# 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 No longer recruiting	Prospectively registered		
17/07/2020		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
14/08/2020	Completed  Condition category	Results		
Last Edited		Individual participant data		
12/11/2024	Other	[X] 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 agerelated 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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## Contact information

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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

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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)

EPSRC Engineering & Physical Sciences Research Council, UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, The Engineering and Physical Sciences Research Council (EPSRC), EPSRC

#### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Protocol file</u>	version 0.3	12/01/2021	07/11/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes