

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 17/07/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/11/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?

Jonathan Rossiter

jonathan.rossiter@bristol.ac.uk

Study website

<https://therighttrousers.com/>

Contact information

Type(s)

Public

Contact name

Prof Jonathan Rossiter

Contact details

Bristol Robotics Laboratory
Coldharbour Lane
Frenchay
Filton
Bristol
United Kingdom
BS16 1QY
+44 (0)117 3315601
jonathan.rossiter@bristol.ac.uk

Type(s)

Public

Contact name

Dr Leah Morris

ORCID ID

<https://orcid.org/0000-0002-4651-1514>

Contact details

Allied Health Professions, Faculty of Health and Applied Sciences
University of the West of England, Glenside Campus, Blackberry Hill
Bristol
United Kingdom
BS16 1DD
+44 (0)117 3286908
Leah.Morris@uwe.ac.uk

Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

264069

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Case series

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

04/11/2019

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

Participant type(s)

Mixed

Age group

Adult

Lower age limit

65 Years

Sex

Both

Target number of participants

30 patients, 6 physiotherapists

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**

England

United Kingdom

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
-

Sponsor information

Organisation

University of Bristol

Sponsor details

1 Cathedral Square
Bristol
England
United Kingdom
BS1 5DD
+44 (0)117 9289000
research-governance@bristol.ac.uk

Sponsor type

University/education

Website

<http://bristol.ac.uk/>

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, EPSRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/10/2025

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

Stored in repository

Study outputs

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