FG technique.

Appendix K Second reflective account example

Analysis Reflections

I was reflecting on the difference between data collected as part of a focus group and as part of an Interview. Interviews generated significantly more in-depth conversations and allow me to really focus on what that individual was saying and delve into their particular experience. The focus groups felt like they bounced around from topic to topic a lot more than the interviews did. Although this did allow subjects to be brought up that hadn't been covered in the interviews, such as fear over loss of benefits.

I found it much harder to get the depth of analysis from a focus group as often other people would change the direction of the conversation.

In hindsight it might be useful to undertake focus groups to help inform more in-depth interviews or conduct interviews and then review the interview guide in an attempt to sense check themes identified from in-depth interviews.

I was also reflecting on the theme names and found that I had named a theme physical activity and on discussion with MDH it appeared that the theme was not about physical activity but was about participation.

This reflection was around whether as a physiotherapist I thought of that theme in terms of something that I focused on in rehabilitation rather than what was coming out of the data. But when we looked through the data it was clear that the themes I had identified were about participation and it was more of an issue with how I had named the theme rather than the content.

I also reflected that the theme of participation seemed to demonstrate a continuum from household activities through to community integration and needed to consider whether this was coming out of the data or whether it reflected my approach to rehabilitation as a physiotherapist ie. Help the patient to become independent in the home and then progress skills and ability outside in more challenging community environments.

Appendix L Research for Patient Benefit (RfPB) application for future work – Lay summary

Research title:

Patient and stakeholder perspectives on routine health data collection, use and sharing: Foundations for data driven improvements in prosthetic care.

Aim(s) of the research

The vision of the project is to understand how to use routinely collected healthcare data, in a patient-centred way, to improve the experience and recovery of people using a prosthesis following lower limb amputation. We will work in partnership with a group of patients and clinicians to co-produce the research. The findings will be used to make recommendations for patient-centred data collection approaches in prosthetic care. This will help patients and clinicians use healthcare data to improve recovery and enable better research. Recommendations could be used by limb centres nationally and as the foundations for a nationwide data collection initiative in prosthetic care.

Background to the research

Due to the increase in conditions like diabetes, many people in the UK are having limbs amputated. These people undertake rehabilitation using a prosthesis, but recovery is not always as good as they would like. Healthcare data can be used to understand why this happens and what can be done about it. However, data initiatives in other settings haven't always realised this potential, and have been criticised for not being patient-centred. There is currently no UK data collection initiative in prosthetic care. We also don't know what is needed to make sure future healthcare data initiatives meet the needs of patients and clinicians.

Design and methods used

Four project stages will be designed, carried out and communicated in partnership with our co-production group.

- **Stage 1** - Review published work to find and learn from patient-centred health data collection projects in other settings. (Systematic review).
- **Stage 2** - Interviews and focus groups with patients, clinicians and wider stakeholders, to understand issues about the value and uses of health data, as well as the barriers and facilitators.
- **Stage 3** – Develop a survey to explore whether people across the UK who were not involved in the interviews agree with the things we found.
- **Stage 4** – Summarise findings and co-produce a set of recommendations for patient-centred data collection in prosthetic care.

Patient and public involvement

The project has been informed through discussion groups with patients, clinicians and researchers. People who attended the groups were invited to join a co-production group, with charities such as the Limbless Association.

Dissemination

We will co-produce short visual infographics of our results and recommendations to share with stakeholders. These will be shared with local patient support groups and limb loss charities, as well as clinical interest groups and networks. We will also publish our findings in peer-reviewed journals and at international scientific conferences, alongside our co-production group.

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