FREEHAB: accessible, comfortable and adaptable wearable rehabilitation and assist devices

Study 1: Physiotherapy analysis of functional mobility: walking, standing and transfer in stroke and older people.

Short title: FREEHAB Physiotherapy analysis of functional mobility (version 0.1)

RESEARCH TEAM

Chief investigator

Professor Jonathan Rossiter, Head of Soft Robotics Group at Bristol Robotics Laboratory, University of Bristol (UoB).

Co-applicants

Dr Ailie Turton, Senior Lecturer, University of West of England (UWE), Bristol

Dr Mary Cramp, Associate Professor in Long Term Conditions, University of West of England (UWE), Bristol

Clinical Collaborators, services and user groups

Liz Britton, Southmead Hospital North Bristol NHS Trust	Neurophysiotherapy & stroke services	• Patients who have had a stroke in hospital • Older people with mild stroke alongside general weakness
Zoe Pascucci, Virgin Care Bath and North East Somerset	Community neuro and stroke early supported discharge service	• Stroke Early Supported Discharge, at home • Older people with mild stroke alongside general weakness
Colin Domaille Domaille Neurophysio	Independent specialist neuro-physiotherapy and physiotherapy practice	• Stroke at home • Older patients in residential care
Mr Chris Priestman	Patient Partner	

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Project name: FREEHAB: accessible, comfortable and adaptable wearable rehabilitation and assist devices (EP/S026096/1)

This first study will start on 22nd February 2021~~3rd August 2020~~ subject to COVID-19 situation and service delivery.

Sponsor

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Patient and Public Involvement

Mr Chris Priestman, patient partner, has contributed to planning this study and has reviewed the participant information. Clinical partner physiotherapists have also reviewed and agreed the physiotherapist participants' information. Two patients at North Bristol Trust were asked by their physiotherapist to look at the patient participants information sheet. They found some grammatical errors but did not have any suggestions for changes to be made.

The FREEHAB programme is using a participatory patient and clinical user approach. Patient and clinical partners will have ongoing involvement in the design, implementation and dissemination of the programme of work.

BACKGROUND AND AIM

There are over 10.8 million disabled people living in the UK today. Nearly 6.5 million have mobility impairments. The largest causes of impairment are age-related degradation (40% of over-60s have disabilities affecting their daily lives) and stroke (there are over 1.2M stroke survivors in the UK). These numbers are growing as the median population age increases and age-related mobility issues dominate. The increasing need for effective rehabilitation may in part be addressed by the development of new devices that will enable more targeted and personalised practice of mobility tasks.

This study is the first work package of a project called FREEHAB. FREEHAB aims to develop and evaluate prototype wearable devices for use by clinical therapists in hospital and home settings, to improve analysis of movement, treatment planning and mobility training. It is envisaged that devices will be developed to suit different mobility tasks and therapeutic purposes. The devices will be developed for assessing and assisting walking, standing and sit to stand movements. Different versions of the devices will be designed to assist therapists to carry out biomechanical analysis of patients' performance to enable personalised training plans, and for the patients to practice their mobility tasks to achieve more effective rehabilitation.

The first step in the FREEHAB project is this observational study of physiotherapists' practice and assessment of patient mobility. The purpose of this study is to determine specifications for end-user cases for improving walking, standing and sit to stand movements. Understanding the perceptions, needs and requirements of potential users is essential for design and successful adoption of new adaptive rehabilitative devices[1]. Lack of user involvement in the selection of assistive equipment contributes to high levels of abandonment[2]. The FREEHAB project is following a participatory design process [3] in order to maximise the likelihood of achieving useful and acceptable devices to assist physiotherapy practice. The first step in the process is to communicate and understand essential processes in physiotherapists' assessment of their patients' mobility impairments. Clinical reasoning in physiotherapy comes from training and the experience of the therapist[4]. Some of this knowledge can be explicitly communicated and some is

tacit. Using analysis of video recording alongside therapists' thinking aloud, can enable understanding of the complexities of clinical decision making and its influences[5,6]

In this study we will be recording and analysing video recordings of physiotherapists' actions and clinical reasoning during their assessment of their patients' functional mobility. In addition, quantitative clinical measures and patients participants' biomechanics during movement of interest will be collected. The analysis will allow us to determine the essential components of movement assessment, and the context of the therapists' reasoning and subsequent actions. Discussion of the findings with clinical partners will enable the establishment of the design envelope for the adaptive rehabilitative devices to be developed in FREEHAB.

Study Aim

To determine precise specification of the design envelope for wearable soft robotic assistive rehabilitation devices for the three mobility tasks.

Research Questions

1. How do physiotherapists assess and analyse a patient's movement to determine treatment plans to improve performance of mobility tasks?
2. What are the common features of assessment, analysis and task specific training for the three mobility tasks?
3. What are the essential components of the assessment and movement analysis process that will be needed in the design specification of devices?

Objectives:

1. Capture and analysis of video of physiotherapists' assessment while the therapists are talking aloud about their diagnostic process.
2. Capture quantitative clinical measures of strength, range of motion and functional performance from patient participants (outside of the therapist's assessment process).
3. Capture biomechanical analysis of patient participant's performance.
4. Map results from physiotherapy assessment with clinical and biomechanical measures.
5. Determine essential components of the assessment and movement analysis process that will be needed in the design specification of devices.

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RESEARCH PLAN AND METHODOLOGY

Participants

FREEHAB devices will be designed for two major groups who have rehabilitation for their mobility: i) stroke; and ii) older people with musculoskeletal impairments. We aim to recruit patient participants from these two populations. The patients will be current users of rehabilitative services either in hospital or at home. They will be working with their physiotherapists to improve performance and ability in one or more of the following mobility tasks: walking, standing, and moving from sitting to standing and standing to sitting. The term 'patient' is used to refer to all participants receiving rehabilitation from these clinical partner physiotherapists. It should be noted that two of the clinical providers are private providers, and one is an NHS trust.

We are aiming to recruit 30 patient participants. Individual patients may be recorded as they are assessed for one of the mobility tasks, for two, or all three tasks. We are not expecting to recruit more than one person per month from each of our clinical partners over 10 months, though if the

service has capacity and can identify, recruit and manage more than one new participant a month, then that will be welcomed.

We will be recruiting physiotherapists and their patients to the study.

1. Physiotherapists

Inclusion criteria:

- Physiotherapists who are working in our clinical partner organisations, with stroke or older patients to improve their mobility.

Exclusion criteria:

- Less than 2 years' experience of working with stroke or older patients.

2. Patients who are being assessed and treated by the physiotherapist participants

Inclusion criteria:

- Diagnosis of stroke with hemiparesis* or older patient (over 65 years) with weakness following musculoskeletal impairment (for example post joint replacement or surgery following a fall).
- Being seen by a physiotherapist in the clinical partner service for rehabilitation of mobility (standing balance, transfers or walking).
- Medically stable.
- Mental Capacity to consent to the study according to members of the clinical team who are working with the patient.

Exclusion criteria:

- Diagnosis of neurological condition, other than stroke.
- Concurrent acute musculoskeletal conditions (e.g. fractures, sprains) which prevent weight bearing.
- Morbidly obese - BMI > 40 kg/m2, - these patients are likely to need more physiotherapists to support them and the technology developed in FREEHAB is unlikely to be suitable for them.
- Presence of ataxia.
- Judged by therapists to have a functional neurological disorder.
- Judged by therapist to have depression or anxiety that might prevent participation, or become increased because of participation in the study.

** Note - Time after stroke is not limited and potential participants who had had a stroke can still take part if the stroke is not the first stroke. Potential participants with poor balance, sensory loss, visual field loss aphasia and cognitive impairments, but who have capacity to consent can be accommodated.*

Recruitment strategy

Participants will be recruited from clinical partner organisations that are acting as the research sites. These sites are NHS and non-NHS organisations, and recruitment will consist of two stages: First, physiotherapists will be recruited, and secondly, service users will be recruited from those that the physiotherapists are working with.

Physiotherapists

The named clinical partners are likely to be therapist participants, but there may also be other therapists working in their services who are interested in participating. The UWE researcher will email the physiotherapists an information booklet prior to meeting with them virtually. At this virtual meeting, they will discuss the study and the researcher will allow an opportunity to ask any questions. In accordance with the UK Policy Framework for Health and Social Care Research, the researcher doing the recruitment procedure has completed training in Good Clinical Practice (GCP). If the physiotherapist provides verbal consent virtually then they will be emailed a consent form. It will be stressed that they should consider their participation before returning their consent form. If the physiotherapist still wants to participate in the study, then they will return the completed form the UWE researcher via an encrypted email. ~~At the first site visit at the clinical partner organisations, the UWE researcher will provide the physiotherapists with information about the study and written consent will be required for participation. In accordance with the UK Policy Framework for Health and Social Care Research, the person doing the recruitment procedure will have completed training in Good Clinical Practice (GCP).~~

Patients

Since the study requires participants in dyads (therapists and their patients in pairs), the patients will be identified by participating therapists. The therapist will give the patient information about the study (PIS) and if the patient is interested in finding out more about the study, the therapist will ask their permission to pass contact details onto the research team. This researcher~~person~~ will be familiar with the correct and ethical recruitment procedures of GCP.

The research physiotherapist or research nurse providing information about the study will clearly state that the study will involve two recording sessions: 1. recording of the patient's physiotherapy assessment and 2. a subsequent appointment where the biomechanics of the patient's movements are measured. The research physiotherapist or research nurse will explain that the patient may consent to participating in the study but if they decide not to continue with the second appointment, they may withdraw their consent and not participate in biomechanical measures if they so choose. The physiotherapist will stress that participation is voluntary and that they will not expect the patient to agree to participate if they do not want to and that their treatment will not be affected if they decide not to participate or if they withdraw their consent at any time.

The physiotherapist will return the completed consent to contact form to the researcher. The UWE researcher will contact the patient via the telephone or virtually, explain the study and offer the person an opportunity to ask questions. If they decide they would like to take part, they will be sent a consent form via email or the post. The patient will be asked to sign the consent form before their physiotherapy assessment and return it to their physiotherapist. These consent forms will be returned to the UWE researcher by the physiotherapist. During this phone ~~,~~call the researcher will also highlight supplementary consent (see p.6), and ask the patient to consider this. The physiotherapist will have spare consent forms in the event of the patient forgetting to bring their form but wanting to participate.

The recruitment strategy will ensure that patients recruited are judged by their physiotherapists to be suitable for the study, to understand their expected burden from participation, to have capacity to consent and also understand that they may withdraw consent at any time.

~~The patient will be provided with a consent to contact form with the PIS, and if they are happy to be contacted by a member of UWE's research team, the physiotherapist will ask them to complete this form and return it to them. The UWE researcher will contact the patient and, if the patient consents, they will meet with the researcher and have an opportunity to ask questions and consider participating. It will be stressed that participation is voluntary and not an expectation of their~~

~~physiotherapist. They will be given time to consider participation. If they decide to take part they will be asked to sign a consent form. These consent forms will be returned to the UWE researcher.~~

Other persons

At the time of the data collection, the physiotherapist may be accompanied by a Rehabilitation Assistant or they may ask for the help of a family member, carer or other person. This would result in this person(s) being in the video. Therefore, this person will be provided with a shortened PIS and a consent form which are tailored to their limited involvement. The person will read and complete this consent form before being video recorded.

~~The recruitment strategy will ensure that patients recruited are judged by their physiotherapists to be suitable for the study, to understand their expected burden from participation, to have capacity to consent and also understand that they may withdraw consent at any time.~~

Supplementary consent

As we will be recruiting patients to the study when they are still dealing with the initial ordeal of stroke, we will re-contact participants whose videos we would like to share outside of the team for future presentations two months after gaining their initial consent to participate in the study. We will only contact those whose videos we would like to include in presentations and therefore only a small number of patients will be contacted.

Before telephone calling the patient participant, the researcher will contact the patient's physiotherapist to receive an update on the health and general well-being of the participant. This will reduce the risk of the researcher contacting the relative of an unwell or deceased patient, or contacting the patient inappropriately. The physiotherapist will check their system for information on the patient's health; patients will have already consented to this in their initial consent form. If there are any challenges in confirming the health status of the individual patient, then this patient's video will not be used, in order to reduce the burden on the physiotherapists.

If it is confirmed ~~as~~ appropriate ~~to be able~~ to contact the patient participant, the researcher will telephone them and explain how the videos would be used. If the patient expresses initial verbal consent for the use of videos, the researcher will email the participant a supplementary consent form and ask the participant to wait at ~~organise a time to visit the participant~~ allow~~at their home at~~ least 48 hours after the telephone call before completing the form and returning it to the researcher via email. This will allow the patient time to review their decision. ~~On this home visit the researcher will answer any questions the patient may have regarding the use of their video. If the patient consents to the use of their video for the purposes outlined above, the researcher will ask them to sign and return a supplementary consent form on that visit.~~ This supplementary consent form clearly outlines how the videos would be used and states that any personal identifiers will be removed and faces will be pixilated. If the participant does not have access to a computer, printer or for some other reason is unable to return the consent form by this method, then they may alternatively provide verbal consent. If the participant expressed initial consent, the researcher would inform the participant that they would ring them again in 48 hours and record them verbally providing their consent. Both these methods remove the need for face to face contacts of the researcher and participant and therefore eliminate potential COVID-19 transmission.

The physiotherapist participants will also be asked for their supplementary consent for the use of their video(s); this consent will only be requested from the physiotherapists whose videos we intend on using for presentations outside of the research team. If verbal consent is provided over the telephone, the physiotherapist will be emailed a consent form. Alternatively, they may over the telephone provide verbal consent; this would be recorded on a Dictaphone. Others who may be filmed in the assessment, such as Rehabilitation Assistants, carers or family will not be contacted two months later, as this would result in the unnecessary collection of their personal data. The faces of these person(s) will be pixilated in the videos we intend on using outside of the research team and this is clearly stated in the PIS and consent form. As the research team will need only a small number of videos to provide examples in presentations, the team will aim to select videos in which do not feature persons classed as 'others' or passers-by.

Data collection

Patient demographic data

To enable patient case description the following participant characteristics will be collected via the therapist:

Gender, age, reason for admission to service, any relevant pre-existing diagnosis that would affect mobility, information about current clinical condition affecting mobility. In the case of stroke, this will include date of stroke, side of stroke and type of stroke.

These participant characteristics will be pseudonymised, participants' details will be entered under a participant ID code onto a secure Excel spreadsheet created for the study.

Observational data

1. *Video recording of physiotherapy practice using talk aloud ~~and qualitative clinical measures~~*

As a result of coronavirus restrictions, it may be a researcher recording the assessment or, in order to reduce unnecessary face-to-face contacts, it may be a physiotherapist,.

A researcher or physiotherapist will set up the video camera and move it around to get the best view of the physiotherapist's interaction with the patient. The therapist will carry out their assessment of the patient's movement as per normal, but they will be talking aloud through the process for the benefit of the researchers' understanding. The recording will include the patient carrying out the mobility task of interest but may also include 'off task' assessment that the therapist does to diagnose movement components and impairments that have a bearing on task performance. Care will be taken to carry out the assessment in a quiet environment and to avoid including passers-by in the recording. Hospital settings are particularly busy environments with limited space and, therefore, it is not possible to fully eliminate the chance of video capturing a passer-by. In the event of filming a passer-by, the person will be anonymised through pixilation of their face and body before processing the data.

At the same occasion of the recording of the assessment, if the researcher has recorded the video. ~~the researcher~~they ~~will~~ will also take quantitative clinical measures of the patient participant.

2. *Review of the video recording and interview with the therapist*

At a convenient time within a few days of the video recording, the researcher will review extracts of the video recording with the therapist to allow elaboration and clarification of the process. This interview will be audio recorded on a Dictaphone; 48 hours after the interview the recording will be saved on to a restricted access, password-protected, One Drive project folder and the recording will be deleted off the device. Once the interview has been transcribed and identifiers removed from the transcript, it will be uploaded to the shared One Drive project folder.

Alternatively, if COVID-19 does not allow a face to face interview, the interview will take place over a virtual platform such as Zoom or Teams, at the preference of the physiotherapist. The researcher will share their screen in order for the physiotherapist to view the video. The interview will be recorded on the platform and immediately after the interview the recording will be saved on to a restricted access, password-protected, One Drive project folder. Once the interview has been transcribed and identifiers removed from the transcript, it will be uploaded to the shared One Drive project folder.

~~*3. Quantitative Clinical Measures*~~

~~4.~~3. *Biomechanical Measures of Functional Performance and Quantitative Clinical Measures*

Quantitative Clinical Measures

Quantitative measures will be taken by the researcher to assess physical capability and functional performance of patient participants during a second appointment subsequent to the physiotherapy observation appointment. Devices used are CE-marked where relevant and the measures are established clinical measures that replicate routine physiotherapy assessment and may include:

Joint range: Passive and active joint range of motion will be measured using a digital inclinometer for ankle dorsiflexion/plantarflexion, knee flexion/extension and hip extension/abduction. Each joint motion will be repeated three times and the maximum value recorded.

Muscle strength: Strength of lower limb musculature (ankle dorsiflexion/plantarflexion, knee flexion/extension and hip extension/abduction) will be assessed using a CE-marked, hand-held dynamometer. Participants will push against a resistance provided by the assessor for approximately 5 seconds and the best of three efforts will be recorded.

Functional Performance: Several functional performance tests will be used to assess various dimensions of mobility where it is safe and feasible to do so with patient participants. Forward functional reach test, the distance that participants can reach from a standardised sitting or standing position and timed sit to stand tests will be used as measures of balance. Timed up and go test, the time taken to rise from a chair, walk 3m, turn, walk back and sit down and a timed walk test will be used as measures of mobility.

Biomechanical Measures

Functional performance will be analyzed using biomechanical measurement tools. Where measures are recorded in the hospital or patient's home, inertial measurement units will be used along with a pressure mat to monitor the relative motion of lower limb body segments. Where measures are recorded at the Human Analysis Laboratory, University of the West of England, a 3D optical motion capture system and force plate will be used in conjunction with the inertial measurement units to allow for comparison with laboratory reference data. The 3D motion capture system will be used to track the position of retro-reflective markers and record ground reaction force. For biomechanical measures, participants will be asked to wear shorts for testing, these can be provided by the researcher. Biomechanical measures will be taken during the three key mobility tasks, standing, sit-to-stand and walking where possible. A minimum of five trials of each task will be recorded and averaged. Hip, knee and ankle joint kinematics (motion) and kinetics (forces) will be calculated to provide information for device design specification. The equipment used will be standard, CE-marked equipment that is widely used for biomechanical assessment.

Design and setting

This is an observational study of physiotherapy practice to improve patients' functional mobility and of quantitative clinical measures and biomechanical features of patients' performance. The physiotherapy assessment and clinical measures will take place in the settings of our clinical partners, i.e. in hospital (Southmead)~~, in care homes (Domaille Neurophysio)~~ and in the patient's homes (Virgin Care and Domaille Neurophysio). These clinical partner settings will be the research sites. The biomechanical and quantitative clinical measures will be recorded in the hospital or patient's home and/or at the Human Movement Analysis Laboratory (HAL), University of the West of England. Currently, a risk assessment has been undertaken and there is a protocol in place for this data collection in HAL, which is COVID-19 secure. Collection of this data in patient homes or in a hospital environment will only take place providing site-specific coronavirus risk assessments have been undertaken and sufficient action has been taken to reduce any risk.~~.~~

The objectives will be achieved using four methods of data collection:

1. *Observation through video recording and content analysis of physiotherapist's practice in which the physiotherapist gives a commentary of their assessment process by thinking aloud* [1,2].

2. *Review of the video recording and interview with the physiotherapist to capture any missing or unclear parts of the process.*
3. *Simple quantitative clinical measures e.g. strength, range of movement, duration of task performance.*
4. *Instrumented biomechanical measurement of patients' functional performance using inertial sensors and/or optical motion capture system at UWE or in patients' homes.*

Data analysis

Objective	Data analysis
Capture and analysis of video of physiotherapists' assessment while the therapists are talking aloud their diagnostic process.	Process/content task analysis [7] of assessment of: walking; standing; sit to stand – stand to sit. Viewing video to identify key components of the assessment process and how these are performed. Determine similarities between assessment processes and the context for these (for example the processes are likely to differ with the severity of weakness, or in different environments. Determine differences between assessment processes and the context for these.
Capture quantitative clinical measures from patient participants. ~~(outside of the therapists' assessment process).~~	Collate in a movement analysis report for each patient participant and summarise measures.
Capture biomechanical analysis of patient participant's performance	Produce a descriptive movement analysis report for each patient participant. Determine similarities/differences of data collected using both inertial and optical capture systems where applicable. Collate descriptive analysis of movement for each mobility task. Identify common features of performance of each mobility task and descriptively compare to biomechanical reference values. Examine similarities and differences of biomechanical characteristics of the movement tasks descriptively and graphically.
Map results from physiotherapy assessment with clinical and biomechanical measures.	Determine how quantitative and biomechanical measures relate to physiotherapists' clinical reasoning, instructions and actions.
Determine essential components of the assessment and movement analysis process that will be needed in the design specification of devices.	Use the findings of the video and kinematic analysis to create a framework of context and processes to discuss with clinical partners the

	essential components to be in the design specification.

Data management

All data collected during this study will comply with the General Data Protection Regulation (https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/ May 2017).

The University of Bristol will be sole data controller and they will appoint the University of the West of England, Bristol, to be the data processor and both parties will comply with GDPR in accordance with an appropriate agreement. It is anticipated that UoB will not need to access participants' personal details without legitimate reason such as UoB's right as the sponsor to inspect any records relating to monitoring, source data verification and adverse event reporting or investigation, as appropriate. Participant information sheets clearly state that UoB may access the participant's data as study sponsor. UWE research staff will collect and store study data including personal data. Participant information sheets clearly state that members of the research team may have access to personal data. Where possible, data will be anonymised and access to personal data will be minimised.

Data will be stored on One Drive which is a secure, password-protected system that complies with both UoB's and UWE's Information Security Policy and the General Data Protection Regulations. There will be two separate One Drive folders in order to manage data access:

1. A restricted folder, which only the UWE researcher will be able to access. This folder will store personal data such as consent forms and contact details. UWE and UoB team members will not be able to access this data unless necessary; the Research Fellow will allow folder access to other team members only if there is a legitimate reason.
2. A shared project folder that all the relevant UWE and UoB researchers can access. This folder will store collected data which has been pseudonymised or anonymised.

The physiotherapists will receive completed consent to contact forms from patients and will store them in a secure on-site filing cabinet. Within 48 hours of obtaining them, the physiotherapist will scan these forms on to a site computer and they will immediately send them to the UWE researcher via an encrypted email. The physiotherapist will destroy the paper copy once the UWE researcher has confirmed receipt of the form. The footer of the consent to contact form clearly states the protocol for data transfer and data storage. The personal details of those who decide not to take part will be deleted from the Excel spreadsheet and their scanned consent to contact forms will be deleted. The research team will only retain the personal details of those who consent to participate in the research.

Each participant will have an identification code which will be recorded in the footer of the consent form. The consent forms for the physiotherapist, patient and, if relevant, 'other persons' who were in the same video will be connected via a 'Case identification code' in the footer of each consent form. The case identification codes and participant identification codes will be recorded in an Excel spreadsheet and stored in the restricted access One Drive folder.

Video recordings will be stored briefly on the camera recording device which will be stored in a secure locked case. ~~Daa~~Data collected from the IMUs and pressure mat will be saved on a password protected and encrypted laptop. All data on these portable devices will be transferred by the researcher to the shared One Drive project folder. The researcher will make the transfer from the recording equipment to the team's shared project folder within 48 hours, via a secure network connection (as opposed to via remote Wi-Fi access). Once the data is securely transferred and backed up, data will be deleted from the cameras and laptop. This electronic data will have a pseudonymous file name through the use of a unique case identification code; these codes will be stored in the restricted access One Drive project folder.

The participants' faces will be pixelated in the videos that they have consented to be shown outside of the research team. These video files will have a pseudonymous file name through saving them under the case identification codes. The pixelated versions of the videos will be saved in the shared project folder that will be accessible by members of the UWE and UoB research team.

The biomechanical data that will be collected at UWE's Human Analysis Laboratory will also be stored on the One Drive project folder and the file name will be pseudonymised. Only the UWE researcher will have access to the re-identification codes for the video and biomechanical data. These re-identification codes will be stored in a restricted access One Drive project folder. In the event of the UWE researcher leaving the project for unforeseen circumstances, there will be the instructions for accessing the re-identification codes. The UWE Principal Investigator will become custodian to the re-identification codes and will have access to this folder.

Data pertaining to publications will be made available on the UoB and UWE's data repositories. At recruitment, participants will be informed that data put onto the repository will not contain their names and contact details.

Those participants who verbally consent to the showing of their video recordings outside the research team will all need to return a supplementary consent form to the UWE researcher. This will be done via email in order to reduce contacts and thus reduce COVID-19 transmission risk~~.~~

~~The researcher will visit these patients at their home to physically collect their supplementary consent form. The patient will keep one copy for their own records. The researcher will transfer paper supplementary consent forms to the UWE site within 48 hours and they will be stored temporarily in a UWE locked filing cabinet. These paper documents will be scanned by a UWE researcher and uploaded to a restricted access, password-protected One Drive project folder within 48 hours of acquiring the documents. Paper copies of the supplementary consent forms will then be destroyed securely.~~

If the physiotherapist withdrew their consent before their assessment of the patient had been recorded on video, we would not collect other measures from the patient i.e. we would not collect quantitative outcome measures or biomechanical data. If the physiotherapist withdrew their consent after the recording of a patients' assessment, we would not collect any more data from the physiotherapist but we would keep the data we had; this is clearly stated in the physiotherapists' information booklet.

Study management

The study steering group will be CI Professor Jonathan Rossiter (UoB), Dr Ailie Turton (UWE) and Dr Mary Cramp (UWE). The role of the steering group will include ensuring study progress, adherence to protocol and patient safety. The steering group will have regular monthly meetings with the research staff working on the project. These will be in addition to meetings held separately within the two universities, i.e. meeting between CI Jonathan Rossiter and the engineers employed on the project by UoB; and meetings between Mary Cramp and Ailie Turton with the Research Fellow at UWE.

The progress of the project will be monitored and audited with reference to the protocol and timeline. Safety will be managed with risk assessments for study involving human participants and by communication with our clinical partners. The University of the West of England requires researchers to enter project details for governance purposes onto a Research Governance Record. This is reviewed quarterly by the Associate Head of Department for research.

The Sponsor, the University of Bristol is responsible for the overall management and conduct of the study.

ETHICAL AND GOVERNANCE ISSUES:

The study conducted will be subject to and NHS ethical opinion and Health Research Authority Approval.

Indemnity and insurance: Covered by University of Bristol and University of the West of England.

Consent

Informed consent will be obtained prior to data collection from participants by GCP trained researchers at the University of the West of England.

Confidentiality

Participants will be provided with an unique identification code at the time of recruitment into the study. Any information collected about the participant will be labelled with the identification code and will not contain names or contact details of participants. Identifiable information used initially for the patient recruitment on consent forms will be scanned by the UWE researcher and uploaded to the restricted access folder on the secure server password protected project folder. Paper copies of these forms will be destroyed.

Only members of the research team will have access to the personal data as required for the purposes of the study. Where possible, only the researcher collecting personal data, such as names and telephone numbers, will access this data. The research team will have access to the video data; this is described in the participant information sheets. After completion of the study, anonymised data will be stored on UoB and UWE research data repositories. No individuals will be identifiable by anyone outside the research team, from the saved data or from the published results. The exception to this will be video extracts from participants who give consent for these to be used for dissemination and training purposes. This consent will be supplementary to consent to participate in the study.

~~Harms~~Harms and COVID-19 risk

No harms are anticipated due to the study. We are not providing any new intervention or taking anything away from usual care. The potential to cause distress to patient participants is mitigated by identifying suitable participants via the therapist. We will work with the clinical partners to smooth the research processes and therefore minimise any burden of their therapists' participation.

Patient participants are at a potential risk of falls during data collection due to their musculoskeletal impairments or impairments from stroke. However, this risk is low as there is continuation of patients' physiotherapists, therefore therapists will be fully aware of the patient's impairments and subsequent necessary management of risk. Furthermore, the collection of quantitative outcome measures and biomechanical data will be undertaken by a UWE researcher who is a HCPC-registered physiotherapist; the researcher will therefore be fully competent in falls risk assessment and subsequent reduction of risk. The researcher who will be with the patient participants for the collection of clinical measurement data and biomechanics data will make sure he/she is aware of procedures and precautions used in mobilising each patient participant.

The study will collect outcome measures that are part of an ordinary physiotherapy assessment, consequently, patients should be at no greater risk during data collection than they were in previous physiotherapy assessments.

In the unlikely event of poor clinical practice, the researcher would have a duty to break confidentiality and must raise their concerns with the physiotherapist's service lead or the Health and Care Professions Council. The researcher would immediately notify the sponsor of any adverse events/harms caused by poor clinical practice and the sponsor's procedure for reporting of adverse events would be implemented.

There is a potential risk of allergic reaction to adhesive tapes used for biomechanical analysis, this will be offset by use of hypoallergenic tape.

In order to reduce the risk of Covid-19 transmission, unnecessary research contacts have been removed from the protocol, and sites will follow these procedures if necessary. This includes the recruitment and consent process, as the researcher no longer has physical meetings with participants for these processes; rather, they have virtual meetings or telephone calls. The original

protocol may be followed if, and only if, it is assessed as safe to do so, the study has Sponsor approval and it follows Government guidelines. The collection of biomechanical data and clinical measures will take place in HAL, which has had a full COVID-19 risk assessment. The protocol for the data from HAL includes rigorous infection control measures including: wearing of face masks; temperature checks; regular cleaning of hands; cleaning of surfaces and touch points; and quarantine of markers and straps used on participants. The research team will remain on high alert and will assess the Coronavirus risk and take the necessary action, which may include stopping the study.

Dissemination

A summary of the study results will be sent to study participants if they indicate they would want this on the consent form. An internal report will be provided for the sponsor, funder and for the study partners. Results will be shared widely via conference presentations and publication in peer-reviewed international journals and through public engagement activities.

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TIMELINE FOR STUDY