The IMPS Study Protocol
[Implicit Learning in Stroke]

A pilot cluster randomised controlled trial, of an implicit learning approach (ILA) versus standard care, on recovery of mobility following stroke.

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Contents

1 Study Synopsis

Title	A pilot cluster randomised controlled trial, of an implicit learning approach (ILA) versus standard care, on recovery of mobility following stroke.
Protocol Short Title/Acronym	Implicit Learning in Stroke Study (IMPS)
Protocol Version Number and Date	V2 24/09/2018
Study Phase	Pilot (with embedded feasibility)
Study Hypothesis	None
Study Duration	24 months
Methodology	Cluster (Stroke Unit) randomised controlled pilot trial, with nested qualitative exploration of participant and therapist views.
Sponsor Name	Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust and University of Southampton
Chief Investigator	Dr Louise Johnson
REC Number	[to be added]
Medical condition under investigation	Stroke
Primary Objective	To establish the feasibility of delivering an ILA during acute stroke rehabilitation (fidelity), and to test the integrity of the study protocol (pilot).
Secondary Objective(s)	To generate data to inform the design of a Phase III trial – including: • Identification of training requirements of clinical teams delivering ILA • Identification of most appropriate outcome measure • Estimation of expected rates of recruitment and retention • Estimation of effect size to enable future sample size calculation • Therapist and patient perceptions of the approach
Number of Clusters	6-8
Number of Participants	60
End Point	3 months post stroke
Main Inclusion Criteria	Clinical diagnosis of stroke; presenting with hemiplegia Within 14 days of stroke onset Medically stable Able to • tolerate daily therapy for a minimum of 30 minutes per session • sit for more than 5 seconds without support • understand and follow 1 stage commands
Primary Outcome Measure	Change in modified Rivermead Mobility Index score at 4 weeks.
Statistical Methodology and Analysis	Within group change scores for all outcome measures with 95% confidence interval

2 Abbreviations

AI	Adverse Incident
HASU	Hyperacute Stroke Unit
ILA	Implicit Learning Approach
FM-LL	Fugl Meyer Assessment – Lower Limb Section
MDT	Multidisciplinary Team
mRMI	Modified Rivermead Mobility Index
MSRS	Movement Specific Reinvestment Scale
SU	Stroke Unit
SwePASS	Modified (Swedish) Postural Adjustment in Stroke Scale

3 Background and Rationale

Around 80% of stroke survivors present with a motor impairment, which affects the control of movement on one side of the body [1]. Much of the focus of rehabilitation, and in particular the work of physiotherapists and occupational therapists, is the recovery of this impaired movement and the associated functions. Yet specific evidence relating to the components of practice that are most effective in promoting motor recovery following stroke is limited.

Regaining the ability to stand, step and walk are important goals for people who have experienced a stroke, and are a common focus during early rehabilitation. Given that one of the key criteria for early discharge from inpatient stroke care is the ability to transfer from bed to chair (+/- assistance) [3], interventions that facilitate the achievement of mobility goals more quickly are also key to reducing length of stay in hospital.

This process of functional recovery post-stroke is underpinned by theories of motor learning, of which there are two broad categories – explicit and implicit. Explicit learning occurs when someone is thinking about what to do, and about how to move – it is a conscious form of learning. Implicit learning occurs through trial and error, and without thinking specifically about how to move – it is a sub-conscious form of learning. There is, already, agreement that two practice conditions are particularly important when differentiating explicit from implicit learning. These are:

a) the ***quantity*** of instructions/feedback that therapists give, and

b) the ***focus of attention*** derived from these instructions/feedback [4].

Experts consider that high quantity of information and/or promotion of an internal focus of attention (i.e. focussing on body movements) are synonymous with an explicit learning model, and that reduced quantity of information and/or an external focus of attention (i.e. focussing on the environment) are synonymous an implicit learning model [4]. Bias toward one or the other form of learning can therefore be mediated by what the therapist says to a patient.

Implicit and explicit approaches have been well investigated with healthy participants. Research has shown that tasks learnt explicitly are less robust and are less likely to be retained over time, than those learnt implicitly [see 9]. Equally, research in sport has consistently shown that giving excessive verbal information during task practice reduces movement automaticity [5, 6]; and that reduced frequency feedback during task practice can enhance learning [7, 8]. There is strong evidence that people master skills more effectively if they are prompted to focus their attention toward the environment, rather than on their body [see 9 for a review]. Based on current evidence relating to motor learning in stroke, we hypothesise that the ILA will be more effective than standard care (and at a minimum, will be equivalent). There is no evidence, theoretical or empirical, to suggest that utilising an ILA will be detrimental to recovery.

The body of evidence favouring implicit learning is persuasive, and should lead us to challenge current rehabilitation practice, which is ***known to be highly explicit in nature*** [1, 10, 11]. However, the reported studies typically involve healthy young adults performing sporting activities. Direct transferability to stroke rehabilitation, which is invariably more complex, requires evaluation.

4 Trial Details

This trial will compare an Implicit Learning Approach (ILA) to usual care, during the rehabilitation of mobility post stroke. It is a pilot trial, with embedded feasibility and qualitative evaluations.

4.1 Aim(s)

- To establish the feasibility of delivering ILA during acute stroke rehabilitation.
- To test the integrity of the study protocol (pilot)
- To generate data to inform the design of a Phase III trial.

4.2 Study Design

This is a multicentre, assessor blind, cluster randomised controlled pilot trial, with embedded feasibility study. It also includes a nested qualitative evaluation, designed to explore the views of participants and therapists.

A cluster randomised design is being used, as it is the only way to protect against contamination between treatment arms. Information about the exact detail of the ILA will only be shared once randomisation has taken place, with the sites who will be delivering the intervention. Standard care clusters will not have access to the trial materials (e.g. treatment manual), or details about the specific elements of the intervention.

4.3 Understanding and Describing Baseline

In order to understand current practice within each unit, we will conduct a small observational study at the beginning of the trial. Between 6-10 standard care treatment sessions will be video recorded at each site. This will take place ***before randomisation*** has taken place, and therefore before clinicians have received any training. We will use non-probability sampling to video record between 6-10 patient-therapist pairs (exact number to be agreed locally, depending on the size of the Unit/Team). Each recorded session will involve a different patient-therapist pair, but the individual patients/therapists may be recorded more than once. Therapists will be asked to continue with a routine therapy session, aimed at improving sit to stand, stepping or gait.

We will analyse the content of these recorded sessions using a previously validated method [1]. This will give us an indication of the likely content of standard care in each participating organisation, and will help us to tailor the required training (for the intervention sites). By later comparing the collective content of these recordings to those taken during the trial, we will also get insight into the differences between the trial interventions and standard care.

These video recordings will be made before recruitment to the pilot trial commences. Patients involved in this stage will not be recruited into the pilot study. A separate Participation Information Sheet and consent form is provided.

4.4 Recruitment of Clusters

4.4.1 Eligibility Criteria for Clusters (Stroke Units)

Criteria for stroke unit eligibility are - a dedicated unit that

i) routinely admits patients with acute stroke; and
ii) has a dedicated therapy (OT/PT) service for at least 5 days per week.

Stroke Units do not need to provide hyper-acute care to be involved, but must admit patients within 5 days of stroke onset. We aim to recruit 6-8 Stroke Units to the trial.

4.4.2 Consent for Clusters

Written informed consent will be obtained by the cluster guardian (senior clinician) at each site.

The cluster guardian is consenting for the *Stroke Unit* to take part in the trial, and to be randomised to either ILA or standard care. Within clusters, individual patients who meet the eligibility criteria will be approached, and will be invited to take part in the trial, for which they will provide informed consent (see 4.5.2).

4.4.3 Randomisation

The unit of randomisation (cluster) is the Stroke Unit. The trial statistician (SE) will use an online randomisation system to allocate sites to control or intervention.

4.5 Recruitment of Individual Participants

4.5.1 Eligibility Criteria for Participants

Inclusion criteria

- Clinical diagnosis of stroke; presenting with hemiplegia
- Within 14 days of stroke onset
- Medically stable
- Able to
    - tolerate daily therapy for a minimum of 30 minutes per session
    - sit for more than 5 seconds without support
    - understand and follow 1 stage commands

Exclusion criteria

- Previous stroke with residual impairments
- Other neurological diagnosis (e.g. PD, MS)
- Clinically relevant pre-morbid disability levels

4.5.2 Consent for Patient Participants

Individual participant informed consent will be taken for participation in the trial. Participants are consenting to receive their rehabilitation using the assigned approach (ILA or standard care), and for collection of data, and completion of additional assessments.

The Easy Read version of the PIS will be used to facilitate a conversation with any potential participant who finds the format of the standard PIS difficult to follow/digest. It is intended as a conversation support tool, to ensure that information about the trial is available in an accessible format for all patients, but particularly those with an impairment of communication or cognition.

All new stroke admissions will be screened for eligibility within 72 hours of admission. Those that meet the criteria will be provided with verbal and written information, which they will be given 24 hours to consider. Those willing to participate will be asked to sign a consent form.

There may be individuals who do not meet the inclusion criteria at the beginning of their Stroke Unit stay, but regain enough function to meet the criteria at a later date. We will continue to monitor potential participants, and will recruit up to 14 days post stroke, if eligibility changes.

The process of recruitment and consent will be led by the research practitioner(s) at each site. Recruitment will take place across an approximate period of four-months at each Unit.

4.5.3 Consent for Participants Deemed to Lack Capacity

Following stroke, is it likely that a proportion of potential participants will be unable to independently make a decision about taking part in the trial (i.e. lack capacity), but otherwise meet the inclusion criteria. This is particularly relevant in the early phase following stroke, where capacity may be borderline or fluctuating, but the person is otherwise engaging in their rehabilitation. For example, an individual may be able to understand the general nature of the research and what participation would involve, but may not fully understand that their data will be used for a research study.

To maintain relevance and ensure generalisability of the findings, it is important to be as inclusive as possible when inviting people to take part. The trial will therefore include participants who do not have capacity to consent to participation. This is deemed appropriate given that:

- Risks associated with the study intervention are negligible
- The trial is not testing a new or novel approach to delivering physiotherapy, but is separating out and comparing approaches that are already in routine use.

4.5.3.1 Process of Assessing Capacity

Potential participants will initially be approached about the trial by a member of the direct clinical team, or a Research Practitioner. If the clinician/research practitioner expresses doubt about the person's ability to provide informed consent for the study, they will notify the Principal Investigator. A capacity assessment will only be completed if the individual meets the criteria, as laid out in the Mental Capacity Act.

The capacity assessment will be completed by the PI at the study site, or a member of the clinical/research team to whom they have delegated responsibility (such as a Research Practitioner or Consultant Physician). The person to whom responsibility had been delegated must have up to date GCP training and have a detailed understanding of the trial protocol. They will be listed on the Delegation Log.

Where appropriate, the person completing the capacity assessment may request assistance from a member of the clinical team, such as a Speech and Language Therapist (SLT) or Psychologist, to aid with the assessment. SLT will provide particular expertise to ensure that people with a language impairment as a result of their stroke are given appropriate and individualised support to understand the information that is presented to them, and to communicate their thoughts and wishes. The Easy Read version of the PIS will be used to support this process.

Irrespective of whether or not someone has capacity, the views expressed by the person will be given precedence when deciding whether or not to proceed. In people who are deemed to lack capacity, any views that are expressed through the facilitated conversation will be given priority when deciding whether or not to pursue a consultee declaration. For example, if the patient expresses anxiety about any part of this process, such as being video recorded, then we will not proceed with seeking a consultee declaration. We will not enrol anyone in the trial who communicates that they do not wish to participate in any aspect of the study.

The capacity assessment will be documented in the patient's medical notes.

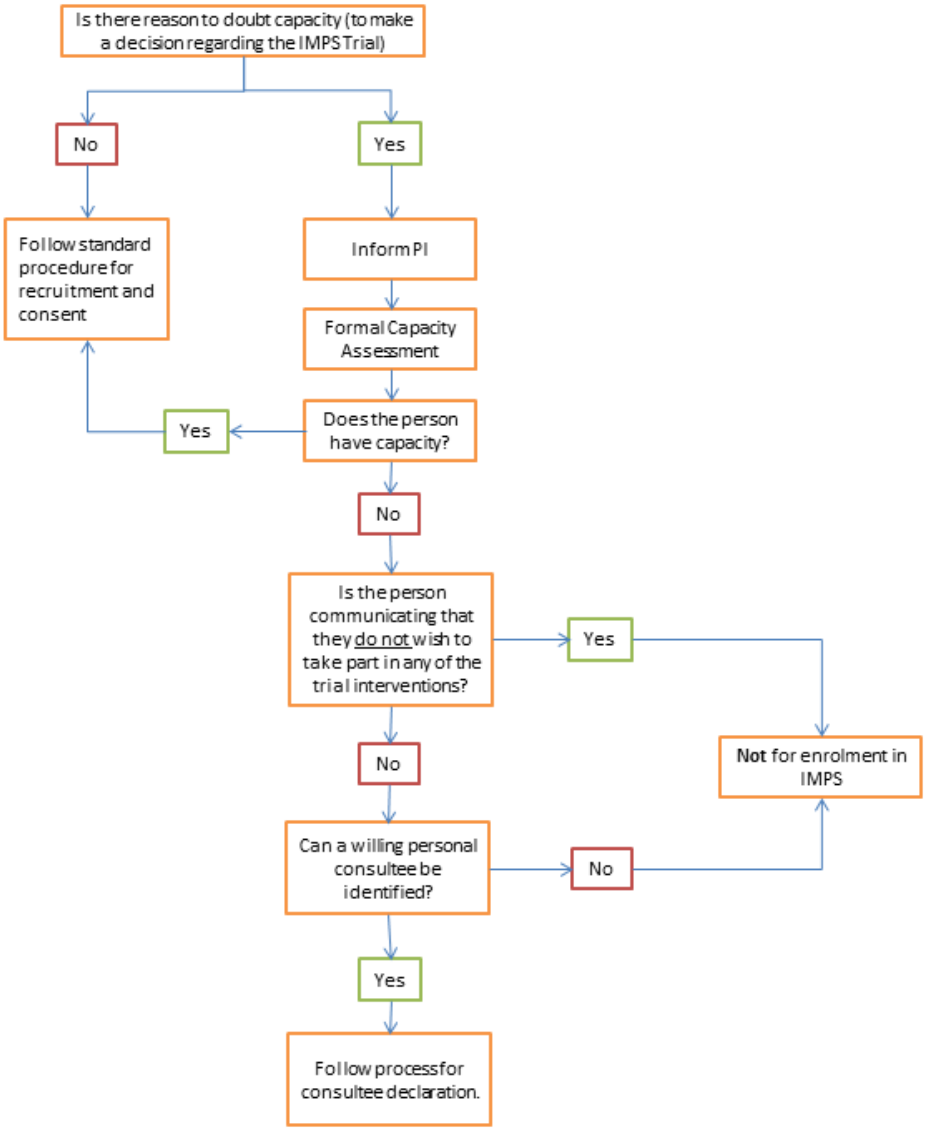


Figure 1: Recruitment Process for Individuals Lacking Capacity

4.5.3.2 Process for Gaining a Consultee Declaration

If a potential participant is deemed unable to consent to the study (i.e. they lack capacity), then a personal consultee (usually the next of kin) will be asked to consider whether they would be willing to provide consent on their behalf, based on the presumed wishes of the potential participant.

The full version of the Participant Information Sheet will be shared with the identified consultee, along with the Easy Read PIS. If they are willing to do so, they will be asked to sign the consultee declaration form, on behalf of their relative/friend.

In the event that a personal consultee cannot be found for someone who is deemed to lack capacity, a professional consultee would not be used. In these circumstances, the person lacking capacity would not be able to participate in the study.

At all times, the wishes of the participant will be upheld. For example, they will not be video recorded if they express that they do not wish for this to happen.

4.5.3.3 Process if a participant regains capacity during the study

It is feasible that a participant who did not have capacity to provide informed consent at the beginning of the study, regains the ability to do so at some point during the study. The therapists who are delivering the treatment interventions, as well as the research team, will be briefed with regards to this. They will be asked to inform the Research Practitioner and local PI if they feel that a participant's ability to consent has changed. This will then be reassessed. If, at this point, the person is deemed to have capacity to make a decision regarding participation in the research, they will be provided with the study information and will be supported to make this decision. If they opt to withdraw from the study, they can do so, without consequence. Data collected up to this point will be included in the final analysis, unless the individual explicitly asks for it not to be.

Therefore, the Consultee Declaration only applies for as long as the participant lacks capacity. Stroke teams manage issues relating to capacity on a frequent basis, and are therefore typically very aware of the principles of the Mental Capacity Act, capacity assessments and informed consent.

4.5.3.4 Process if a participant loses capacity during the study

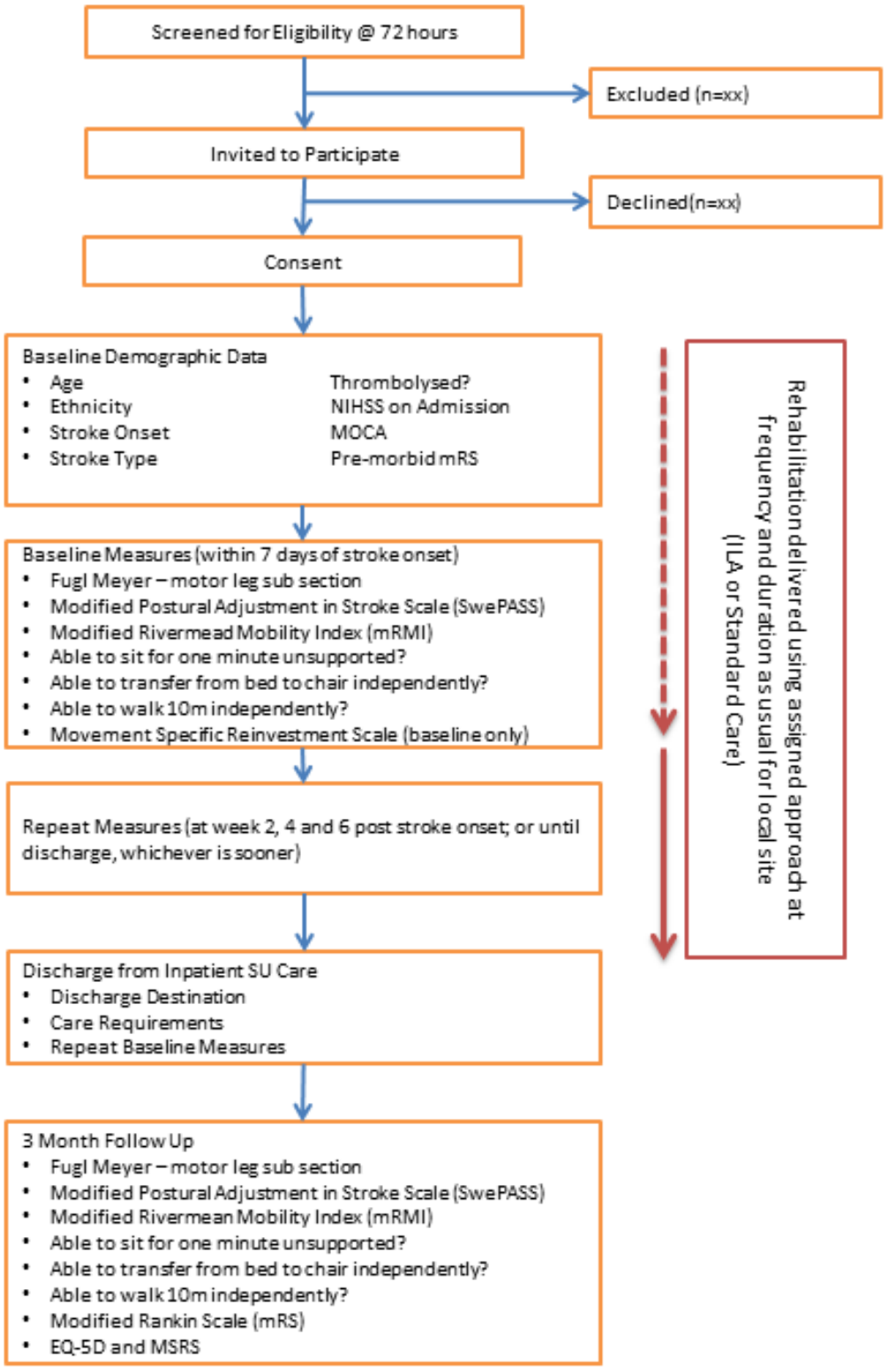
Although unlikely, a participant who gave informed consent at the point of recruitment, may lose capacity during the course of the research. It is likely that any loss of capacity at this stage reflects medical instability - such as a further stroke, or an infection.

The study will adhere to the principles, as laid out and defined in the Mental Capacity Act (2005). At the time of the person consenting to the trial, they have expressed a wish to participate. Therefore, the person will remain in the study, as long as it is appropriate clinically, and there is no observable or communicated evidence that they do not wish to continue.

If the individual is communicating that they do not wish to continue in the trial, or are demonstrating an unwillingness to participate in any of the trial interventions (e.g. assessments, video recording, or therapy treatment sessions), then they will be withdrawn

The most likely cause of loss of capacity is a further stroke, or another medical event. In these circumstances, then (irrespective of capacity) the person will not be clinically appropriate to remain in the trial, and will be withdrawn.

4.6 Trial Flowchart



4.7 Intervention

All mobility focussed rehabilitation sessions will utilise the ILA, as usual care. This includes rehabilitation (delivered by a physiotherapist, occupational therapist or therapy assistant) that focusses on sitting, sit to stand, standing, stepping, transfers and walking. The content of therapy will be based on the treatment guidelines and intervention manual, which have been developed by an international expert group (using Delhi methodology). As this is a clinically grounded, pragmatic trial, therapists will have freedom to tailor the specific content of each treatment session to patient need, whilst remaining true to the ILA. Other therapy interventions, such as upper limb rehabilitation, will be provided as usual. Whilst the content of this additional therapy will not be monitored, the quantity of other therapy, outside of the trial interventions, will be recorded and compared between groups. Frequency of treatment will be based on the usual practice of the treating hospital. The actual number of sessions received by each participant will be recorded.

Specific details relating to the IMPS intervention will be shared with intervention sites, once randomisation has taken place. Standard care sites will continue to delivery rehabilitation as normal, but will be asked to recruit eligible patients for data collection. An overview is given in table 1.

	Control Group Standard Care*	**Experimental Group** Implicit Learning Approach
Quantity and Frequency of Coaching Statements (Instructions and Feedback)	**HIGH** • Instructions given at the beginning and throughout the task (i.e during practice) • Feedback given during task practice – at least once for every 5 repetitions of any given task	**LOW** • Instructions only given at the beginning of task practice • Feedback or further instruction avoided throughout task practice
Focus of Attention	**INTERNAL** Direct attention to the action itself. Use the term "focus on [a reference within the body]". Example: *"Bend your knee and lift your foot onto the block. Focus on moving your leg"*	**EXTERNAL** Direct attention to the effects of the action. Use the term "focus on [a reference in the environment]" Example: "Step onto the marker on the block. Focus on the marker"
Task Set Up	Activity and environment set up to facilitate a focus on the person – i.e. without using external reference points/feedback.	Activity and environment set up to facilitate a focus on the environment – through use of external reference points, markers, audio feedback.

* Guidance for standard care is based on published observational studies describing usual practice in stroke rehabilitation [1, 10, 11].

Table 1: Overview of Intervention

4.8 Control

Standard care, as per usual working practice for the stroke unit. Control stroke units will have minimal contact with the research team, other than for data collection. They will be aware of the broad aims of the study, but not the specific detail of the intervention.

4.9 Duration of Treatment

Patients will be recruited as soon as eligible, and up to 14 days of stroke onset. Trial interventions will be delivered for the duration of each participant's inpatient stay, as deemed appropriate by the treating team. This approach is pragmatic and will ensure that the intervention can be fitted into the current care pathway, but accepting that discharge will be at different times for different patients.

4.10 Training for Intervention Sites

For sites randomised to the intervention arm, all physiotherapists, occupational therapists and therapy assistants will be trained in the ILA. Training is anticipated to last no more than 3 hours. Additional training sessions will be offered if new members join the team during the recruitment phase. A manual including written, photographic and video resources will demonstrate how to adapt standard care interventions to the ILA. Therapists will be able to refer to the manual throughout their involvement in the study.

Whilst the wider multidisciplinary team (e.g. nurses, doctors, other AHP's) will not specifically be asked to change their approach with patients, those at intervention sites will be invited to attend a short education session to raise their awareness of the trial, and will be provided with written information about the study, and the concepts under investigation. As these professions wouldn't typically be analysing movement or giving specific instructions/feedback, this level of engagement is deemed appropriate and realistic.

The therapy team will be encouraged to give the MDT (particularly nurses) specific guidance about how to instruct an individual patient during movement (as part of a manual handling care plan, and in line with the ILA approach). These awareness raising sessions will support the MDT to understand and follow through these instructions.

As part of the training, clinical staff will be reminded of the options to withdraw participants from the study, should there be concerns about the impact the ILA has on their recovery (see 7.1.1).

4.11 Bias Protection

Outcome assessors will be blind as to the intervention group. Video recording of outcome measures will be used to achieve this. Participants will be blind as to whether their Stroke Unit is providing control or intervention. Whether or not participants have guessed their treatment arm will be explored in the qualitative interviews.

4.12 Measures

Measures will be performed and recorded by the stroke research practitioner(s), or designated clinician, at each site. As the research practitioner will not be blind to the intervention arm, all measures will be video recorded, and later scored by a blinded second assessor. Frequent measures are required to understand *rate* of change. Outcome measures have been selected with consideration of international recommendations for measurement of sensorimotor recovery in stroke [12].

At baseline:

- Movement Specific Reinvestment Scale (Self-Report Questionnaire) (MSRS)

At baseline, week 2, week 4, week 6 post enrolment (or up to the point of discharge):

- Fugl Meyer – motor leg sub section
- Modified Postural Adjustment in Stroke Scale (SwePASS)
- Modified Rivermead Mobility Index (mRMI)
- Able to sit for 1 minute unsupported?
- Able to transfer from bed to chair independently?
- Able to walk 10m independently?

At point of discharge

- Discharge destination and care requirements immediately on discharge (number of care visits per day multiplied by the number of carers required)
- Fugl Meyer – motor leg sub section
- Modified Postural Adjustment in Stroke Scale (SwePASS)
- Modified Rivermead Mobility Index (mRMI)
- Able to sit for 1 minute unsupported?
- Able to transfer from bed to chair independently?
- Able to walk 10m independently?
- Movement Specific Reinvestment Scale (MSRS)

At 3 months post enrolment:

- Fugl Meyer – motor leg sub section
- Modified Postural Adjustment in Stroke Scale (SwePASS)
- Modified Rivermead Mobility Index (mRMI)
- Able to sit for 1 minute unsupported?
- Able to transfer from bed to chair independently?
- Able to walk 10m independently?
- Modified Rankin Scale (mRS)
- EQ-5D
- Movement Specific Reinvestment Scale (MSRS)

4.13 Proposed Sample Size

Our sample size calculation is based on estimated rates of recruitment and retention. We are aiming to recruit 60 participants in total, across the 6-8 clusters. Each cluster will therefore be required to recruit 7-10 participants.

4.14 Criteria for Premature Withdrawal

If there is a significant deterioration in a participants clinical signs (for example, if they have a further neurological event), then they will be withdrawn from the study. Reasons for withdrawal will be recorded.

4.15 Monitoring Fidelity (Feasibility)

All trial treatment sessions will be video recorded and a random sample (1 in 6) will be selected by the PI for analysis. A small and unobtrusive video camera will be used to do this. To avoid observer bias, the treating therapists will be asked to set up the video camera for each session. The sample will be analysed using a previously validated method, and will be compared for coherence with the written records of the treatment session.

4.16 Analysis

Data will be stored and managed using SPSS. Statistical support will be provided by the University of Southampton. Double data entry will be used for paper-based assessments.

The unit of analysis is the individual patient. As this is a pilot study, analysis will primarily be descriptive. Descriptive methods will be used to estimate feasibility 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 4 weeks).

Fidelity of the interventions will be established by comparing the number and type of coaching statements delivered to each group. We will describe the mean number of coaching statements per person (and the breakdown of these statements as externally- or internally-focussed) in each group. While we expect large differences, we will not formally test the difference as the study is not designed to do so; we will instead provide an estimate of the difference with corresponding 95% confidence interval. Differences in outcome and potential effect size for the Fugl Meyer, SwePASS and mRMI will be calculated using confidence interval estimation.

5 Process Evaluation

To enable us to understand patient and therapist perceptions and experiences of the ILA, will we be inviting a sub-set of participants to take part in a qualitative evaluation of the ILA.

5.1 Patient Interviews

We will invite 20 participants (10 from the intervention arm and 10 from the control arm) to take part in a semi-structured interview. These will be carried out within 1 week of the final treatment session to ensure that the intervention is recent enough for the patient to recall.

Interviews will be conducted by the Principal Investigator (PI). They will focus on patients' experiences of therapy and their perceptions of the benefits and disadvantages of the therapeutic style received. They will take place whilst the patient is in hospital or following their return home, will last for around 45 minutes, and will be audio recorded. Where necessary to comply with COVID-19 restrictions, interviews will be conducted remotely, over the telephone or via video call.

We will use maximum variation sampling to identify the sample, to include those with differing stroke severities (including differing levels of language and cognitive impairments), ages, gender and family/care situations.

Separate informed consent will be sought for the interview; participation in the clinical trial will not be dependent on participation in this qualitative evaluation. Participants from 4 of the clusters will be included.

5.1.1 Consent Process for Interviews that are conducted remotely

Where the patient remains an inpatient, the interviewer will liaise with the patient via the clinical team, to agree a mutually convenient date, time and method (phone or video call) for the interview.

Where the patient has returned home, the clinical team will pass the patients name and contact details to the researcher, after seeking permission from the patient to do so. The researcher will then contact the patient to explain more about the interview, and to agree a mutually convenient date, time and method (phone or video call) for the interview.

On the day of the interview, consent will be sought verbally. After discussing details of the purpose and nature of the interview, the researcher will inform the participating that the call is being audio recorded, and will then read each statement on the consent form, which they will seek verbal consent for. The researcher will then sign the form, and two copies will be sent to the participant via post. They will be asked to sign and return one copy in a pre-paid envelope. Audio recording will capture the verbal consent process.

5.2 Therapist Discussion Groups

Four discussion groups, (one at each *intervention* site), involving therapists who took part in the study, will take place at the end of the trial, after all treatment sessions have been delivered. All therapists and therapy assistants who are involved in delivering the ILA will be invited to take part. The insights gained from the discussion groups will give us a more valid understanding of the potential application of the Implicit Learning Approach in clinical practice.

6 Ethical Issues

6.1 Cluster Randomised Design

The cluster randomised design presents its own unique ethical issues. Rather than individual patients providing consent prior to randomisation, whole Stroke Units (clusters) will be randomised to either the Implicit Learning Approach or control. Consent to participate in the study and be randomised will be given at Stroke Unit level, by a cluster guardian.

Individual patients who meet the inclusion criteria, will be asked to give consent to take part in the trial, to have their data included in the study, and to complete additional measures.

For units randomised to the ILA, therapy teams will be asked to adopt the ILA for participants who have agreed to take part in the trial. For all other patients on that Unit, they will continue with standard care. However, because the therapists will have been trained in the ILA, and will be using it with trial participants, there is the possibility that elements of the ILA drift into the rehabilitation of non-trial patients. Given that implicit learning approaches are used in standard practice already, it is acceptable that therapists may adopt elements of the ILA for non-trial patients. This is entirely within their own professional autonomy and clinical judgement.

This cluster randomised approach has been chosen to ensure fidelity of the intervention, and therefore to ensure that the study is most likely to provide useful insights and data - this in itself is ethically important. From an ethical point of view, this design is justifiable because:

- Current therapy practice includes both implicit and explicit behaviours. These are not therefore novel or experimental concepts. This research is delineating two approaches already in use, to answer important questions about the effectiveness of each.
- There are no significant risks to those individuals who will receive the ILA.
- Only patients who provide consent to take part will receive the full ILA.

No Unit will use the ILA wholly as its approach, and therefore there is still a risk that fidelity isn't maximised for the trial participants. This is an accepted limitation at this stage – it will be closely monitored in the study, and is one of the key feasibility questions.

7 Monitoring

7.1 Assessment of Safety

7.1.1 Expected ILA Adverse Events

Although unlikely, there is a possibility that the ILA is perceived as less personal/motivating for patients, and this may be associated with a reduced willingness to participate in therapy. We will monitor adherence with rehabilitation across all sites. Non-compliance will be considered an AE if (i) a patient is declining to participate in rehabilitation sessions over a period of 5 days and (ii) the clinical team are unable to account for this in any other way. This will be addressed on an individual basis through discussion with the patient and the clinical team. If indicated, they will be withdrawn from the study.

If the treating team have any concerns about using the ILA with an individual patient, for example, should they feel that a patient is not responding /recovering as expected, they should discuss this with the Chief Investigator. If indicated, the participant will be withdrawn from the study, and their rehabilitation will revert to standard care. This decision will be taken on an individual basis, following discussion with the clinical team, Chief Investigator and (if appropriate) the participant. Withdrawal due to unanticipated/unexplained lack of progress in rehabilitation will be considered an AE.

It is important to note that, whilst therapists at the intervention sites are encouraged to adhere as much as possible to the ILA guidance, this is a pragmatic trial, and they can use their own clinical judgement during each individual treatment session. This is monitored as part of the feasibility aspect of this trial.

7.1.2 Stroke Related Expected Adverse Events

In addition to the above, the following AE's have been deemed as potentially relevant to the study. They will therefore be recorded if they occur during the study, and will be monitored throughout the study as deemed appropriate by the PI/CI:

- Death
- Falls
- Further vascular events
- Cardiac events
- Epileptic seizures
- Infections
- Pain
- Mood disturbance
- Deep Vein Thrombosis

If any of these adverse events occur then they will be recorded in the CRF and followed up until either resolution (if appropriate); the end of the study period for that participant, or until the PI deems the AE as stable, whichever is sooner.

All adverse events listed in section 7.1.2 will be recorded from the date of consent, to the end of the trial intervention period (i.e. discharge from hospital).

7.1.3 Serious Adverse Event Reporting

For this study (and in accordance with HRA guidance), a serious adverse event (SAE) is defined as an untoward occurrence that:

(a) results in death

(b) is life-threatening

(c) requires hospitalisation or prolongation of existing hospitalisation

(d) results in persistent or significant disability or incapacity

(e) consists of a congenital anomaly or birth defect;

(f) is otherwise considered medically significant by the investigator.

Serious Adverse Events will be recorded in the medical notes and in the CRF. If the event is deemed to be related to the intervention, the SAE will be submitted to the Sponsor immediately. The Sponsor or CI will inform the Research Ethics Committee within 15 days of the CI becoming aware of the event. The acknowledgement of the receipt of the SAE will be sent to the RBCH R&D directorate. SAEs which are not related to the intervention will be recorded as other AEs.

For this study there are no expected adverse events.

7.2 Trial Steering Committee (TSC)

A trial steering committee will oversee the delivery of the study. The committee will meet at least 6 monthly. The TSC will include a patient partner, statistician, research expert(s) and clinical expert(s).

7.3 Ethics and Regulatory Approvals

The study will undergo full REC Approval, as well as local R&D review/approval.

8 Data Handling

8.1 Confidentiality

Patient confidentiality will be ensured by allocation of a unique identification number (ID). All data that links patient personal information with the ID will be kept in a separate locked filing cabinet. Institutional guidelines for Research Governance procedures for good clinical practice in research will be followed.

Video recordings will be transferred onto an encrypted memory card, which will be handed to the PI in person. They will then be uploaded onto the secure NHS server, in a password protected file.

Audiotapes from interviews and focus groups will be transcribed verbatim. Transcripts will be anonymous. Once data analysis is complete, original audio recordings will be deleted.

All records will be anonymised, and will be kept for a minimum of 10 years after the end of the trial, after which they will be destroyed.

9 Finance

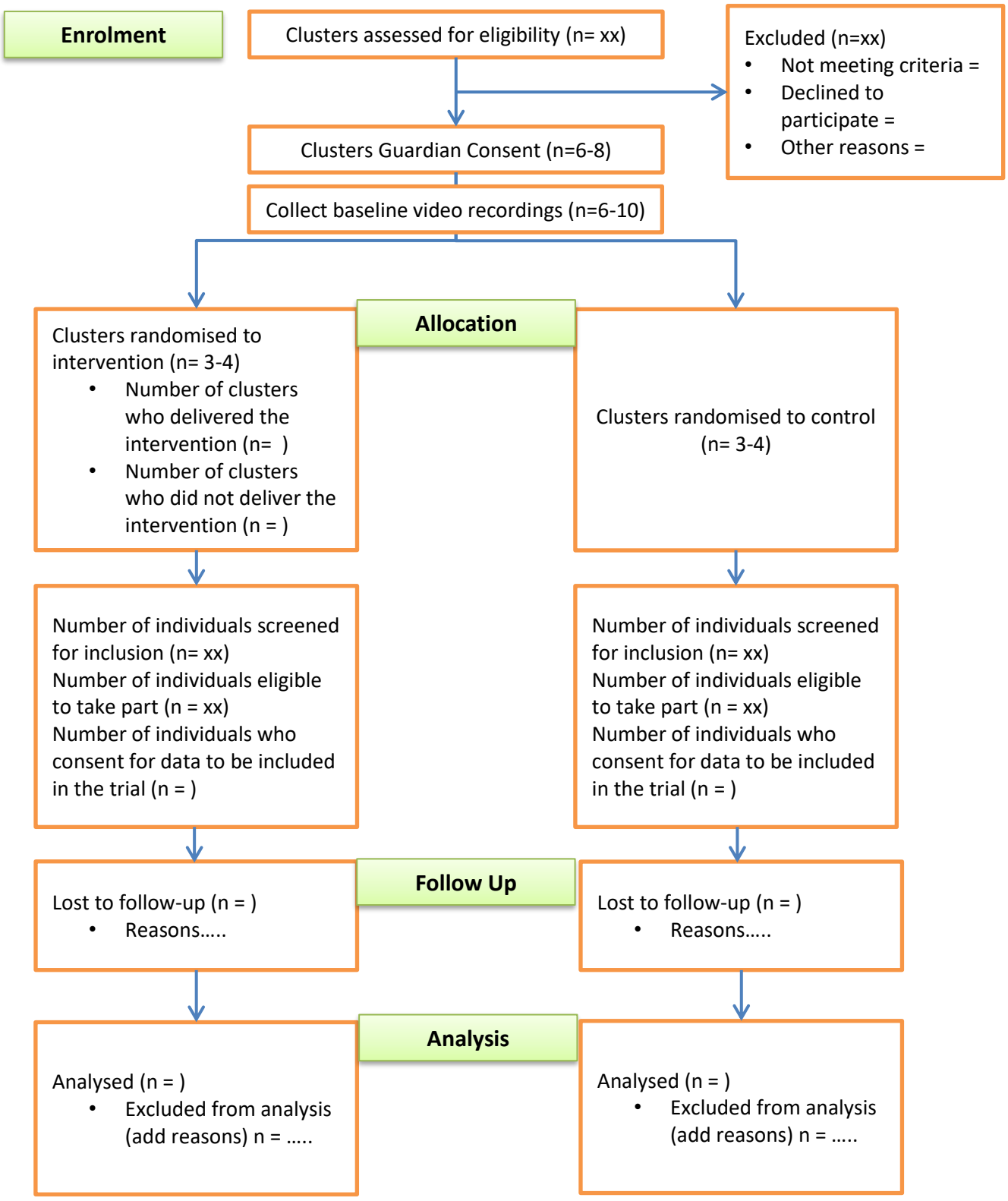
This trial is funded by the National Institute of Health Research, through a Clinical Lectureship, awarded to the Chief Investigator. The funding will be managed by Royal Bournemouth and Christchurch NHS Foundation Trust.

10 Dissemination

Findings from this research study will be shared through open access publication, conference presentations and local training sessions. All participants will be offered the opportunity to receive a summary of the research findings.

All data will be anonymised prior to publication. The support of the funding body will be acknowledged as follows: *this research was funded by the National Institute of Health Research (NIHR), UK. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health.*

Appendix 1: Consort Diagram



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12 Appendices

12.1 SwePASS

The modified version of PASS - SwePASS

Item	Scale	Item	Scale
1. Supine to affected side lateral		**7. Standing without support**	
Cannot perform the activity	0	Cannot stand without support	0
Can perform the activity with support from 2 persons	1	Can stand without support for 10 s or leans heavily on 1 leg	1
Can perform the activity with support from 1 person	2	Can stand without support for 1 minute or stands slightly asymmetrically	2
Can perform the activity without any help	3	Can stand symmetrically without support for more than 1 minute and at the same time draw hand/s from forehead to neck (like pulling your fingers through your hair) alternating with arm/s hanging parallel to the trunk to avoid tiredness	3
2. Supine to non-affected side lateral		**8. Standing on non-affected leg**	
Cannot perform the activity	0	Cannot stand on the non-paretic leg	0
Can perform the activity with support from 2 persons	1	Can stand on the non-paretic leg up to 5 seconds	1
Can perform the activity with support from 1 person	2	Can stand on the non-paretic leg for more than 5 seconds	2
Can perform the activity without any help	3	Can stand on the non-paretic leg for more than 10 seconds	3
3. Supine to sitting up on edge of bed towards the non-affected side		**9. Standing on affected leg**	
Cannot perform the activity	0	Cannot stand on the paretic leg	0
Can perform the activity with support from 2 persons	1	Can stand on the paretic leg up to 5 seconds	1
Can perform the activity with support from 1 person	2	Can stand on the paretic leg for more than 5 seconds	2
Can perform the activity without any help	3	Can stand on the paretic leg for more than 10 seconds	3
4. Bedside sitting with feet supported on the floor and hands in the lap		**10. Standing, picking up a shoe from the floor**	
Cannot sit	0	Cannot perform the activity	0
Can sit with slight support, for example with the help of their own hand	1	Can perform the activity with support from 2 persons	1
Can sit for more than 10 s without support	2	Can perform the activity with support from 1 person	2
Can sit for 5 min without support	3	Can perform the activity without any help	3
5. Sitting to standing up		**11. Sitting down from standing up**	
Cannot perform the activity	0	Cannot perform the activity	0
Can perform the activity with support from 2 persons	1	Can perform the activity with support from 2 persons	1
Can perform the activity with support from 1 person	2	Can perform the activity with support from 1 person	2
Can perform the activity without any help	3	Can perform the activity without any help	3
6. Standing with support		**12. Sitting on edge of bed to supine**	
Cannot stand, even with support	0	Cannot perform the activity	0
Can stand with support from 2 persons	1	Can perform the activity with support from 2 persons	1
Can stand with support from 1 person	2	Can perform the activity with support from 1 person	2
Can stand with only slightly support of 1 hand	3	Can perform the activity without any help	3

Corrected version 2013-11-29.
Equipment: a stopwatch and a shoe/slipper.
The test is performed with the patient barefoot. Only one attempt per item is allowed. Ensure that the patient meets the criteria for the scores below, as well as the criterion for the registered score. A stopwatch is used in items 4 and 7-9, where the patient should maintain a position within a specific time. In items 1-3, 5-6 and 10-12, the patient´s postural balance/control should be scored according to different degrees of support (verbal, tactile or supervision). The SwePASS, developed by Carina U Persson, Maria Edvinsson, Katharina Stibrant Sunnerhagen and Ulla Svantesson, published in *J Rehab Med* 2011; 43:348-53, is a synthesis of the original French version and the published English version of the Postural Assessment Scale for Stroke Patients by Benaim C, Pérennou DA, Villy J, Rousseaux M, Pelissier JP. *Stroke* 1999; 30: 1862-1868.
Correspondence address: Carina Persson, Institution of Neuroscience and Physiology, Rehabilitation Medicine, Sahlgrenska Academy, Gothenburg University, and Department of Physiotherapy, Sahlgrenska University Hospital/Östra, Gothenburg, Sweden carina.persson@vgregion.se

12.2 Modified Rivermead Mobility Index

The modified Rivermead Mobility Index

Patient's name: **Test date:**

Assessor's name: **Test location:**

Scoring:

0	unable to perform
1	assistance of 2 people
2	assistance of 1 person
3	requires supervision or verbal instruction
4	requires an aid or an appliance
5	independent

Item	Score
1. Turning over Please turn over from your back to your ..... side	....
2. Lying to sitting Please sit up on the side of the bed	....
3. Sitting balance Please sit on the edge of the bed (The assessor times the patient for 10 seconds)	....
4. Sitting to standing Please stand up from your chair (The patient takes less than 15 seconds)	....
5. Standing Please remain standing (The assessor times the patient for 10 seconds)	....
6. Transfers Please go from your bed to the chair and back again (The assessor places the chair on the patient's unaffected side)	....
7. Walking indoors Please walk for 10 meters in your usual way	....
8. Stairs Please climb up and down this flight of stairs in your usual way	....

12.3 Fugl Meyer – Motor Leg Sub-Section

FMA-LE PROTOCOL — Rehabilitation Medicine, University of Gothenburg

FUGL-MEYER ASSESSMENT
LOWER EXTREMITY (FMA-LE)
Assessment of sensorimotor function

ID:
Date:
Examiner:

Fugl-Meyer AR, Jaasko L, Leyman I, Olsson S, Steglind S: The post-stroke hemiplegic patient. 1. a method for evaluation of physical performance. Scand J Rehabil Med 1975, 7:13-31.

E. LOWER EXTREMITY					
I. Reflex activity, supine position			**none**	**can be elicited**	
Flexors: knee flexors			0	2	
Extensors: patellar, achilles (at least one)			0	2	
Subtotal I (max 4)					
II. Volitional movement within synergies supine position			**none**	**partial**	**full**
Flexor synergy: Maximal hip flexion (abduction/external rotation), maximal flexion in knee and ankle joint (palpate distal tendons to ensure active knee flexion).	Hip	flexion	0	1	2
	Knee	flexion	0	1	2
	Ankle	dorsiflexion	0	1	2
Extensor synergy: From flexor synergy to the hip extension/adduction, knee extension and ankle plantar flexion. Resistance is applied to ensure active movement, evaluate both movement and strength (compare with the unaffected side)	Hip	extension	0	1	2
		adduction	0	1	2
	Knee	extension	0	1	2
	Ankle	plantar flexion	0	1	2
Subtotal II (max 14)					
III. Volitional movement mixing synergies sitting position, knee 10cm from the edge of the chair/bed			**none**	**partial**	**full**
Knee flexion from actively or passively extended knee	no active motion less than 90° active flexion, palpate tendons of hamstrings more than 90° active flexion		0	1	2
Ankle dorsiflexion compare with unaffected side	no active motion limited dorsiflexion complete dorsiflexion		0	1	2
Subtotal III (max 4)					
IV. Volitional movement with little or no synergy standing position, hip at 0°			**none**	**partial**	**full**
Knee flexion to 90° hip at 0°, balance support is allowed	no active motion or immediate, simultaneous hip flexion less than 90° knee flexion and/or hip flexion during movement at least 90° knee flexion without simultaneous hip flexion		0	1	2
Ankle dorsiflexion compare with unaffected side	no active motion limited dorsiflexion complete dorsiflexion		0	1	2
Subtotal IV (max 4)					
V. Normal reflex activity supine position, assessed only if full score of 4 points is achieved in part IV, compare with the unaffected side			**0 (M), hyper**	**lively**	**normal**
Reflex activity knee flexors, Patellar, Achilles,	0 points on part IV or 2 of 3 reflexes markedly hyperactive 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive		0	1	2
Subtotal V (max 2)					
Total E (max 28)					

Approved by Fugl-Meyer AR 2010 — 1 — Updated 2015-03-11

12.4 Modified Rankin Score

MODIFIED RANKIN SCALE (MRS)

Patient Name: _____
Rater Name: _____
Date: _____

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

TOTAL (0–6): _____

References

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Van Swieten JC, Koudstaal PJ, Visser MC, Schouten HJ, van Gijn J. "Interobserver agreement for the assessment of handicap in stroke patients."
Stroke **1988;19(5):604-7**

Provided by the Internet Stroke Center — www.strokecenter.org

12.5 Movement Specific Reinvestment Scale

Movememet Specific Reinvestment Scale

Directions: Below are a number of statemetns about your movemets in general. Circle the answer that best describes how you feel for each question.

1. **I remember the times when my movements have failed me**

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

2. **If I see my reflection in a shop window, I will examine my movements**

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

3. **I reflect about my movement a lot**

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

4. I try to think about my movements when I carry them out

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

5. I am self conscious about the way I look when I am moving

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

6. I sometimes have the feeling that I am watching myself move

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

7. I am aware of the way my body works when I am carrying out a movement

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

8. I am concerned about my style of moving

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

9. I try to figure out why my actions failed

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

10. I am concerned about what people think about me when I am moving

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Weakly disagree	Weakly agree	Moderately agree	Strongly agree

If the participant was unable to complete the assessment, please give reason: