UNIVERSITY OF WINCHESTER

Protocol Document

Study title: Identifying vertical perception loss in people with acute stroke: A feasibility study.

Short title: Feasibility of measuring vertical perception in acute stroke.

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Sponsor/Funder: University of Winchester

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

Chief Investigator: Amelia Shaw

Signature: 

Date: 21st Oct 2023

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Documentation Amendment History

Document	Version No.	Date Issued	Author(s) of Changes	Details of Changes Made

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ii. List of Key Abbreviations

SVV: Subjective Visual Vertical

SCP: Scale for Contraversive Pushing

MRS: Modified Rankin Scale

NIHSS: National Institute for Health Stroke Scale

DC: Discharge

iii. Trial Summary

Study Title: Identifying vertical perception loss in people with acute stroke: A feasibility study.

Short Title: Feasibility of measuring vertical perception in acute stroke

Study Design: Cross sectional, feasibility study

Study Participants: Acute stroke patients in inpatient care

Planned Sample Size: As this is a feasibility study no planned sample size but up to 250 people could be screened for participation

Length of Participant Involvement: Equal to length of stay on the stroke unit

Planned Study Period: 01/03/24 – 31/8/24

Primary Objective: To establish the feasibility of completing the Catherine Bergego Scale, Scale for Contraversive Pushing (SCP) and bucket test in a clinical environment with acute stroke patients to assist with identification of vertical perception loss

Primary Outcome Measure:

The primary outcome is to understand the feasibility of completing the suite of outcome measures in an acute stroke setting:

- Proportion (%) of patients on whom the assessments are attempted.
- Percentage of patients who are able to complete all three assessments within four weeks of admission.
- Time taken to complete the three measures in an acute clinical setting
- A recommendation regarding the most feasible time point to complete these assessments.

Secondary Objectives:

To gain a further understanding of vertical perception loss in acute stroke patients.

Secondary Outcome Measures:

- An understanding of factors that prevent or facilitate completion of these three assessments
- An understanding of healthcare professionals' experiences of completing these assessments in an acute stroke unit.

- An understanding of whether people with stroke (or their advocates) find it appropriate to complete all three assessments in an acute stroke setting.
- Percentage of patients admitted to an acute stroke unit showing a positive test for vertical perception loss within four weeks of admission.
- To explore the relationship between vertical perception loss and:
    - Discharge destination
    - Care package size on discharge
    - Number of inpatient falls
    - Level of functional independence on discharge
- To explore if any elements of the Catherine Bergego Scale or Scale for Contraversive Pushing show a trend for a relationship to vertical perception loss

Primary Endpoint: Discharge from the stroke unit.

Intervention(s): Completion of three outcome measures as part of rehabilitation; Catherine Bergego Scale, Scale for Contraversive Pushing and Bucket Test

iv. Funding

Funder(s): There is no direct funding for this research

Financial support given: The University of Winchester pay all members of the supervisory team (Prof. James Faulkner, Dr Katherine Cook, and Dr Louise Johnson) for their time supervising Amelia Shaw throughout her PhD. They are not directly funding the research study itself.

Non-financial supporters: Royal Hampshire County Hospital are providing support by practitioners identifying potential patients, explaining the study to participants and obtaining written informed consent. The rehabilitation team on the stroke unit will also complete the outcome measures as part of routine therapy sessions.

v. Role of sponsor and funder

The members of the research team (Amelia Shaw, Prof James Faulkner, Dr Katherine Cook and Dr Louise Johnson) are responsible for the design and management of the research. The funder/non-financial supporters themselves have not had a direct impact in the design or management of the research, but members of the research team are employed by them.

vi. Protocol contributors

All members of the research team have contributed to the protocol.

People with stroke known to the supervisory team will be asked prior to the study beginning to provide feedback on a lay summary of the proposed protocol, participant information sheets and consent forms with any recommendations considered and the documents adjusted if necessary.

vii. Keywords

Vertical perception; Stroke; Rehabilitation; Neglect; Pushing behaviour; Subjective visual vertical.

1. Background and Rationale

It is known that some people with stroke present with loss of vertical perception (Dai et al., 2021b, Utz et al., 2011, Perennou et al., 2008, Karnath et al., 2000). It has been established that loss of vertical perception is related to an inability to actively align the body with respect to gravity following stroke (Dai et al., 2022). It is measured using subjective visual vertical (SVV) (Perennou et al., 2008), subjective haptic vertical (SHV) (Utz et al., 2011) or subjective postural vertical (SPV) (Karnath et al., 2000). Furthermore, it has been associated with neglect (a disorder of spatial awareness whereby people with stroke fail to attend to their contralesional space/body) (Gammeri et al., 2020, Utz et al., 2011, Funk et al., 2010), and pushing behaviour (in which the patient uses their nonparetic extremities to push themselves to their paretic side leading to a loss of balance) (Bergmann et al., 2016, Karnath and Broetz, 2003). There is much debate about the terminology used to describe pushing behaviour (Nolan et al., 2022, Dai and Pérennou, 2021). This debate has led to a lack of a consistent approach to research, measurement tools and effective interventions to address this problem (Dai and Pérennou, 2021). A recent recommendation has been made that lateropulsion should be used to describe all those people that present with a tilted posture following stroke (Nolan et al., 2022, Dai and Pérennou, 2021). It could be argued that lateropulsion describes a wider range of those with stroke who are unable to align to vertical whereas pushing describes those at the more severe end of this spectrum. This argument is compounded by the different scales and cut off points used to identify pushing in research studies (Paci et al., 2023). Recently, the magnitude of visual vertical loss has been found to be related to that of lateropulsion (Dai et al., 2021b). It has been established that people with stroke that present with neglect or lateropulsion require longer periods of rehabilitation and have a worse functional outcome (Nolan et al., 2021, Babyar et al., 2015, Funk et al., 2011). Lateropulsion has been identified as the primary factor in disordered gait and balance after stroke (Dai et al., 2021a). This contributes to greater disability for the individual, safety concerns during rehabilitation and in the community, increases the burden on family and caregivers (Gomes-Osman and Kloos, 2021) and contributes to an estimated societal cost of £26 billion per year in the UK (Patel et al., 2019).

Identification of vertical perception loss early after stroke may be important in allowing identification of:

- Those who will require longer periods of rehabilitation
- Those who are likely to present with lateropulsion/pushing or neglect
- Those who may require more care and support on discharge

- Those with milder vertical perception loss who may be at risk of falling (Dai et al., 2021a), but do not have neglect or lateropulsion
- Changes in vertical perception over time
- Changes in vertical perception in response to rehabilitation interventions
- Those who will and will not respond to rehabilitation interventions and hence support appropriate allocation of therapy resources.

Currently, the established methods of measuring subjective vertical perception (visual, haptic or postural) are not feasible in the acute stroke environment (Piscicelli and Pérennou, 2017, Perennou et al., 2008). The main reasons are the equipment required being unsuitable in a clinical environment and the burden on the person with stroke. There is evidence that it is possible to use the more basic 'bucket test' to identify those with subjective visual vertical loss in the acute setting (Chang et al., 2019, Zwergal et al., 2009). Participants in these studies had central and peripheral vestibular disorders so is not translatable to the acute stroke population. Furthermore, some people with stroke who present with vertical perception loss present with normal visual vertical but a tilt in postural vertical (Karnath et al., 2000). Therefore, assessment of visual vertical alone may not identify all of those with vertical perception difficulties. As discussed, above vertical perception loss has been related to lateropulsion and neglect. Hence, the measurement of SVV, lateropulsion and neglect, is likely to be required to identify most people with vertical perception loss in the acute stroke setting.

The aim of this research is to establish the feasibility of using this suite of known outcome measures to identify those with vertical perception loss following stroke in the acute setting. If the use of these outcome measures is found to be feasible it will be the basis of further research to design and propose a reliable and valid method for measuring vertical perception loss in an acute stroke setting.

The principal research question that this study will aim to address is:

To establish the feasibility of completing the Catherine Bergego Scale (neglect) (Azouvi et al., 1996), Scale for Contraversive Pushing (SCP) (Karnath et al., 2002) and bucket test (SVV) (Zwergal et al., 2009) in a clinical environment with acute stroke patients to assist with identification of vertical perception loss.

The secondary research questions that this study will aim to address are:

- What percentage of patients admitted to an acute stroke unit show a positive test for vertical perception loss within four weeks of admission (evidence of subjective visual vertical (SVV) tilt on either bucket test or Catherine Bergego Scale or evidence of subjective postural vertical (SPV) tilt on SCP)
- For those able to complete the assessments, does vertical perception loss show any relationship with:
    - Discharge (DC) destination
    - Care package size on discharge
    - Number of inpatient falls
    - Level of functional independence on discharge
- Is there a trend for any element of the SCP or the Catherine Bergego to be more correlated with SVV tilt.

2. Objectives and outcome measures.

Primary objective:

To establish the feasibility of completing the Catherine Bergego Scale, the Scale for Contraversive Pushing (SCP) and the bucket test in a clinical environment with acute stroke patients, to assist with identification of vertical perception loss.

Primary outcomes:

The primary outcome is to understand the feasibility of completing the suite of outcome measures in an acute stroke setting:

- Proportion (%) of patients on whom the assessments are attempted.
- Percentage of patients who are able to complete all three assessments within four weeks of admission.
- Time taken to complete the three measures in an acute clinical setting
- A recommendation regarding the most feasible time point to complete these assessments.

Secondary outputs:

The secondary aims are to gain a further understanding of vertical perception loss in acute stroke patients.

- An understanding of factors that prevent or facilitate completion of these three assessments
- An understanding of healthcare professionals' experiences of completing these assessments in an acute stroke unit.
- An understanding of whether people with stroke (or their advocates) find it appropriate to complete all three assessments in an acute stroke setting.
- Percentage of patients admitted to an acute stroke unit showing a positive test for vertical perception loss within four weeks of admission.
- To explore the relationship between vertical perception loss and:
    - Discharge destination
    - Care package size on discharge
    - Number of inpatient falls
    - Level of functional independence on discharge
- To explore if any elements of the Catherine Bergego Scale or Scale for Contraversive Pushing show a trend for a relationship to vertical perception loss

3. Trial Design

This is a mixed methods feasibility study with data collected using a cross sectional design, focus groups and surveys. As the nature of acceptability is subjective a qualitative element utilising a phenomenological approach (Nicholls, 2009) will be nested into the study. This will allow an exploration of the experiences of professionals in completing or undertaking the outcome measures via focus groups. People with stroke (or their advocates) acceptability will be explored using a survey, a pragmatic approach to reduce the burden on research participants. Hence, a convergent mixed methods approach will be used (Creswell and Creswell, 2018) to fully answer the research aim and questions.

4. Trial Setting

The population to be studied will be acute stroke patients admitted to a stroke unit. A non-probability, convenience sample will be used. All patients with a diagnosis of stroke admitted for 72 hours to a single stroke unit at Royal Hampshire County Hospital will be considered in the present study.

Calculation of the sample size for a feasibility study is challenging (Hooper, Unknown). Sample sizes of between 24 and 50 participants have been recommended to allow calculation of a sample size for

a full-scale study (Sim and Lewis, 2012, Lancaster et al., 2004, Browne, 1995). Therefore a pragmatic approach to calculating the sample size will be taken. All those admitted to the stroke unit over a six-month period will be eligible for inclusion, meaning approximately 250 people will be screened for participation.

5. Participant Eligibility Criteria

Inclusion and exclusion criteria:

INCLUSION	**EXCLUSION**
Diagnosis of first stroke by stroke consultant based on clinical or radiographical findings	Under the age of 18
Admitted to stroke unit with a length of stay of over 72 hours	Diagnosis of Transient Ischaemic Attack (TIA)
Ability to consent or an advocate to consent on their behalf	Previous diagnosis of stroke or other neurological diagnosis affecting the brain with residual impairment
Pre-morbid Modified Rankin Scale of less than 4	Patients on an end of life pathway
	Patients with pre-morbid visual impairment that will not allow them to see the bucket test. Glasses can be worn.
	Inability to speak the English language and no interpreter can be found

6. Trial Procedures

Recruitment

All patients admitted to an acute stroke unit, who meet the inclusion criteria, may be invited to participate. Potential participants will be identified during the daily handover by members of the clinical or research team. Those meeting the inclusion criteria will be approached by a member of the research or clinical team and invited to participate. This will take place between 48 hours and one week after admission. Potential participants will be provided with the participant information sheet (PIS) regarding this study. If the patient is unable to consent due to cognitive or language impairment or low level of consciousness then their advocate will be approached. Where possible potential participants will be supported to consent using information in different formats (e.g.

through use of pictures) or the skill of appropriate members of the clinical team (e.g. speech and language therapists).

The number of people admitted to hospital with stroke who have language or cognitive impairments that may prevent them being able to consent is substantial. To exclude these potential participants would significantly impact the validity and generalisability of the results. Especially as those with significant strokes are more likely to present with vertical perception loss as well as cognitive and language impairment. If they were excluded a large number of patients with vertical perception loss may not be identified. These groups are often underrepresented in stroke research. If someone is unable to consent an advocate will be approached to consent on their behalf.

Those taking consent will decide on capacity. This includes the chief investigator and the stroke research nurse. Both have significant experience working with people with stroke. Both have undergone Good Clinical Practice training and Mental Capacity Act Training. If in any doubt about capacity other members of the healthcare team (e.g., Speech and Language Therapists) can give advice as to whether the potential participant has capacity or whether their advocate should be approached.

Participants will only be enrolled in the research if an advocate can be found to consent on their behalf. If someone lacks capacity and does not have an advocate they will be ineligible for inclusion in the research. Advocates will be identified through the medical records of the potential participant and will usually be their next of kin or other named contact. They will only be able to consent once they have read a PIS and had time to ask questions of the research team.

On reading the PIS if the patient or their advocate is willing to participate then they will be asked to sign a consent form, by the research team or chief investigator. Potential participants will have a minimum of 12 hours to read the PIS.

If a participant who lacked capacity, and was consented by an advocate, regains capacity then their informed consent to continue will be sought.

Study protocol

For those patients who consent, the qualified physiotherapists or occupational therapists on the stroke unit, will then attempt to complete all 3 outcome measures with the patient (see assessors and outcome measures below). If the patient is unable to complete any elements of the outcome measure for any reason, this will be recorded. If the patient is unable to complete the outcome measures, then an attempt will be made to complete the outcome measures at 1 week post

admission, if still unable they will be attempted again at 2 weeks and 4 weeks post admission. At the point participants complete all 3 outcome measures or at 4 weeks (whichever is earliest) most will have no further active participation in the quantitative part of the study. The assessments do not need to all be completed in one sitting and can be spread across sessions. If a patient is unable to be consented at 48 hours they will be consented as soon after this point as possible up to one week after admission, and this will be recorded. If patients are discharged or have a change in status following consenting to participate but prior to completion of the outcome measures any data collected to date will be utilised in the study results and the reasons for non-completion of the outcome measures will be noted as this will inform the feasibility of these outcome measures. The length of time taken to complete the measures will be recorded by the administrator. The expectation is that administration of all three outcome measures will take no longer than one hour. Due to the observational nature of the SCP and Catherine Bergego Scale elements of these can be completed during therapy sessions. The results and implications of the results of the outcome measures will be discussed with the patient or their advocate should they wish. The impact of the results on the therapists will be explored in a focus group.

At the point the participants are discharged from the stroke unit (this could include but not be restricted to: transfer to another rehabilitation facility, to undergo further neurological observation or intervention, discharge home, to undergo further unrelated medical interventions) their notes will be accessed and the following data extracted:

- Demographic details (age, gender)
- Type and location of stroke
- NIHSS on admission
- Number of in-patient falls
- Discharge (DC) destination
- Level of care required on DC – either care home or size of care package
- Functional ability on DC using the Modified Rankin Scale (MRS) (van Swieten et al., 1988) and the Barthel Index (Mahoney and Barthel, 1965) as these are routinely collected for all patients
- Amount of physiotherapy and occupational therapy received during inpatient stay as submitted to the Sentinel Stroke National Audit Programme (SSNAP). This includes minutes of therapy received per session of therapy, number of sessions of therapy per day and number of days on which therapy was received

At the time of discharge a small sub-selection of the study participants will have the outcome measures reassessed. Participants will be identified as having a mild, moderate or severe vertical perception loss in order to allow a spectrum of loss to be measured during inpatient stay. The burden of reassessing all patients on both patients and staff is deemed too onerous. Therefore, if possible one third of each group will have their outcome measures reassessed. This will be adjusted as the study progresses depending on the numbers that are able to complete the outcome measures on admission. The participant will be deemed to be mild, moderate or severe based on meeting the criteria below on at least one of the outcome measures (Dai et al., 2021b, Azouvi et al., 1996). If a participant scores mild for one outcome measure but moderate or severe on another their most severe outcome will determine their group.

Mild

Catherine Bergego Scale score of 1-10

SCP 0.5 OR >0.5 plus score of less than one on the three components

SVV tilt >2.5^{o} – 4^{o}

Moderate

Catherine Bergego Scale score of 11-20

SCP >0.5 plus score of at least one on one of the three components

SVV tilt 4.1^{o} – 7.9^{o}

Severe

Catherine Bergego Scale score of 21-30

SCP >3 and score of one all three components

SVV tilt <8^{o}

Once discharged from the stroke unit participants will have no further input into the study.

Assessors

Outcome measures will be undertaken by a qualified member of the therapy team on the stroke unit. This includes physiotherapists and occupational therapists ranging from NHS band 5 (newly qualified, these professionals rotate into the stroke unit for periods of 4 (physiotherapists) or 6 (occupational therapists) months), to NHS band 8 (advanced practice therapists). All those

undertaking the outcome measures will be trained on their use by the main author (AS) to ensure consistency of approach. The assessments are used in clinical practice so are within the scope of all qualified therapists. This training is estimated to take 1-2 hours to complete and will be undertaken on the stroke unit prior to the study commencing. New members of staff will be trained if they join the unit during the course of the research. The inter-rater reliability of the outcome measures has been established and is discussed below. All trained therapists will have to complete each outcome measure with AS on one occasion to ensure competence.

AS is a clinician who works on the stroke unit to be used in the research, as well as a lecturer and PhD student at the local university. She will be part of the data collection team, will support training of the rest of the team on the outcome measures, will be principle investigator for the trial and will facilitate the focus groups alongside another member of the research team.

Outcome measures

SVV will be measured using the bucket test (Zwergal et al., 2009). Measurement of SVV usually involves expensive equipment designed to be used in a laboratory situation. The bucket test was designed to measure SVV as a bed side assessment. The bucket test involves the patient being sat upright (ideally in a chair but it is possible with the head of the bed raised) and looking into a translucent bucket with the bucket covering their complete field of vision. See figure 1 below. On the inside of the bucket on the bottom is a dark straight line. On the outside of the bottom of the bucket is a matching dark line, the bottom of the bucket is divided into degrees with the zero-degree line being equivalent to the line inside the bucket. For measurement the bucket will be randomly rotated right or left by the examiner to 45 degrees and then slowly rotated back to the zero-degree position. Patients will signal when they estimate the inside bottom line to be truly vertical by saying "stop" or by raising their non-paretic hand. Degrees will be read off on the outside scale by the examiner. The procedure will be repeated 6 times (3 to left and 3 to right) in a random order. Measurements are made with both eyes open. A mean of the 6 tests will be calculated to be the tilt of SVV. Positive degrees will be used for contralesional tilts and negative degrees for ipsilesional tilts. The standard deviation (SD) of the mean of the 6 tests will be calculated to represent the uncertainty of SVV. The intertest reliability and validity of the bucket test have been established (Zwergal et al., 2009).

Figure 1. The bucket test.

Neglect will be assessed using the Catherine Bergego Scale (Azouvi et al., 1996). This established outcome measure for neglect is free and observational, it reflects existing practice and therefore reduces the burden on research participants. The scale is a 10-point scale with each item scored between 0 (no neglect) and 3 (severe neglect). The Catherine Bergego Scale has been shown to have excellent inter- and intra-rater reliability (Marques et al., 2019) and excellent construct validity with the Behavioural Inattention Test (Pitteri et al., 2018). See figure 2.

Lateropulsion will be assessed using the Scale for Contraversive Pushing (SCP) (Karnath et al., 2002). This observational assessment can be conducted as part of routine therapy sessions. Scores are assessed in sitting and standing giving a maximum score of 6. The SCP has been found to be a reliable and valid measure (Babyar et al., 2009). The classification used in a recent study (Dai et al., 2021b) will be utilised. Participants will be split into those who are:

- Upright SCP <0.5
- Tilters SCP >0.5 plus score of at least one on one of the three components
- Pushers SCP >3 and score of one all three components

In this study (Dai et al., 2021b) most of those who were upright had a SVV tilt of 0.6^{o} or less and therefore those who are tilters or pushers will be deemed to have a vertical perception tilt.

Scale for Contraversive Pushing (SCP):

A Posture (symmetry of spontaneous posture) Sitting and Standing

Score 1_severe contraversive tilt with falling to the contralesional side

Score 0.75_severe contraversive tilt without falling

Score 0.25_mild contraversive tilt without falling

Score 0_no tilt/upright body orientation

Total (maximum_2)

B Extension (use of the arm/leg to extend the area of physical contact to the ground) Sitting and Standing

Score 1_performed already in rest

Score 0.5_performed only until position is changed[a]

Score 0_no extension

Total (maximum_2)

C Resistance (resistance to passive correction of posture to an upright position)[b] Sitting and standing

Score 1_resistance is shown

Score 0_resistance is not shown

Total (maximum_2)

[a] For sitting, ask the patient to glide the buttocks on the mattress toward the nonparetic side, to transfer from bed to wheelchair toward the nonparetic side, or both. For standing, ask the patient to start walking. If pushing already occurs when the patient is rising from the sitting position, section B is given the value of 1 for standing.

[b] Touch the patient at the sternum and the back. Give the following instructions: "I will move your body sideward. Please permit this movement."

	0	1	2	3
1. Forgets to groom or shave the left part of his/her face	❑	❑	❑	❑
2. Experiences difficulty in adjusting his/her left sleeve or slipper	❑	❑	❑	❑
3. Forgets to eat food on the left side of his/her plate	❑	❑	❑	❑
4. Forgets to clean the left side of his/her mouth after eating	❑	❑	❑	❑
5. Experiences difficulty in looking towards the left	❑	❑	❑	❑
6. Forgets about a left part of his/her body (eg, forgets to put his/her upper limb on the armrest, or his/her left foot on the wheelchair rest, or forgets to use his/her left arm when he/she needs to)	❑	❑	❑	❑
7. Has difficulty in paying attention to noise or people addressing him/her from the left	❑	❑	❑	❑
8. Collides with people or objects on the left side, such as doors or furniture (either while walking or driving a wheelchair)	❑	❑	❑	❑
9. Experiences difficulty in finding his/her way towards the left when traveling in familiar places or in the rehabilitation unit	❑	❑	❑	❑
10. Experiences difficulty finding his/her personal belongings in the room or bathroom when they are on the left side	❑	❑	❑	❑
Total score (/30)				

0=no neglect; 1=mild neglect; 2=moderate neglect; 3=severe neglect

Figure 2. The Catherine Bergego Scale

Withdrawal procedure

Participants are free to withdraw from the research study at any point, without giving a reason and without any consequences. Participation in the study (including withdrawing) will not influence the care that they receive. This is explained in the information sheets, which a participant must read prior to consenting to participate.

The end of study participation

For most participants, the end of the study participation will be defined as the completion of all three outcome measures or 4 weeks post consent, whichever is the sooner. For the subsection who have their outcomes repeated it will be equal to their length of stay.

7. Additional Research Activities.

Focus Groups

Prior to the study commencing a focus group will be completed with the therapists undertaking the outcome measures. This will be held following training on the outcome measures. Therapists will be invited to attend by AS at the end of the training session and provided with a PIS. They can then decide if they wish to participate or not.

This will allow exploration of how feasible or acceptable the therapists feel it will be to complete the outcome measures before data collection. This can then be compared with their thoughts, and the thoughts of people with stroke and their advocates, on acceptability following use of the outcome measures.

At the six month point of the study the focus group will be repeated, with approximately 10 therapists, to allow exploration of the experiences of the therapists that undertook the outcome measures (Bowling, 2014). This data will add richness to the quantitative data and give a greater understanding of the feasibility of the use of the outcome measures to assess vertical perception loss. This will allow collection of data from multiple participants using an unstructured but guided discussion of the use of the outcome measures in the acute stroke setting (Braun and Clarke, 2013).

Potential participants will be members of the therapy team on the stroke unit who have undertaken the outcome measures. They will be known to the chief investigator who works in the team. To mitigate for this they will be approached to participate via email or through the research team. They will be provided with a PIS explaining the post-trial focus groups and the time and date at which the group will be undertaken. They can then decide if they wish to participate or not.

If they wish to participate they will be asked to sign a consent form and attend the group at the dedicated time. The groups will be moderated by the lead researcher (AS) using a list of topics/questions to guide the conversation. A second member of the research team, unknown to the participants, will assist in the groups to ensure smooth running of the groups and mitigate for the fact that AS will be known to many participants. Face to face groups will be held in the hospital setting at a time convenient to a majority of participants. The focus groups will last no longer than

1.5 hours. Ground rules will be introduced at the beginning of the groups to allow smooth running of the group and to put participants at ease (Braun and Clarke, 2013). Focus groups will be recorded for transcription on MS Teams and stored behind two factor authentication on a password protected computer. Each group member will be assigned a participant number to assist with data analysis. The focus group will be anonymised and transcribed verbatim and following transcription the original recording will be deleted. At this point participants will no longer be able to withdraw from the study. Should a member of staff who undertook the assessments leave the stroke unit prior to the post study focus group they will be contacted by email by the chief investigator to ask if they wish to participate.

Patient Participant Feedback

For people with stroke or their advocates, acceptability of the measures will be assessed throughout. Alongside their ability to complete the outcome measures, their willingness to complete them will be documented. At the point they complete all the outcome measures (or at 4 weeks if they are unable to complete the measures) participants (or their advocates) will be asked, by the therapist completing their measures or a member of the research team, to complete a short survey asking about the acceptability of the outcome measures. The questions will be based on the theoretical framework of acceptability (Sekhon et al., 2017). Participants will be provided with details of the survey in the PIS when they enter the study. Consent to participate in the survey will be taken at the point of entry to the study. Participants will be under no obligation to complete the survey and can participate in the feasibility arm of the study without completing it. The survey will be anonymous and the participant can withdraw up to the point it is completed. Questions will ask about their attitude towards, understanding of and burden of completing the outcome measures. It will be a mix of choice and Likert scale questions with some free text open questions. The survey should take no more than 15 mins to complete. Participants can be supported to complete the survey by an advocate, therapist or member of the research team who can read out the questions and record their responses, but will not influence the answers. The survey will be on paper for ease of completion in the clinical setting.

8. Statistics and Data Analysis

To answer the research questions mainly descriptive statistics will be used and data presented using bar charts and pie charts. The focus group data will be analysed using thematic analysis (Braun and Clarke, 2013).

The percentage of patients who:

a. are admitted for at least 72 hours and are approached
b. are approached who agree to participate
c. agree and can complete the three measures

will be calculated. Demographic data of the participants will be tabulated for display including: number of patients with left or right stroke, number of patients with haemorrhage or infarct stroke, female/male/non-binary/other gender, mean length of stay, location of stroke, median NIHSS on admission, median MRS and Barthel Index on discharge, place of discharge (home/care home/other), care needs on discharge (nil, one, two, three or four calls per day or 24 hour and number of carers required), number of in-patient falls, median minutes of therapy per day (for OT and Physiotherapy) and median number of days on which OT and Physiotherapy were received.

The main outcome will be the percentage of consenting patients who are able to complete the three outcome measures within four weeks of admission. The percentage of patients able to complete each of the outcome measures individually will be calculated to see if one of the outcome measures is more feasible than the others. Reasons for non-completion will be collated for each of the outcome measures and presented using an appropriate tool. The mean time and standard deviation (SD) to complete all three and each individual outcome measure will be presented. To identify the most feasible time point to complete the outcome measures median (and confidence intervals) time to completion of each outcome measure and time to completion of all three outcome measures will be calculated. The percentage of participants completing each or all of the measures at 48 hours, 1 week, 2 weeks and 4 weeks will be presented.

The median scores and confidence intervals for the SCP and Catherine Bergego scale will be calculated, as well as the mean and SD for the bucket test. The percentage of patients with vertical perception loss will be reported – this will be defined as a positive test on one or more of the measures (SVV >2.5^{o}, Catherine Bergego Scale >1, SCP >0.5). For each patient it will be noted if they test positive on one, two or all three measures. This will assist in informing which of the measures will be required in future studies.

To identify trends for vertical perception loss and discharge status narrative statistics will be utilised. For instance the numbers of participants identified as having vertical perception loss who are discharged home will be investigated. If possible a Spearman Rank Correlation with Fisher-Z between outcome measure score and discharge information (e.g. length of stay in days, MRS score or Barthel Score) will be used. These tests have been chosen as the data is ordinal and are expected to be non-

parametric in nature. An ordinal regression will allow identification of which outcome measure is most likely to relate to discharge information.

A Spearman Rank Correlation with Fisher-Z will be completed on each element of the SCP and Catherine Bergego Scale against SVV to identify if any specific elements of the measures are more indicative of vertical perception loss than others. An ordinal regression will allow identification of which elements of the SCP and Catherine Bergego Scale are most likely to relate to SVV tilt.

The percentage of patients able to complete the measures, along with scores and confidence intervals for the outcome measures will be used to determine potential sample size for larger trials (Eldridge et al., 2016) and assess the change in vertical perception loss during in-patient admission.

It is known that neglect (Esposito et al., 2021) and pushing behaviour (Dai et al., 2022) improve over time. Therefore, changes in a sub-sample of the population will be tracked to inform future interventional research. For the subsample who have outcomes taken on discharge a Wilcoxon Sign Rank test will be used to identify the change in scores of the measures during in-patient stay. This will be completed for the whole study population and for each of the subgroups defined as mild, moderate or severe vertical perception loss.

Analysis of the focus groups will be undertaken by AS using NVivo (1.6.1) software. They will be analysed using the six steps of thematic analysis (Braun and Clarke 2013). An inductive approach will be taken. The transcripts will be read and reread to allow the researcher to become familiar with the data. Codes will be identified by highlighting relevant words or phrases. Themes will be highlighted by linking codes with similar meanings. Appropriate names for the themes will be chosen, and the research findings written up. During the analysis process AS will work with reflexivity to reduce the impact of her being known to the team. Triangulation of the qualitative analysis will occur with the second member of the research team who attended the group as well as the rest of the supervisory team who will have access to the group transcriptions. Themes arising from the therapist focus groups prior to and after administration of the outcome measures will be compared using a narrative process.

For the acceptability survey, closed questions will be analysed using descriptive statistics and open questions using thematic analysis. Simple means, modes and medians will be used to analyse the categories from the questionnaire and frequency of response will also be calculated.

A priori progression criteria should be recommended for feasibility studies (Eldridge et al., 2016). However, it has been suggested that progression criteria are not required for early formative trials (Pearson et al., 2020). Furthermore, a pragmatic selection of criteria (Hallingberg et al., 2018)

including acceptability and stakeholder involvement (Bugge et al., 2013) should determine progression criteria (Pearson et al., 2020). Therefore, the decision as to whether it is feasible to use these outcome measures to identify those with vertical perception loss will be made on the basis of collated results of this trial.

9. Data Management

Necessary personal data processes

Access to medical records: Only members of the clinical team will access medical records. To facilitate this, the clinical team/research practitioner from within the clinical team will identify potential participants and obtain written informed consent.

Electronic transfer by, email, or computer networks: There will need to be electronic transfer of data from Royal Hampshire County Hospital to the University of Winchester. The data will be kept in a password protected Microsoft OneDrive folder, which will only be accessible by members of the research team. All data which leaves the research site will be anonymised (including electronic data) by assigning each participant a code.

Storage of personal data on manual files and university computers: Any quotes from focus groups will be anonymised prior to publication.

Focus groups will be recorded - the recordings will be stored on a University One Drive (password protected) behind two factor authentication. Once the focus groups have been transcribed and anonymised the original recordings will be deleted.

Personal data related to recruitment will be kept in a site file that will be in a locked room used by the research team on the stroke unit. Paper copies will be kept to a minimum and information will be stored on an NHS computer only able to be accessed by the direct healthcare team and the research departments.

Surveys will be paper based but contain no identifiable data and will be stored with the site file.

Any information stored on a university computer will relate to the findings and results of the study and will be anonymised data.

Physical storage of data

Hard copies of any records with personal data will be kept to a minimum. Copies of signed consent forms will be stored in the medical records and the site file. It is possible that the site file may contain other logs and documents with personal data and this file will be kept in a locked room on the stroke

unit. It will also contain hard copies of the surveys but these will be anonymous. Access to this room is limited to the direct healthcare team only.

Data (recruitment logs, and consent) will be stored on NHS computers or in the participant's healthcare record and therefore only be accessible to the direct healthcare team. Access will be password protected and in a secure folder at the NHS site.

Only anonymised data will be stored on University of Winchester computers but this will be on a password protected OneDrive behind two factor authentication.

Data will be kept for 10 years after the study has concluded to allow investigations to return to the source of the data if/when needed.

Confidentiality

Following consent each participant will be given a participant number and then any data collected will only be related to the participant number rather than name. All data will be held in relation to the NHS code of confidentiality. Hence all data will be anonymised. All data shared with the supervisory team or utilised for publication will be fully anonymised. Surveys will be anonymous. Participants of the focus groups will also be given a unique participant number and all data will be anonymised during transcription. Following transcription (10 days after the groups) original recordings will be destroyed. Data collection will be minimised and healthcare records will be used to store data where appropriate.

10. Ethical and Regulatory Considerations

Ethical clearance will be sought from an NHS Research Ethics Committee (REC) using the Integrated Research Application System (IRAS). The outcome of which will be shared with the University of Winchester ethics committee. Approval will be sought from the Research and Development (R&D) department at Hampshire Hospitals NHS Foundation Trust (HHFT).

The study will comply with the Declaration of Helsinki and follow the ethical principles of beneficence, non-maleficence, autonomy and justice.

Eligibility and Consent

All participants must sign a consent form, if the patient is unable to consent this will be sought from an appropriate advocate, if no advocate can be found the patient will not be eligible for inclusion.

Risks and Burdens

There are no substantial risks to participating in this research. Completing the measures will be some additional burden to the therapy team on the unit but as the assessments can be integrated into therapy sessions this burden is minimised. There is a minor risk that some participants may find the bucket test challenging, if so it will be stopped.

Benefits

There is no direct benefit to the research participants but this study will however, help to inform our understanding of how feasible it is to identify vertical perception soon after stroke. Through this greater understanding it is hoped to build more evidence-based assessments and treatments for people with stroke who are unable to align to vertical.

The therapists undertaking the assessments will benefit from being involved in a research study and improved understanding of the research process.

Withdrawal

The participant information sheet will make it clear that there is no obligation to participate and that it will not impact their future care. Participants will have the right to withdraw from the study at any point until the time of discharge without detriment and any data already collected up to the point of withdrawal will be utilised in the results.

Confidentiality

All data will be fully anonymised and no participant will be identifiable in any resulting outputs from this research. Data will be stored on a NHS computer or required platforms and anonymised data will be stored on a University of Winchester password protected OneDrive behind a two factor authentication. General Data and Protection Regulations (GDPR) will be followed at all times. Participants of the focus groups will have the right to withdraw up to the point at which the focus group has been transcribed (10 days after the focus group). At this point the original recording will be deleted, the participants anonymised and withdrawal will not be possible. Anonymised data will be shared with the researcher's supervisory team.

Additional Ethical considerations

All participants will be given information on how to seek support or who to contact to ask questions regarding the research.

If a participant loses capacity during the study any data collected to date will be anonymised and used in the results but no further data would be collected, unless they regain capacity. This is made clear in the participant information sheet and can be discussed with the participant prior to them consenting.

Stakeholders will be engaged throughout the study. Patient and public involvement (PPI) has become an important part of research activity and is supported by government guidelines (Department of Health, 2006). The use of PPI is an important ethical component of research (National Institue for Health and Care Research, 2021). It is important to acknowledge the positive impact of PPI whilst avoiding it being tokenistic (Lauzon-Schnittka et al., 2022). There are difficulties with ensuring that PPI is utilised effectively; some stroke survivors feel that people with stroke should not be involved in research (Harrison and Palmer, 2015), it can lead to participants feeling compelled or inequalities being reproduced (Clarke et al., 2017) and the evidence for the use of PPI needs strengthening (Brett et al., 2010). PPI has been described as being at three levels; consultative, collaborative or user controlled (Harrison and Palmer, 2015). In this study PPI will be at the consultative level. This is a pragmatic decision based on the nature of the research being undertaken and the resources available to the research team. It would be unethical to further involve PPI volunteers without the ability to appropriately acknowledge their contribution (Lauzon-Schnittka et al., 2022).

The research team will invite people with stroke and their carers who are known to them to comment on the proposed research design, read and update the consent forms and PIS and shape the wording of questions of the participant/advocate survey. People with stroke and their carers will be participants in the study and will directly influence the results by completing a survey. Hence, offering them the opportunity to directly answer the research question in relation to acceptability and feasibility. Results will be shared with those that support the study.

11. Dissemination

The research team from the University of Winchester will own the data from the trial.

Once completed and written up it is hoped to disseminate the results of the study widely. This will be through publication in scientific journals, presentations at appropriate conferences and through production of a plain English summary that can be shared with those involved in the study (should they request it) and organisations that support people with stroke. The target audience for the results will be those with lived experience of stroke and healthcare professionals involved in the

rehabilitation and care of people with stroke and therefore publication will be targeted at these audiences.

No identifiable personal data will be published. All data will be anonymised.

12. Safety Reporting

A serious adverse event occurring to the participant should be reported to the Research Ethics Committee (REC) that gave a favourable opinion of the study where, in the opinion of the Chief Investigator, the event was: 'related' - that is, it resulted from the administration of any of the research procedures; and 'unexpected' - that is, the type of event not listed in the protocol as an expected occurrence. Reports or related or unexpected serious adverse events should be submitted within 15 days of the Chief Investigator becoming aware of the event using the NRES 'report of serious event' form (see NRES website). Serious adverse events will also be reported to the University of Winchester Ethics Committee and to the approving Research and Development (R&D) at Hampshire Hospitals NHS Foundation Trust.

A serious adverse event is any untoward medical occurrence that:

- Results in death
- Is life-threatening (the term 'life-threatening' in the definition of 'serious' refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which may have caused death had it been more severe)
- Requires patient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Other important medical events (other events that may not result in death, are not life threatening, or do not require hospitalisation, may be considered a SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above).

Patients will also be provided with local contact details on the participant information sheet, should they believe they were harmed in any way due to participation in the study.

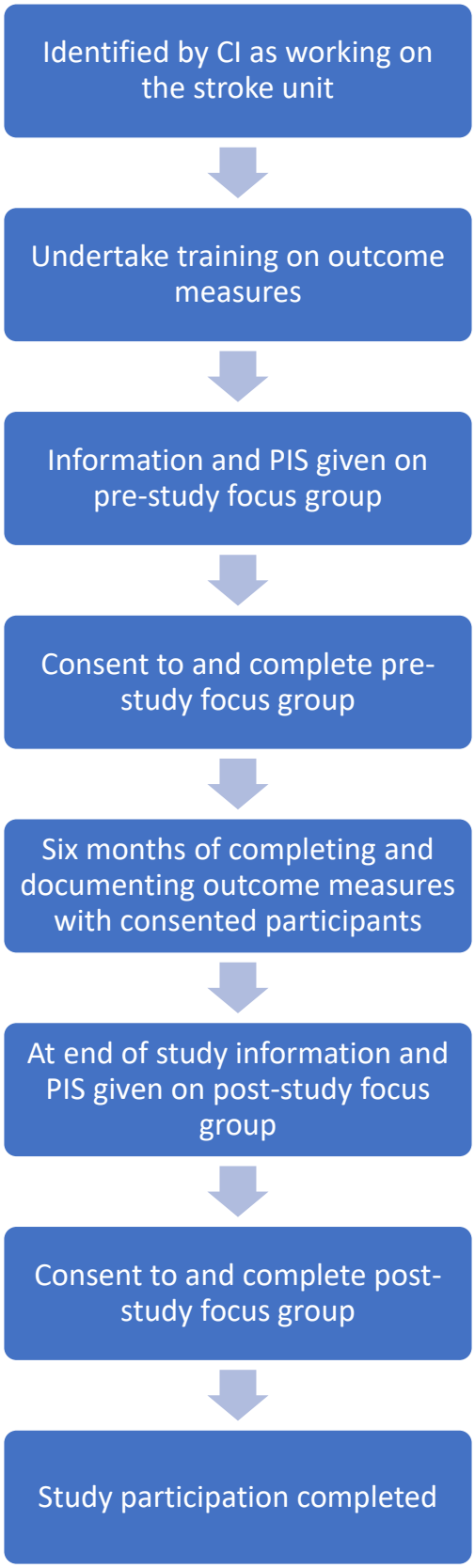
13. Financing and Insurance

Involvement in the study is voluntary and unpaid.

The University of Winchester will provide insurance and indemnity cover for the research study. The University of Winchester is also the study sponsor.

Flow Diagram – Patient participant

Flow Diagram -Therapist participation



References

AZOUVI, P., MARCHAL, F., SAMUEL, C., MORIN, L., RENARD, C., LOUIS-DREYFUS, A., JOKIC, C., WIART, L., PRADAT-DIEHL, P., DELOCHE, G. & BERGEGO, C. 1996. Functional Consequences and Awareness of Unilateral Neglect: Study of an Evaluation Scale. *Neuropsychological Rehabilitation,* 6**,** 133-150.

BABYAR, S., PETERSON, M. & READING, M. 2015. Time to recovery from lateropulsion dependent on key stroke deficits: a retrospective analysis. *Neurorehabilitation and Neural Repair,* 29**,** 207-213.

BABYAR, S. R., PETERSON, M. G. E., BOHANNON, R., PÉRENNOU, D. & READING, M. 2009. Clinical examination tools for lateropulsion or pusher syndrome following stroke: a systematic review of the literature. *Clinical Rehabilitation,* 23**,** 639-650.

BERGMANN, J., KREWER, C., SELGE, C., MÜLLER, F. & JAHN, K. 2016. The subjective postural vertical determined in patients with pusher behavior during standing. *Topics in Stroke Rehabilitation,* 23**,** 184-190.

BOWLING, A. 2014. *Research Methods in Health. Investigating health and health services,* Maidenhead, Open University Press.

BRAUN, V. & CLARKE, V. 2013. *Successful qualitative research: A practical guide for beginners,* London, Sage Publications Ltd.

BRETT, J., STANISZEWSKA, S., MOCKFORD, C., SEERS, K., HERRON-MARX, S. & BAYLISS, H. 2010. The PIRICOM Study: A systematic review of the conceptualisation, measurement, impact and outcomes of patients and public involvement in health and social care research. Available: http://ukcrc-org.stackstaging.com/wp-content/uploads/2014/03/Piricom+Review+Final+2010.pdf [Accessed 28.05.2023].

BROWNE, R. H. 1995. On the use of a pilot sample for sample size determination. *Statistics in Medicine,* 14**,** 1933-40.

BUGGE, C., WILLIAMS, B., HAGEN, S., LOGAN, J., GLAZENER, C., PRINGLE, S. & SINCLAIR, L. 2013. A process for Decision-making after Pilot and feasibility Trials (ADePT): development following a feasibility study of a complex intervention for pelvic organ prolapse. *Trials,* 14**,** 353.

CHANG, T.-P., WINNICK, A. A., HSU, Y.-C., SUNG, P.-Y. & SCHUBERT, M. C. 2019. The bucket test differentiates patients with MRI confirmed brainstem/cerebellar lesions from patients having migraine and dizziness alone. *BMC Neurology,* 19**,** 219.

CLARKE, D., JONES, F., HARRIS, R. & ROBERT, G. 2017. What outcomes are associated with developing and implementing co-produced interventions in acute healthcare settings? A rapid evidence synthesis. *BMJ Open,* 7**,** e014650.

CRESWELL, J. W. & CRESWELL, J. D. 2018. *Research Design,* Thousand Oaks, California, Sage Publications, Inc. .

DAI, S., LEMAIRE, C., PISCICELLI, C. & PÉRENNOU, D. 2022. Lateropulsion Prevalence After Stroke: A Systematic Review and Meta-analysis. *Neurology,* 98**,** 1-11.

DAI, S. & PÉRENNOU, D. 2021. Renaissance of "lateropulsion". *Annals of Physical and Rehabilitation Medicine,* 64**,** 101595.

DAI, S., PISCICELLI, C., CLARAC, E., BACIU, M., HOMMEL, M. & PÉRENNOU, D. 2021a. Balance, lateropulsion, and gait disorders in subacute stroke. *Neurology,* 96**,** e2147-e2159.

DAI, S., PISCICELLI, C., CLARAC, E., BACIU, M., HOMMEL, M. & PÉRENNOU, D. 2021b. Lateropulsion After Hemispheric Stroke: A Form of Spatial Neglect Involving Graviception. *Neurology,* 96**,** e2160-e2171.

DEPARTMENT OF HEALTH 2006. *Best research for best health: A new national health research strategy,* London, Department of Health.

ELDRIDGE, S. M., CHAN, C. L., CAMPBELL, M. J., BOND, C. M., HOPEWELL, S., THABANE, L. & LANCASTER, G. A. 2016. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Pilot and Feasibility Studies,* 2**,** 64.

ESPOSITO, E., SHEKHTMAN, G. & CHEN, P. 2021. Prevalence of spatial neglect post-stroke: A systematic review. *Annals of Physical and Rehabilitation Medicine,* 64**,** 101459.

FUNK, J., FINKE, K., MÜLLER, H., PREGER, R. & KERKHOFF, G. 2010. Systematic biases in the tactile perception of the subjective vertical in patients with unilateral neglect and the influence of upright vs. supine posture. *Neuropsychologia,* 48**,** 298-308.

FUNK, J., FINKE, K., MULLER, H., UTZ, K. & KERKHOFF, G. 2011. Visual context modulates the subjective vertical in neglect: evidence for an increased rod-and-frame-effect. *Neuroscience,* 173**,** 124-34.

GAMMERI, R., IACONO, C., RICCI, R. & SALATINO, A. 2020. Unilateral Spatial Neglect After Stroke: Current Insights. *Neuropsychiatric Diseases and Treatment,* 16**,** 131-152.

GOMES-OSMAN, J. & KLOOS, A. 2021. Lateropulsion: An Overlooked Driver of Balance and Gait Deficits in Stroke? *Neurology,* 96**,** 779-780.

HALLINGBERG, B., TURLEY, R., SEGROTT, J., WIGHT, D., CRAIG, P., MOORE, L., MURPHY, S., ROBLING, M., SIMPSON, S. A. & MOORE, G. 2018. Exploratory studies to decide whether and how to proceed with full-scale evaluations of public health interventions: a systematic review of guidance. *Pilot and Feasibility Studies,* 4**,** 104.

HARRISON, M. & PALMER, R. 2015. Exploring patient and public involvement in stroke research: a qualitative study. *Disability and Rehabilitation,* 37**,** 2174-83.

HOOPER, R. Unknown. *Justify sample size for a feasibility study* [Online]. London: NHIR Research Design Service. Available: https://www.rds-london.nihr.ac.uk/resources/justify-sample-size-for-a-feasibility-study/ [Accessed 28.05.2023].

KARNATH, H.-O. & BROETZ, D. 2003. Understanding and Treating "Pusher Syndrome". *Physical Therapy,* 83**,** 1119-1125.

KARNATH, H.-O., FERBER, S. & DICHGANS, J. 2000. The origin of contraversive pushing: evidence for a second graviceptive system in humans. *Neurology,* 55**,** 1298-304.

KARNATH, H.-O., JOHANNSEN, L., BROETZ, D., FERBER, S. & DICHGANS, J. 2002. Prognosis of contraversive pushing. *Journal of Neurology,* 249**,** 1250-3.

LANCASTER, G. A., DODD, S. & WILLIAMSON, P. R. 2004. Design and analysis of pilot studies: recommendations for good practice. *Journal of Evaluation in Clinical Practice,* 10**,** 307-12.

LAUZON-SCHNITTKA, J., AUDETTE-CHAPDELAINE, S., BOUTIN, D., WILHELMY, C., AUGER, A.-M. & BRODEUR, M. 2022. The experience of patient partners in research: a qualitative systematic review and thematic synthesis. *Research Involvement and Engagement,* 8**,** 55.

MAHONEY, F. I. & BARTHEL, D. W. 1965. Functional Evaluation: The Barthel Index. *Maryland State Medical Journal,* 14**,** 61-65.

MARQUES, C. L. S., DE SOUZA, J. T., GONÇALVES, M. G., DA SILVA, T. R., DA COSTA, R. D. M., MODOLO, G. P., CORRENTE, J. E., BAZAN, R. & LUVIZUTTO, G. J. 2019. Validation of the Catherine Bergego Scale in patients with unilateral spatial neglect after stroke. *Dementia and Neuropsychologica,* 13**,** 82-88.

NATIONAL INSTITUE FOR HEALTH AND CARE RESEARCH. 2021. *Briefing notes for Researchers* [Online]. Available: https://www.nihr.ac.uk/documents/briefing-notes-for-researchers-public-involvement-in-nhs-health-and-social-care-research/27371 [Accessed 14.06.2023].

NICHOLLS, D. 2009. Qualitative Research: Part Two – Methodology. *International Journal of Therapy and Rehabilitation,* 24**,** 71-77.

NOLAN, J., GODECKE, E. & SINGER, B. 2021. The association between contraversive lateropulsion and outcomes post stroke: A systematic review. *Topics in Stroke Rehabilitation,* 29**,** 92 - 102.

NOLAN, J., JACQUES, A., GODECKE, E., ABE, H., BABYAR, S., BERGMANN, J., BIRNBAUM, M., DAI, S., DANELLS, C., EDWARDS, T. G. S., GANDOLFI, M., JAHN, K., KOTER, R., MANSFIELD, A., NAKAMURA, J., PARDO, V., PERENNOU, D., PISCICELLI, C., PUNT, D., ROMICK-SHELDON, D.,

SAEYS, W., SMANIA, N., VAES, N., WHITT, A. L. & SINGER, B. 2022. Post-stroke lateropulsion terminology: pushing for agreement amongst experts. *Annals of Physical and Rehabilitation Medicine,* 65**,** 101684.

PACI, M., MACCHIONI, G. & FERRARELLO, F. 2023. Treatment approaches for pusher behaviour: a scoping review. *Topics in Stroke Rehabilitation,* 30**,** 119-136.

PATEL, A., BERDUNOV, V., QUAYYUM, Z., KING, D., KNAPP, M. & WITTENBERG, R. 2019. Estimated societal costs of stroke in the UK based on a discrete event simulation. *Age and Ageing,* 49**,** 270-276.

PEARSON, N., NAYLOR, P.-J., ASHE, M. C., FERNANDEZ, M., YOONG, S. L. & WOLFENDEN, L. 2020. Guidance for conducting feasibility and pilot studies for implementation trials. *Pilot and Feasibility Studies,* 6**,** 167.

PERENNOU, D., MAZIBRADA, G., CHAUVINEAU, V., GREENWOOD, R., ROTHWELL, J., GRESTY, M. & BRONSTEIN, A. 2008. Lateropulsion, pushing and verticality perception in hemisphere stroke: a causal relationship? *Brain,* 131**,** 2401-13.

PISCICELLI, C. & PÉRENNOU, D. 2017. Visual verticality perception after stroke: A systematic review of methodological approaches and suggestions for standardization. *Annals of Physical Rehabilitation and Medicine,* 60**,** 208-216.

PITTERI, M., CHEN, P., PASSARINI, L., ALBANESE, S., MENEGHELLO, F. & BARRETT, A. M. 2018. Conventional and functional assessment of spatial neglect: Clinical practice suggestions. *Neuropsychology,* 32**,** 835-842.

SEKHON, M., CARTWRIGHT, M. & FRANCIS, J. J. 2017. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Services Research,* 17**,** 88-101.

SIM, J. & LEWIS, M. 2012. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *Journal of Clinical Epidemiology,* 65**,** 301-8.

TANLAKA, E. F., EWASHEN, C. & KING-SHIER, K. 2019. Postpositivist critical multiplism: Its value for nursing research. *Nursing Open,* 6**,** 740-744.

UTZ, K., KELLER, I., ARTINGER, F., STUMPF, O., FUNK, J. & KERKHOFF, G. 2011. Multimodal and multispatial deficits of verticality perception in hemispatial neglect. *Neuroscience,* 188**,** 68-79.

VAN SWIETEN, J. C., KOUDSTAAL, P. J., VISSER, M. C., SCHOUTEN, H. J. & VAN GIJN, J. 1988. Interobserver agreement for the assessment of handicap in stroke patients. *Stroke,* 19**,** 604-607.

ZWERGAL, A., RETTINGER, N., FRENZEL, C., DIETERICH, M., BRANDT, T. & STRUPP, M. 2009. A bucket of static vestibular function. *Neurology,* 72**,** 1689-92.