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An observational study of physiotherapy practice to determine essential processes in the assessment of walking, standing and rising from a chair in patients with stroke and in older people with musculoskeletal impairments

Submission date	**Recruitment status**	[_] Prospectively registered
17/07/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/08/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/11/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Nearly 6.5 million in the UK have mobility impairments. The largest causes of impairment are age-related changes (40% of over-60s have disabilities affecting their daily lives) and stroke (there are over 1.2 million stroke survivors in the UK). These numbers are growing as the 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 study as part of the FREEHAB project, which aims to observe physiotherapy practice and patients' performance to inform the design of wearable devices to assist in the rehabilitation of mobility. The questions the study addresses are:

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

The study's objectives are to:

1. Capture a video of physiotherapists' assessment of patients, 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 the essential components of the assessment and movement analysis process that will be needed in the design specification of devices.

Who can participate?
Physiotherapists working in clinical partner organisations with stroke or older patients to improve their mobility
Patients being seen by a physiotherapist in the clinical partner service for rehabilitation of mobility who have had a diagnosis of stroke with hemiparesis* or are an older patient (over 65) with weakness following musculoskeletal impairment (for example after joint replacement)
* Note - Time after stroke is not limited and participants may have had multiple strokes.
Potential participants with poor balance, sensory loss, visual field loss aphasia and cognitive impairments but who have the capacity to consent can be accommodated.

What does the study involve?
Physiotherapists' actions and clinical reasoning during their assessment of their patients' functional mobility will be video recorded and analysed. Quantitative clinical measures and patient participants' biomechanics during movement of interest will be collected. The analysis will determine the essential components of movement assessment, and the context of the therapists' reasoning and actions. Discussion of the findings with clinical partners will inform the design for the rehabilitative devices to be developed.

What are the possible benefits and risks of participating?
Physiotherapists will be able to reflect on their practice and have the opportunity to experience research, which can be recorded in their professional portfolio. There are no immediate benefits for the patient participants other than the satisfaction of supporting research. The study is 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. Patient participants are at 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 and a UWE researcher who is an HCPC-registered physiotherapist will be collecting biomechanical data. The study will collect outcome measures that are part of an ordinary physiotherapy assessment. There is a potential risk of an allergic reaction to adhesive tapes used for biomechanical analysis, this will be offset by the use of hypoallergenic tape.

Where is the study run from?
This is a Bristol-based study by the University of Bristol in collaboration with the University of the West of England. It involves physiotherapy partners in local NHS Trusts and Community Rehabilitation Services.

When is the study starting and how long is it expected to run for?
November 2019 to October 2023

Who is funding the study?
Engineering and Physical Sciences Research Council (UK)

Who is the main contact?
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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
264069

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 264069

Study information

Scientific Title

FREEHAB study 1: physiotherapy analysis of functional mobility: walking, standing and transfer in stroke and older people

Acronym
FREEHAB

Study objectives
The purpose of this observational study is to determine specifications for end-user cases for improving walking, standing and sit to stand movements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2020, South West Frenchay Research Ethics Committee (Bristol HRA Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8360, +44 (0)207 104 8041; frenchay.rec@hra.nhs.uk), REC ref: 20/SW/0092

Study design
Observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
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)

Interventions
Physiotherapists’ actions and clinical reasoning during their assessment of their patients’ functional mobility will be video recorded and analysed. Quantitative clinical measures and participants' biomechanics during movement of interest will be collected. The analysis will determine the essential components of movement assessment, and the context of the therapists’ reasoning and 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.

Intervention Type
Other

Primary outcome(s)
Measured at a single timepoint:
1. Lower limb joint range of motion (passive and active) measured using a digital goniometer
2. Strength of lower limb musculature (ankle dorsiflexion/plantarflexion, knee flexion/extension and hip extension/abduction) measured using a Lafayette Hand-held Dynamometer
3. Functional performance measured using forward functional reach test and timed up and go

test
4. Biomechanical measures of pelvic and lower limb motion using three-dimensional motion capture

Key secondary outcome(s))
Collected from patients' medical notes at a single timepoint:
1. Patient's gender, age
2. Reason for admission to service
3. Any relevant pre-existing diagnosis that would affect mobility
4. 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

Completion date
31/10/2023

Eligibility

Key inclusion criteria
Patients:
1. 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)
2. Being seen by a physiotherapist in the clinical partner service for rehabilitation of mobility (standing balance, transfers or walking)
3. Medically stable
4. Mental capacity to consent to the study according to members of the clinical team who are working with the patient
* 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

Physiotherapists:
Physiotherapists who are working in clinical partner organisations with stroke or older patients to improve their mobility

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
65 years

Sex
All

Total final enrolment
30

Key exclusion criteria
Patients:
1. Diagnosis of neurological condition, other than stroke
2. Concurrent acute musculoskeletal conditions (e.g. fractures, sprains) which prevent weight-bearing
3. Morbidly obese - BMI > 40 kg/m2
4. Presence of ataxia
5. Judged by therapists to have a functional neurological disorder
6. Judged by therapist to have depression or anxiety that might prevent participation, or become increased because of participation in the study

Physiotherapists:
Less than 2 years' experience of working with stroke or older patients

Date of first enrolment
04/08/2020

Date of final enrolment
24/02/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital North Bristol NHS Trust
Bristol
United Kingdom
BS10 5BN

Study participating centre
St Martin's Hospital
Virgin Care
Bath and North East Somerset
Bath
United Kingdom
BA2 5RP

Study participating centre
Colin Domaille
Not applicable (community provider)
Bristol and South West

United Kingdom
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Research council

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Participant level data will be available on the University of the West of England's research data repository. All data that is made available will be anonymised and will not include video data.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 0.3	12/01/2021	07/11/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes