**A pilot cluster randomised controlled trial, of an IMPlicit learning approach versus standard care, on recovery of mobility following Stroke (IMPS).**

**Short Title:** Implicit Learning in Stroke Study

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**Introduction**

Recovery of motor function following stroke is underpinned by the process of neural plasticity. The key factors driving plasticity are similar to those important during skill acquisition (i.e. through motor learning processes) [1]. An understanding of the behavioural aspects of skill acquisition, and how to apply these within a clinical context, is essential to effective rehabilitation delivery.

Rehabilitation is a complex process, and one size rarely fits all. Generating knowledge about the scientifically grounded *principles* that underlie effective stroke rehabilitation is an important enabler of evidence informed rehabilitation practice. Principles can be applied in a manner that suits the individual context, whilst staying true to the underpinning evidence base. Several authors have sought to identify the active ingredients that lead to effective motor recovery following stroke, by extrapolating the “active ingredients” from experimental studies to inform a set of guiding principles for rehabilitation delivery [1-3]. These include factors such as repetitive practice, task specificity, variability, increasing difficulty (graded practice), action observation, and feedback (type and timing).

Translating principles into clinical practice faces the challenge of operationalising them [3]; deciding which principles to apply, how to do this, and adapting to the circumstances and preferences of the individual patient. Few clinical trials have sought to understand *how* to apply skill acquisition principles into practice, and few have directly *evaluated* *the benefits* in a clinical setting. Thus, the theory, knowledge, practice gap, remains a challenge.

Explicit and implicit motor learning are fundamental concepts within the motor learning literature. Differentiation between the two is mainly based on awareness of the learned skill [4]. Whilst explicit learning requires active attention and generates verbal knowledge of movement (facts and rules), implicit learning progresses with no or minimal increase in verbal knowledge of movement performance (facts and rules), and without awareness [5]. In practice, a bias toward implicit learning can be achieved by ~~The intervention primarily~~ incorporating two conditions that promote implicit motor learning, a) reducing the quantity of verbal instructions/feedback; and b) promoting an external focus of attention (derived from the task, instructions and feedback) [5].

In the field of sport, the effectiveness of implicit learning models is well evidenced [6]. Although evidence for any form of learning is limited within rehabilitation settings, observational studies show that current physiotherapy practice biases explicit motor learning conditions [7]; it is unclear whether this is the most effective approach. ~~Whilst implicit learning is a promising concept in stroke rehabilitation, we do not know how this approach can be effectively delivered, tailored and evaluated in a clinical setting.~~

This current research investigates the application of implicit learning principles in a clinically grounded pilot trial. Specifically, we ~~we investigated the application of an Implicit Learning Approach during acute stroke~~ rehabilitation [8]. Implicit ~~learning is a sub-conscious form of learning, which occurs through trial and error, and without thinking about the specific components of movement [5].~~

~~This study~~ compared an Implicit Learning Approach (ILA) to usual care, during the rehabilitation of mobility in the acute phase following stroke [8].  The clinical focus was on lower limb recovery – i.e. sitting, sit to stand, transfers, stepping and walking.

We had two primary aims. Firstly, to establish the feasibility of delivering rehabilitation using the principles of implicit learning, in an acute stroke care setting. Secondly, to inform the development of a future definitive trial evaluating motor learning principles in a clinical setting, by establishing the appropriateness of the overall study design.

The specific objectives were to:

* establish the feasibility of delivering the ILA during inpatient stroke rehabilitation (intervention fidelity)
* confirm whether the intervention delivered in this trial differed from usual care
* test delivery of the study protocol, including recruitment and retention of participants
* generate data to inform the design of a Phase III trial, including estimation of treatment effect to inform a sample size calculation
* understand and report differences in patient experience, as a result of the two intervention types being compared

**Methods**

The detailed study protocol is described elsewhere [8]. In brief, this was a multisite, assessor blind, pilot cluster randomised controlled trial (cRCT), comparing an implicit learning approach (intervention) to usual care (control), for the delivery of lower limb rehabilitation during inpatient stroke care. The study also included a nested qualitative evaluation, with data collected via focus groups (with clinicians) and semi structured interviews (with patient participants). The findings from the part of the qualitative evaluation that explored implementation have already been reported [9]. Themes relating to participant experience are included here. The study was approved by the Berkshire Research Ethics Committee B (18/SC/0582) and registered on ClinicalTrials.gov [NCT03792126].

The experimental approach, implicit learning, is a complex intervention. In line with guidance for developing and evaluating complex interventions, the phase of work reported here focussed on the feasibility of the intervention and of the evaluation design [10]. The Implicit Learning Approach (ILA) involves a number of interacting components, which are tailored to the individual participant. Delivering the intervention requires therapists to change their behaviour (particularly communication), and to apply clinical reasoning to apply the principles to each clinical scenario. These factors contribute to complexity [10], and require special consideration in terms of research methodology. Our intention was to enhance the application of the ILA by the whole therapy team at each site. To maximise fidelity of intervention delivery, and to minimise contamination bias between groups, we chose a cluster randomised design. The unit of randomisation was the Stroke Unit.

To define usual care (i.e. control group intervention), and to describe changes in practice as a result of implementing the ILA, six sites collected data at baseline, prior to any study related training and prior to randomisation. This consisted of direct, non-participation observation of routine physiotherapy sessions, with data collected via video recording. Participating physiotherapists and patients provided informed written consent for data collection, and data were analysed using a previously validated method [11]. The process and results from this baseline period of observation have already been reported [7], confirming the content of usual care.

Randomisation took place after the baseline data collection period. Clusters were assigned (1:1) with a simple randomisation procedure (using computer-generated numbers) to one of the 2 treatment groups. The first round of randomisations was carried out when 6 sites had been recruited, and these were randomised in a block size of 6. A block of size 2 was used to randomise further sites. Randomisation was conducted by the trial statistician (SE), and sites were informed of their group allocation by the Chief Investigator (LJ).

Recruited individuals in each site received all lower limb rehabilitation using the assigned approach, for the duration of their inpatient stay.

*Intervention Clusters*

In the intervention group (consisting of 4 clusters), therapists and therapy assistants were trained to deliver rehabilitation using principles of implicit learning, which are outlined in Supplementary File 1. We aimed for trial participants within these clusters to receive all lower limb rehabilitation using the implicit learning guidance. The active ingredients of implicit learning were defined as a) using verbal instructions sparingly and avoiding their use *during* task practice; b) promoting an external focus of attention more frequently than an internal focus; c) ensuring feedback was specific and targeted. We did not specifically prescribe the type of exercise of activity; this was at the discretion of the treating therapist. However, the goal was to adapt interventions to incorporate the principles of implicit learning.

*Control Clusters*

In the control group (consisting of 4 clusters), therapists continued to deliver rehabilitation as per their usual working practices. These sites had minimal contact with the research team, other than for data collection. They were aware of the broad aims of the study but did not have access to any of the ILA training or study materials.

We did not ask clusters (whether intervention or control) to make any changes to the frequency or duration of rehabilitation sessions – they were asked to follow usual local practice with regards to this.

Participants were recruited based on the following criteria: clinical diagnosis of stroke resulting in hemiplegia; within 14 days of stroke onset; medically stable; able to tolerate daily therapy for a minimum of 30 minutes per session; able to sit for more than 5 seconds without support; able to understand and follow 1 stage commands. Patients were excluded if they: experienced a previous stroke with residual deficits; had another neurological diagnosis (e.g. Parkinson’s, Multiple Sclerosis); required physical assistance to transfer or mobilise pre-morbidly.

Consent took place at the individual participant level. An amendment was made 8 months into the study to enable recruitment of those who lacked capacity. This change was made as several potential participants were unable to take part as they were not able to provide fully informed consent, despite otherwise meeting the inclusion criteria and being engaged in active rehabilitation. We were concerned that this would not only affect recruitment but would limit generalisability of the study findings. We therefore sought, and were granted, approval to recruit participants who lacked capacity via a Consultee.

Full details of the sample size calculation are reported elsewhere [8]. In summary, sample size was based on estimating the recruitment rate to a desired level. We anticipated being able to recruit 50% of eligible patients. Based on this, our target was to approach 120 eligible participants, and to recruit 60, split evenly between treatment arms.

Physiotherapists at both intervention and control clusters were asked to video record any treatment sessions that focussed (fully or in part) on lower limb recovery, for all participants that were enrolled in the trial. Therapists were provided with recording equipment (Panasonic HC-V770 video recorder mounted on a tripod), and recorded treatment sessions without the presence of a researcher. Our intention was to record all sessions, and later to analyse a random sample. We took this approach to minimise the risk that therapists applied the principles when they were under observation, but not consistently across all treatment sessions.

Video recording and subsequent observational analysis was used to a) describe adherence to the IMPS guidance at the intervention sites, b) compare the input received at intervention and control sites and c) to confirm (or not) that the IMPS intervention was different to usual care (by comparing to baseline observational data).

Primary outcomes relate to the feasibility of delivering the ILA, and the effectiveness of the trial protocol overall. This included: ability to recruit and retain both clusters and individual participants; suitability and acceptability of data collection processes (e.g. video recording); appropriateness of methods used to monitor fidelity; appropriateness of the chosen outcome measures; and willingness of participants to be followed up. At a cluster level, we evaluated the ability of intervention site therapists to adhere to the implicit learning principles, and we compared the differences in the therapy received between the control and intervention groups.

Secondary outcomes were: recovery of activity and function in the lower limb, measured using Fugl Meyer Lower Extremity Sub Section [12], Swedish Postural Adjustment in Stroke Scale (SwePASS) [13-16] and Rivermead Mobility Index (mRMI) [17]. To understand differences in patient preferences, we collected the Movement Specific Reinvestment Scale [18] at baseline, discharge and 3 months post stroke; and completed interviews with a subset of participants from each treatment arm. We also recorded modified Rankin Score [19] and EuroQol-5 Dimension Questionnaire [20] at 12 week follow up.

Adverse events were recorded in line with the study protocol. Whilst we did not anticipate study related AE’s, we did consider the possibility of the ILA being perceived as less personal/motivating for patients, and this being associated with a reduced willingness to participate in therapy. We therefore monitored adherence with rehabilitation across all sites.

Whilst therapists were involved in the delivery of the intervention and could not be blind, patient participants were not informed of their cluster allocation. All outcome measures were completed by a clinician or research practitioner at the cluster site. Outcome measures were video recorded and later analysed by a blind assessor who was not otherwise involved with the study. Fidelity monitoring (through analysis of the treatment videos) was completed by a researcher who was not aware of allocation.

*Data Analysis*

Data were stored and managed using Statistical Package for Social Sciences (SPSS)® software, and analysis was carried out in SPSS and Stata [21]

Feasibility and fidelity analysis took place at cluster level. Descriptive methods were used to estimate practicality of factors relating to the protocol, such as recruitment (proportion of eligible people who consent to the study) and retention (completion of outcome measures at 3 months).

Fidelity of the intervention was established by comparing the number and type of coaching statements delivered to each group. We describe the mean number of coaching statements per person (and the breakdown of these statements as externally or internally focussed) in each group. The study was not designed to have statistical power to detect differences in outcome between the two treatment arms.

Participant interviews were conducted by the primary researcher (LJ), within one week of the end of the trial interventions. This was to ensure that an individual’s recollection of their rehabilitation input was recent, and that their views were not impacted by subsequent therapy received in the community. Interviews were audio recorded and transcribed verbatim. Data were analysed using a thematic approach [22], to describe how participants perceived and experienced therapy, and how this compared across groups.

**RESULTS**

*Clusters and Participants*

10 clusters were invited to take part, and 8 agreed to participate. Reasons for declining were lack of capacity within the clinical team and involvement in a conflicting research trial.

Site opening was staggered, with the first site commencing recruitment in March 2019, and the final site in March 2020. All clusters paused recruitment from April 2020 due to the COVID-19 pandemic, with a phased reopening according to local capacity and policy, from March 2021. Of the 8 clusters who originally took part in the trial, three were unable to re-open due to COVID-19 related capacity issues within clinical and research teams. Details of each cluster, including the period for which they were actively recruiting, is given in Table 1.

**[INSERT TABLE 1 HERE]**

Figure 1 shows the flow of participants through the trial. 474 patients were screened for inclusion, of which 112 (24%) met the eligibility criteria and 75 (16%) were invited to take part.

72% (54/75; 95% confidence interval [61.0% to 80.9%]) of those invited, agreed to take part and were enrolled in the trial. This represents 90% of the original recruitment target of 60 participants, and exceeds our anticipated proportion of eligible patients agreeing to participate (anticipated 50%; actual 72%). Recruitment rate varied across sites (see Table 1), with an average enrolment rate of 0.8 participants month (control group mean 0.9, range 0.1-1.2; intervention group mean 0.7, range 0.3 – 1.3).

**[INSERT FIGURE 1 HERE]**

3 participants were withdrawn due to their symptoms resolving at baseline assessment, meaning 51 were included in the intervention phase. 10 participants were lost to follow up, giving an overall attrition rate of 20% (10/51). Of note, 5 of these loses were due to restrictions imposed through the COVID-19 pandemic, meaning follow up assessments could not take place. Excluding pandemic related losses, the attrition rate was 11% (5/46); which is slightly higher than the average of 8% reported for trials recruiting in the acute setting [23].

Average time since stroke at the point of enrolment was 6 days (SD 3.42, range 0-14). Group characteristics were similar at baseline (Tables 2 and 3).

**[INSERT TABLE 2 HERE]**

**[INSERT TABLE 3 HERE]**

*Intervention Fidelity*

Compliance with collection of video data varied across sites; although this wasn’t impacted by group of randomisation. Once enrolled, there were no incidences of participants declining to be video recorded. However, a range of reasons contributed to therapists not recording some treatment sessions, including lack of time, equipment needing to be stored away from the ward, a lack of private space (e.g. gym) to deliver the sessions, and not getting into the habit of doing it. To account for fewer sessions being recorded, we increased the frequency of video analysis to 1 in 2, with a minimum of 3 per participant; ensuring sufficient fidelity data were analysed for each participant. A total of 249 treatment sessions were recorded: 135 (54%) of these were analysed (70 from the intervention group and 65 from the control group).

Figures 2a-c show data from fidelity monitoring, with comparison to baseline (pre-randomisation). Data from baseline observations and control group monitoring was similar, providing confirmation that the intervention received by the control group was aligned to usual care. For control group participants, the median number of coaching statements per minute was 6.4 (IQR 4.7-8.0), compared to 4.8 (IQR 1.3-10.1) in the intervention group. The mean difference was 1.87 (6.61 [control] versus 4.74) with corresponding 95% confidence interval of 1.08 to 2.65. (Note, the confidence interval was calculated assuming unequal variances, and ignoring clustering.) In the control group, 12% of instructions and 5% of feedback statements were externally focussed. This compared to 32% of instructions and 31% of feedback in the intervention group. In both the control and intervention groups, the use of unfocussed or mixed focused statements remained high at 51% and 55% respectively. When analysing only the statements that did convey a specific focus of attention, there was a clear difference between groups (Figures 2b and 2c). In the control group, 25% of focussed instructions and 5% of focussed feedback were categorised as externally focussed. In the intervention groups, these proportions rose to 71% and 31%; albeit it with greater variability across sessions.

**[INSERT FIGURE 2 HERE]**

To understand individual patient participants’ tendency to consciously control movement (also termed “reinvestment”), and to compare this between groups and over time, we collected the Movement Specific Reinvestment Scale (MSRS) at baseline and week 12. The MSRS is a self-report measure, comprising of 10 statements within 2 domains – movement self-consciousness and conscious motor processing [24]. A higher score on the MSRS indicates a greater tendency for an individual to attempt to consciously control movement. Although average MSRS was higher in the intervention group at baseline, it dropped to lower by week 12 – possibly indicating that the reduction in therapists imparting explicit knowledge, led to less likelihood of movement being consciously controlled (Figure 3e). We also explored the frequency and type of “rules” reported by participants within the semi-structured interviews. Rules are statements that contain information about movement or position of a limb/joint, the velocity of movement, angle or directions of a joint, placement of a walking aid or changes in step characteristics (bigger steps, wider steps etc) [25]. It is anticipated that those learning implicitly develop and therefore report, fewer verbal rules [26].Interview transcripts were analysed to identify the rules that were developed by participants. The average number of different rules reported in the control group was 3 (range 1-5), with the same rule often repeated during the interview. These statements related to posture (shoulders down or trunk extension), foot position, conscious control of balance, knee control in stance, gait pattern, weight shift in standing, dorsiflexion for early stance, and heel strike. In some instances, the rules were specific and technical:

*“He asked me to move my, put my weight over my leg and move more forward with my head to make me move better and it works. But I don’t get it right all the time but most of the time I do”* [Participant C-07 – Control Group]

Intervention group particiants reported an average of 1 rule (range 0-4), with 3 interviewees not reporting any movement specific rules. In this group, the rules were typically more broad, with the majority relating to general posture. Foot placement, knee control (in stance) and step lenth/pattern were also mentioned.

*“I’m just trying to think about which part of my foot is not working, why is my foot dragging. I think basically the one part that isn’t functioning properly is the walking on my heel”* [Participant B-07 – Implicit Learning Group]

There were several examples of participants in the intervention group noting the benefits of fewer or more concise instructions; this was not heard from the control group.

*“But when you become a little bit better with your walking you just see that the concentrate on the walking is not good, it’s better to do something else. So I think it’s very important sometimes to switch from the training when you use the focus on the leg, on your walking and sometimes it’s better just walking and singing a song or talk to someone”* [Participant B-06 – Implicit Learning Group]

*“But no they were pretty concise, pretty clear with their instructions, yes”* [Participant B-07 – Implicit Learning Group]

*“They only tell you the things they need you to do, they don’t waffle around it, there’s no chit chat there to confuse you”* [Participant F-02 – Implicit Learning Group

*Clinical Outcome Data*

Outcome measures were recorded at enrolment (baseline), every 2 weeks for the duration of a participant’s inpatient stay and at hospital discharge. At this point, trial interventions stopped, and participants in both groups continued with usual care. Follow up was at 12 weeks post stroke. With an average of 26 days (SD 14.9) between enrolment and discharge, the majority of participants completed data collection at four time-points – baseline, day 14, discharge and 12 week (follow up). It is these time-points that are included in our analysis (Table 4).

**[INSERT TABLE 4 HERE]**

**[INSERT TABLE 5 HERE]**

**[INSERT FIGURE 3 HERE]**

For all clinical outcomes, there were no specific concerns relating to the intervention, based on informal assessment of outcome; i.e. the ILA did not appear to be inferior to usual care. Participants in the intervention group had a shorter hospital length of stay and lower care requirements at 12 weeks post stroke, than those in the control group (Table 5). No study related adverse events were reported. Two participants had a further stroke, and one participant died from stroke related complications.

*Sample size for future trial*

We lastly consider the potential sample size calculation for a future study, using Fugl-Meyer at 12 weeks as the primary outcome. We used the following information for the calculations:

* A clinically meaningful difference of 6 [27]
* Cluster-size adjusted estimate of the standard deviation (8.556)
* Power of 0.9 and alpha of 0.05
* Intracluster correlations (ICC) of 0.05 and 0.1
* Number of clusters 16, 24 or 30

The final two inputs provide a range of sample sizes to demonstrate the effect of assumptions relating to the ICC and the impact of changing cluster size. The ICC was estimated to be 0.07 in this study (based on a mixed model containing group and baseline Fugl-Meyer score, fit using restricted maximum likelihood), but given the wide 95% confidence interval (0.00 to 0.83), this should not be taken as a reliable estimate. Based on the above inputs, the required sample sizes were 120, 110 and 104 respectively for increasing cluster sizes when the ICC was 0.05, and 176, 132 and 116 when the ICC was 0.1.

**Discussion**

In this study, clinical physiotherapists were required to integrate principles of implicit motor learning for participants enrolled in the trial. Delivery of the intervention necessitated behaviour change on the part of therapists, who were required to change the way in which they design and deliver rehabilitation, and alter the way in which they coach patients during treatment sessions.

Standard RCTs are challenging to perform in rehabilitation settings [28], and given the complex nature of the implicit learning approach, we chose cluster randomisation. Cluster randomised trials (cRCTs) are useful when evaluating the way in which a healthcare intervention, in this case gait rehabilitation, is delivered [29, 30]. By introducing the intervention to a whole organisational unit (i.e. physiotherapy team on a Stroke Unit), treatment contamination is minimised [31].

Our intention was for therapists at the intervention sites to adopt the principles of implicit learning as part of their routine practice for the duration of the trial (i.e. for all patients on the Unit); and for data to be collected from eligible participants who provided consent for this. This approach would have enabled full integration of the approach within clinical care, giving therapists the opportunity to build their capability and confidence in delivering implicit learning, maximising intervention fidelity. However, it was a requirement of the ethics review board that the ILA principles were only introduced for individual patients after they had consented to the study, and that the approach was not used across the service as a whole. This requirement potentially diluted the opportunity to truly embed implicit learning principles across a team and a service. Coupled with the relatively slow recruitment rate and the disruption resulting from the COVID-19 pandemic, scope for the trial intervention to be robustly implemented by clinical teams was hindered. Given that a) both learning approaches are used and accepted as part of standard care (albeit to different degrees), and b) our study demonstrated non-inferiority of implicit learning when compared to usual care, a future study could ethically take a more robust approach to fully embedding the ILA interventions across clusters, without requiring informed consent from each individual patient. This would further enhance fidelity, and would ensure any benefits arising from the ILA are maximised and identified within data collection.

Recruitment into rehabilitation trials early after stroke is challenged by both patient and service related factors [32]. We sought to recruit patients within 2 weeks of admission to ensure that the majority of participants’ inpatient rehabilitation was delivered in line with the trial intervention (maximise “dose”) and to avoid the impact of explicit rules being acquired through prior therapy (reduce contamination). Our average recruitment rate of 0.8 participants per site per month falls slightly below the typical rate for stroke rehabilitation studies, which has been reported at around 1 participant per site per month in similar (UK) settings [23]. Our narrow recruitment window meant that a number of potential participants were excluded due to medical instability, or not reaching the motor requirements during this time. We recommend that any future trial recruits participants as early as possible, but with an increased cut off for enrolment of 4 weeks post stroke. Implementing the approach fully across the cluster would minimise any limitations caused by a longer recruitment window, as all patients at intervention sites would be exposed to implicit learning regardless of the timepoint of recruitment. Loss to follow up was higher than reported in comparable studies [23] but is not surprising given the acuity of the population studied and the COVID 19 pandemic. No patients opted to withdraw for study related reasons.

The use of video recording and observational analysis enabled us to effectively monitor and describe two aspects of fidelity:

1) treatment integrity - demonstrating that therapists carry out the intervention with adequate levels of adherence and competence to the treatment model/protocol; and

2) treatment differentiation - ensuring that the experimental intervention condition differs from the control condition [33, 34].

Although treatment integrity was achieved; this was more robust for some elements of the intervention than others. We identified a clear difference in the use of focus of attention, but the difference in overall quantity of instructions/feedback between groups, was small. Factors impacting implementation have been explored through focus groups, the results of which are reported separately [9]. Key themes relate to how therapists interpreted and understood the intervention and how it related to their existing values and beliefs. Multiple reasons may account for this finding, not least the disruption caused by the COVID-19 pandemic, which made it more difficult for therapists to consistently apply the approach over a period of time. Our data confirms the implicit learning approach to be different to usual care; treatment differentiation was achieved. Although a range of approaches were used within usual care, we identified that the implicit learning principles were not a routine or consistent part of this.

Our exploration of wider factors relating to fidelity provide additional confidence in the trial interventions. Two such factors are the participants recollection of “rules”, and an individual’s tendency to consciously control automated movements (measured using the MSRS). Higher MSRS scores have been associated with altered gait kinematics [35] and an increased risk of falls [36] in older adults. We noted a trend towards a greater reduction in MSRS scores by week 12 in the intervention group, when compared to the control group. We also analysed interview transcripts to identify the type and frequency of rules being recalled by participants. The reporting of rules varied between participants, with greater and more specific accumulation of rules in those from the control group. If stroke rehabilitation delivered using implicit learning principles does reduce conscious motor processing and as a result, reinvestment, it could feasibly improve movement accuracy and function [37], and may lead to a reduction in falls risk.

It is feasible to investigate the application of motor learning principles within clinical practice, using a cRCT design, and our sample size calculation is viable. However, multiple strategies are required to robustly monitor and understand treatment fidelity, and a mixed methods approach can enhance this. Furthermore, to optimise robust implementation, a comprehensive approach to training and supporting intervention delivery is necessary [9]. Specific knowledge translation interventions, involving strategies to aid implementation, can increase physiotherapists confidence to apply motor learning principles, with particular benefit to therapists’ self-efficacy [38]. Optimal support is likely to be multifaceted, including a range of complementary strategies such as didactic training, conceptual frameworks, case reviews and structured clinical-thinking tools [39]. One of the next steps is to evaluate the impact of such strategies on patient outcome, through hybrid implementation-efficacy trials [40].

A particular strength of this study, is the robust way in which treatment fidelity was monitored. As a result, we can be confident in the content of both usual care and the intervention, and that there was a difference between the two. We also included a range of clinical outcomes, measuring both impairment and function. Furthermore, our mixed methods approach has allowed us to better understand perspectives of both participants and staff, providing vital insights to inform the development of future study, with early consideration of future potential implementation into practice.

A challenge of this study, as in any cRCT design, was our ability to capture and describe the differences in wider stroke care delivery at each site. We had intended to describe usual care in terms of rehabilitation provision at each site using the Stroke Sentinel National Audit Programme, which would allow some comparison of the typical frequency of standard care interventions within each cluster, and the services received post discharge. However, mandatory reporting to SSNAP was paused during the COVID-19 pandemic, and it is therefore difficult to confidently use this data to articulate any potential differences between sites.

Furthermore, the Units included in this trial were similar in terms of size and patient population. To enhance generalisability, it will be important to include clusters from a range of geographical settings, including those serving a more diverse population, in any future work.

During this study, the intervention period stopped at the point of discharge from hospital, and final follow up took place at 12 weeks post stroke. Whilst this is a pragmatic approach that accounts for the patient need over a set period of intervention, it does mean that participants will have received the intervention for different periods of time, and also will have received different levels of community service post discharge

Motor learning is complex – it is composed of multiple elements that can be characterised in a variety of ways [39]. Our intervention was directed towards the frequency and attentional focus of instructions and feedback; an intervention that can be widely implemented, with little or no resource implications. It is possible that motor learning principles interact, and the greatest benefit may be seen when they are applied consistently and collectively. A challenge for future research is understanding how best to optimise recovery through the implementation of multiple motor learning principles, whilst recognising the need for these to be adapted to each individuals’ clinical circumstances and learning preferences. Consideration of implicit and explicit motor learning principles, how and when to use each approach, is an important part of this.

**Clinical Messages:**

* It is feasible to evaluate different motor learning principles within an acute stroke setting, using a cluster randomised controlled design.
* An implicit motor learning approach is feasible, is acceptable to both patients and therapists, and may benefit motor recovery.
* Implicit motor learning principles can be adopted by physiotherapists following relatively little training, although robust and consistent implementation is likely to require multifaceted and ongoing implementation strategies.

**Trial registration:** ClinicalTrials.gov: NCT03792126

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Table 1: Recruitment Rate per Cluster

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Site** | **Group** | **Active Recruitment Period (months)** | **Type of Service** | **Number of stroke admissions per yeara** | **Total number of participants recruited to IMPS Trial** | **Number of participants recruited per month)** |
| A | Control | 15 | Acute and Rehabilitation | 873 | 18 | 1.2 |
| B | Intervention | 15 | Acute and Rehabilitation | 533 | 11 | 0.73 |
| C | Control | 9 | Acute and Rehabilitation | 619 | 10 | 1.11 |
| D | Control | 7 | Acute and Rehabilitation | 425 | 1 | 0.14 |
| E | Intervention | 10 | Acute and Rehabilitation | 861 | 7 | 0.7 |
| F | Intervention | 3 | Acute and Rehabilitation | 1102 | 4 | 1.33 |
| G | Control | 5 | Acute and Rehabilitation | 296 | 2 | 0.4 |
| H | Intervention | 3 | Acute Care only | 691 | 1 | 0.3 |
| a Annual stroke admission numbers for 2019-2020 given to provide an indication of size of service. Source: Stroke Sentinel National Audit Programme (SSNAP) Annual Portfolio Clinical Audit Report, Kings College London. |

Table 2: Baseline Characteristics: \*values are mean (SD) [range]; or %

|  |  |  |
| --- | --- | --- |
|  | **Control\*****N = 30** | **Intervention\*****N = 21** |
| **Age** (years) – mean (SD) [range]  | 74 (15)(25 – 91) | 73 (12)(45 – 94) |
| **Gender** – n (%) |  |  |
| Male | 15 (50.0%) | 14 (66.7%) |
| Female | 15 (50.0%) | 7 (33.3%) |
| **Time Since Stroke** (days) – mean (SD) [range] | 5.7 (2.9)[2 – 12] | 6.7 (4.0)[0 – 14] |
| **Stroke Type** – n (%)TACSPACSLACSPOCSICH | 3 (10.0%)17 (56.7%)4 (13.3%)1 (3.3%)5 (16.7%) | 3 (14.3%) 11 (52.4%)3 (14.3%)2 (9.5%)2 (9.5%) |
| **Admission NIHSS** – mean (SD) [range] | 8.9 (5.5)[2-24] | 9.7 (5.1)[4-22] |
| **MOCA** – mean (SD) [range] | 20.5 (5.2)[10-29] | 23 (2.9)[18-27]  |
| **Fugl Meyer Lower Limb** – mean (SD) [range] | 14.1 (7.4)[0-25] | 10.8 (6.7)[0-27] |
| **SwePASS** – mean (SD) [range] | 17.7 (6.1)[8-28] | 18.3 (7.0)[5-33] |
| **Modified Rivermead Mobility Index** – mean (SD) [range] | 16.5 (7.4)[4-29] | 17.6 (7.6)[5-34] |
| *TACS = total anterior circulation stroke; PACS = partial anterior circulation stroke; LACS = lacunar stroke; POCS = posterior circulation stroke; ICH = intracerebral haemorrhage; NIHSS = National Institute for Health Stroke Scale; SwePASS – Swedish Postural Adjustment in Stroke Scale; MOCA – Montreal Cognitive Assessment.* |

Table 3: Comparison of Groups at Baseline

|  |  |  |
| --- | --- | --- |
| **Characteristic** | **Estimate** | **p-value** |
| Age | -0.15 | 0.98 |
| Sex1 | 0.69 | 0.24 |
| Time since stroke | -2.32 | 0.16 |
| Stroke type2 | - | 0.83 |
| NIHSS | 1.34 | 0.53 |
| MOCA | 2.15 | 0.36 |
| Fugl-Meyer (Lower Extremity) | -4.66 | 0.13 |
| SwePASS | -0.04 | 0.99 |
| mRMI | 0.87 | 0.71 |

*Linear mixed effects model (unless otherwise indicated) results, with the baseline characteristic as the outcome, group as a main effect and site as random effect. 1Logistic mixed effects model. 2Multinomial logistic mixed effects model did not fit; a χ2 test was carried out instead (ignoring site).*

*NIHSS – National Institute for Health Storke Scale; MOCA – Montreal Cognitive Assessment; SwePASS – Swedish Postural Adjustment in Stroke Scale; mRMI – modified Rivermead Mobility Index*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Measure** | **Allocation** | **Week 0 (Baseline)** | **Week 2** | **Week 12 (Follow Up)** |
| Fugl Meyer Lower Limb | Control | 14.0 (7.6, 0-25) | 17.65 (7.2, 5 – 31) | 21.1 (8.0, 5-34) |
| Intervention | 11.5 (7.0, 0-27)  | 16.3 (9.7, 0-34) | 24.9 (6.0, 15-34) |
| SwePass | Control | 17.7 (6.2, 8-28) | 22.1 (6.8, 8-33) | 26.4 (7.8, 6-35) |
| Intervention | 19.3 (7.5, 5-33) | 23.9 (8.1, 4-34) | 29.1 (5.3, 18-34) |
| mRMI | Control | 16.5 (7.6, 4-29) | 22.9 (10.1, 5-38) | 30.2 (11.6, 5-40) |
| Intervention | 18.4 (8.0, 5-34) | 25.1 (10.7, 3-40) | 34.4 (7.5, 18-40) |
| MSRS | Control | 40.1 (12.9, 11-60) |  | 41.1 (11.0, 15 – 65) |
| Intervention | 43.2 (10.9, 21 -59) |  | 39.0 (11.1, 27 – 59) |
| mRS | Control | 4.0 (0, 4-4) |  | 4.0 (0.9, 2-5) |
| Intervention | 4.0 (0.21, 3-4) |  | 2.6 (1.0, 1 – 4) |
| EQ 5D VAS | Control |  |  | 69.9 (20.3, 20 - 100) |
| Intervention |  |  | 59.3 (27, 21 - 95) |
| EQ 5DIndex Score | Control |  |  | 12.0 (4, 8 - 22) |
| Intervention |  |  | 13.2 (4, 5 - 18) |

Table 4: Descriptive statistics for each outcome variable according to group allocation. Values are mean (SD, range)

*SwePASS – Swedish Postural Adjustment in Stroke Scale; mRMI – modified Rivermead Mobility Index; MSRS – Movement Specific Reinvestment Scale; mRS – modified Rankin Score; EQ5D VAS – EuroQol 5 Dimension Visual Analogue Scale.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Measure** | **Allocation** | **Discharge Data** | **Week 12** |
| Discharge destination/current location | Control | Home: 70%Residential Care: 20%Transfer to another hospital: 6%Died: 3% | Home: 70%Residential Care: 35%Transfer to another hospital: 0Died: 5% |
| Intervention | Home: 79%Residential Care: 19%Died: 5% | Home: 88%Residential Care: 6%Died: 6% |
| Hospital length of stay (days) | Control | 34 (17.5) |  |
| Intervention | 31 (11.5) |  |
| Care requirements a, b | Control | 2.68 (2.68) | 1.68 (2.85) |
| Intervention | 2.35 (2.32) | 0.71 (1.49) |
| 1. number of carers x number of visits per day
2. calculated for participants returning home (excludes those in 24 hour residential care)
 |

Table 5: Comparison between groups of discharge and care requirements

Figure 1: Consort

Attached.

Figure 2



Figure 2a: Box and Whisker plot comparing the rate of coaching statements (number per minute) between groups.



Figure 2b: Box and Whisker plot comparing the proportion (%) of instructions categorised as external focus of attention between groups.



Figure 2c: Box and Whisker plot comparing the proportion (%) of feedback statements categorised as external focus of attention between groups

**Figure 3**

Figure 3: Comparison between group mean for each outcome measure at Week 0 and Week 12.