ISRCTN12643856 https://doi.org/10.1186/ISRCTN12643856

FREEHAB clinical evaluation of a prototype physiotherapy device

Submission date
06/06/2023

Recruitment status
No longer recruiting

Registration date
14/06/2023

Overall study status
Completed

Last Edited
29/04/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Each year in the UK 100,000 people have strokes. Stroke can cause one-sided weakness of the body and difficulties with physical functions. Physiotherapy aims to improve the mobility of individuals, with repetitive movements crucial for re-learning motor functions. Physiotherapy sessions are restricted by staffing capacity and therapist fatigue. Exoskeletons may ameliorate these challenges; however, rigid exoskeleton development has been poorly informed by clinical expertise and uptake is poor. The FREEHAB study is part of The Right Trousers project, which is the development of soft exoskeletons for use in stroke rehabilitation. The developed device for testing is a soft wearable that will provide some physical assistance to help the patient to perform the sit-to-stand (STS) motion (moving from a sitting position in a chair to a standing position).

Who can participate?
People who have had a stroke or a traumatic brain incident and as a result have a weakness

What does the study involve?
This is a non-randomised clinical investigation of the effects of a wearable device for improving patients' performance in moving from STS and of the safety and acceptability of the device when worn in a single test session. Biomechanical features of patients' performance will be collected and compared when participants (patients) are performing their STS when (i) not wearing the device (ii) when it is worn but not active and (iii) when wearing the device and it is active, in either of two assistance modes. A qualitative assessment of patient participants' perceptions of the acceptability and usefulness of the device will also be collected. Incidents when trialling the device will be logged and safety will be assessed.

The performance of the device for assisting STS will be assessed using STS movements. Continuous trunk, hip, knee and ankle joint angles will be recorded using a Qualysis camera-based movement analysis system and Inertial Measurement Units (IMUs). Weight distribution between the feet will be recorded using a FOOTSCAN pressure mat. Clinical measures of impairment describing the ability of the participant will be taken and used to determine the amount of assistance provided by the device. Any adverse events or malfunctions in the device during the investigation will be logged. Serious adverse events will be reported to the sponsor

on the day of its occurrence. Participants will be asked to complete a questionnaire to determine the acceptability of the device and the improvements needed.

What are the possible benefits and risks of participating?
There is no particular benefit to the participant. There is a very low risk of a fall.

Where is the study run from?
The investigation will take place at the Human Movement Analysis Laboratory, University of the West of England. The University of Bristol is the study Sponsor overseeing the project (UK)

When is the study starting and how long is it expected to run from?
July 2022 to November 2024

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

Who is the main contact?
Dr Leah Morris, leah.morris@uwe.ac.uk (UK)

Study website
https://therighttrousers.com/

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316393

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 316393; EPSRC Grant Ref: EP/S026096/1

Study information

Scientific Title
FREEHAB within session evaluations of a prototype device for improving patients' sit to stand movements

Acronym

FREEHAB

Study objectives
H1 – Wearing the device when it is active will improve the participant's kinematic performance of sit-to-stand (STS) tasks and time to STS, compared with not wearing the device and when wearing it switched off.
H2 – The hazard mitigations will be effective and there will be no adverse events experienced from wearing the device.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/08/2023, West of Scotland REC 4 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 23/WS/0111

Study design
Non-randomized single-centre study design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment, Safety

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
Stroke or acquired brain injury

Interventions
This is a small non-randomised clinical investigation of sitting-to-standing performance in a controlled laboratory setting, followed by a questionnaire about the acceptability of an assistive robotic knee device. The study is undertaken from a single centre and the sample will be purposefully selected.

The patients involved are people who have had a stroke or a traumatic brain incident and as a result, have a weakness. The investigation population will have a moderate disability in that they will be capable of carrying out sit-to-stand tasks but will be slow in performance. This is so the study team can measure changes in performance attributable to the use of the devices.

The proposed wearable device is a modular soft wearable device that will provide some physical assistance to help the participant (patient) perform the sit-to-stand motion (moving from a sitting position in a chair to a standing position).

This is a proof-of-concept study of an early prototype device using a within-subject design to compare the patient participants' performance when not wearing the device and when wearing it with the assist function switched off and wearing it when the assist is switched on and active in two assistance modes. The proposed wearable device is a modular soft wearable device that will provide some physical assistance to help the participant (patient) perform the sit-to-stand motion (moving from a sitting position in a chair to a standing position). The device has two assistance modes which will both be tested. Assistance mode 1 provides a pre-programmed assisting torque depending on the measured thigh angle, and assistance mode 2 provides a controlled assisting torque within the set timed interval.
The investigation of the first three participants will act as a pilot for this proof-of-concept study. The within-subject design controls are for heterogeneity. It will not be possible to 'blind' participants to the condition because they will know they are wearing the device and when it is active. It will not be possible to blind the investigator as they will be operating the device.

The investigator undertaking the data collection is a Research Fellow who is also a non-practising registered physiotherapist. The investigator is trained in Good Clinical Practice, is first aid trained and has expertise in qualitative research and is trained in collecting biomechanical data. At least one engineer from the research team will be present to support the investigator with the technical components.

The investigation will be undertaken in the Human Analysis Laboratory at Glenside Campus, the University of the West of England, Bristol. Participants will have body measurements and impairment measures taken and recorded, to confirm suitability for the device, to ensure the correct fit of the device and to establish assistance required from the device. Measurements will include height, weight, circumference and length of the thigh and shank, range of movement at the knee, quadriceps strength (using a handheld dynamometer), a sensory test of the lower limb, and measuring sit-to-stand time at a fast pace and a self-selected pace.

We will track the movement of the participant while performing sit-to-stand through the use of two investigational devices/systems, with the option of also using a third:
1. 3D optical motion capture system and force plate.
2. Footscan pressure plate.
3. We may use Inertial measurement units (IMUs).

They are all commercially available measurement devices. Reflective markers will be attached to the participant at key points to enable the vision-based tracking system to record participant movement based on the CAST marker model. IMU sensors may be attached to the participant at key points to enable a second means to record motion tracking. These IMUs are used for motion tracking only and are not part of the wearable device.
The investigation will be partitioned into five blocks (Blocks 1-5). Each block will consist of 3 repeated trials.
The order of blocks is as below, where blocks 2 and 4 will alternate in order, in consecutive patients. The final block (5) is included as a control measure for any fatigue that occurs over the course of the test session.
o Block 1: No device
o Block 2: Device worn and switched on and active in either assistance mode 1 or assistance mode 2 (alternate with consecutive patients)
o Block 3: Device worn and switched off

o Block 4: Device worn and switched on and active in alternative assistance mode
o Block 5: No device

For each block, the participant will be asked to move from sitting to standing 3 times.
Once the test session is complete, the participant will be provided with a 5-point Likert scale questionnaire. It is divided into 5 sections, regarding acceptability, comfort/adjustments, effectiveness, safety and weight. They will be advised that the questionnaire should take 10 to 15 minutes, but that they may take longer if required. The questionnaire is adapted from two commonly used scales, the System Usability Scale (SUS) and the Quebec User Evaluation of Satisfaction with assistive technology (QUEST).
The session will be complete and no further data collection will be undertaken with the participant.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Wearable soft robotics for independent living

Primary outcome measure
The centre of mass vertical velocity measured using a Qualysis camera-based movement analysis system and Inertial Measurement Units (IMUs) while performing the movement of sit to stand (repeated three times, for each block)

Secondary outcome measures
Knee joint velocity and weight-bearing asymmetry measured using a Qualysis camera-based movement analysis system and Inertial Measurement Units (IMUs) while performing the movement of sit to stand (repeated three times, for each block)

Overall study start date
08/07/2022

Completion date
01/11/2024

Eligibility

Key inclusion criteria
1. Diagnosis of stroke or acquired brain injury with hemiparesis (weakness on one side of the body)
2. Received or are receiving treatment from a physiotherapist in the clinical partner service for rehabilitation of mobility including sitting to standing (STS) in the previous 6 months
3. Able to STS without help from another person (e.g. physiotherapist), but may need to use a high seat and be slow to stand up

4. Medically stable
5. Mental capacity to consent to the study according to members of the clinical team who are working with the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
95 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Patients with concurrent acute musculoskeletal conditions (e.g., Fractures, sprains) which prevent weight bearing
2. Patients with skin or soft tissue damage or pressure ulcers that would impact the application of the device
3. Patients with a percutaneous endoscopic gastrostomy (PEG) feeding tube
4. Patients regularly experiencing drowsiness or dizziness
5. Patients with a diagnosis of any neurological disorder other than stroke or traumatic brain injury
6. Patients with balance problems, e.g., orthostatic hypotension, vertigo
7. Patients with a body weight in excess of 90Kg

Date of first enrolment
12/02/2024

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

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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 journal

Intention to publish date
01/08/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the publically available research repositories.

10 years after the end of the study, the anonymised data will be stored in the University of Bristol secure research data store (http://www.bristol.ac.uk/acrc/research-data-storage-facility/). Anonymised data will also be stored in the University of the West of England's secure research repository (http://eprints.uwe.ac.uk/).
These data will include biomechanical measures and qualitative questionnaire feedback. It will not be possible to re-identify the participant.
These data will be available within 3 months of the end of the data analysis. Participants will provide informed consent which will be recorded on an informed consent form.

Data will be retained in electronic forms on a secure University system in a password-protected project folder. Where paper records are used, the document will be scanned and stored electronically within 48 hours. Personal identification information will be retained in a separate folder and will be retained for up to 12 months after the end of the project and then securely deleted by the project PI. Pseudo-anonymised data will be stored in the restricted access OneDrive project folder and will be retained for up to 2 years. Data pertaining to publications will be made available on the University of Bristol and UWE’s data repositories.

IPD sharing plan summary
Stored in publicly available repository