ISRCTN84987845 https://doi.org/10.1186/ISRCTN84987845

Development of a hand exoskeleton for precise stretch and resistance measurement in hand spasticity assessment

Submission date
17/12/2023

Recruitment status
Recruiting

Registration date
23/04/2024

Overall study status
Ongoing

Last Edited
19/03/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Many people who have had a stroke face a tough challenge with hand spasticity. This can make muscles overactive and probably lead to a clenched fist, making it hard to use the hand. If not treated correctly, this can get worse and lead to permanent tightness. This study aims to test a newly designed device developed by the study team, a hand exoskeleton, to see how well it can measure and distinguish different levels of resistance in the hand joints. By understanding this, the study hopes to improve how doctors and therapists assess hand spasticity and, ultimately, help in the treatment and recovery of stroke survivors.

Who can participate?
Adults aged 18 years old and over who are suffering from hand spasticity

What does the study involve?
The study is specifically looking for individuals who experience some stiffness in their hands but can still move their fingers to a certain degree. Both men and women can participate, and they do not need to be in perfect health, as long as their stroke and hand condition fit the inclusion criteria. Physiotherapists will use the exoskeleton to conduct the experiments on participants, which will gently move their main finger joints at different speeds. Each participant will experience several trials, and the sensor data will be recorded and collected during the experiments. There is no need for any medication or invasive procedures—it's all about measuring movement.

What are the possible benefits and risks of participating?
Participants will not directly benefit from taking part in the study, but they will contribute to a greater understanding of hand spasticity, which may benefit future stroke survivors. The risks are minimal. Some might feel a little discomfort when moving their fingers, but we will be careful to avoid any significant discomfort or pain.

Where is the study run from?
The study will be conducted at the Charles Bell Pavilion in Astley Ainslie Hospital, Edinburgh, under the supervision of the hospital's specialised staff member, Dr Alyson Nelson.

When is the study starting and how long is it expected to run for?
December 2023 to October 2025

Who is funding the study?
EPSRC Centre for Doctoral Training in Robotics and Autonomous Systems under the grant reference EP/S023208/1

Who is the main contact?
Hao Yu (a PhD candidate) and his academic supervisor, Dr. Mustafa Suphi Erden, are leading the study, they can be reached for further information at hy2020@hw.ac.uk.

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
336874

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 336874

Study information

Scientific Title
Validation of a novel hand exoskeleton for discriminating hand spasticity levels in post-stroke patients based on stretch-induced resistance

Acronym
HEXAS (Hand EXoskeleton for Assessing Spasticity)

Study objectives
This study is a device evaluation and diagnostic testing study. It aims to validate a new hand exoskeleton for assessing spasticity and advance the assessment of hand spasticity in post-stroke patients, addressing the unreliability of traditional manual assessment methods like the Modified Ashworth Scale (MAS). These conventional techniques, while widely used, lack consistent reliability and precise quantification, especially in differentiating neural and non-neural components of finger joint resistance. Our novel hand exoskeleton prototype shows promise in overcoming these limitations by providing objective, data-driven assessments based on stretch-induced resistance of finger joints. Although previous prototype testing on healthy individuals has demonstrated its movement and measurement functionality and safety, there is a critical need for experimental data from actual patients with hand spasticity. This study will analyse the sensor data collected with the exoskeleton prototype in the experiments to test two hypotheses:
1. The hand exoskeleton is capable of differentiating healthy individuals and those with hand spasticity.
2. The hand exoskeleton is capable of discriminating spastic hands with different MAS scores (0, 1, 1+, 2, and 3)

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted 15/12/2023, National Health Service Research Ethics Committees (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom)

Study design
Single-centre experimental study

Primary study design
Observational

Secondary study design
Device evaluation and diagnostic testing study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not avaliable in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Assessment of hand spasticity in adult patients 1 week to 6 months post-stroke, with a Modified Ashworth Scale (MAS) score of 0-3.

Interventions
Initially, participants will be assessed for spasticity using the Modified Ashworth Scale (MAS) by a physiotherapist. Before deploying the device, the researchers will measure the length of each finger segment and estimate the natural range of motion (ROM) for the main joints of their dominant hand suffering from spasticity. These measurements will then be input into the exoskeleton's control software. The exoskeleton will be utilised to extend and flex these joints at various speeds ranging from 30 to 300 degrees per second (in 30-degree-per-second increments, from slow to a speed that would cause discomfort, staying within their ROM). Five trials will be conducted at each speed, during which joint angles and resistance forces will be recorded for subsequent analysis. After using the exoskeleton, participants will be asked to complete the System Usability Scale about their experience with the device.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hand exoskeleton

Primary outcome measure
1. Hand spasticity measured using the Modified Ashworth Scale (MAS) by a physiotherapist at baseline
2. Features of the experimental data (e.g. mean resistance force) will be identified and used as the variables of hypothesis tests of the difference between healthy people and the spastic participants.

3. All experimental data will also undergo machine learning analysis to ascertain if any discernible patterns or characteristics can effectively discriminate between different levels of hand spasticity, as categorized by the MAS.

Secondary outcome measures
The usability of the device and user experience will be evaluated with questionnaires based on the System Usability Scale at [timepoint]

Overall study start date
15/12/2023

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Adults who have been medically diagnosed with hand spasticity
2. Participants' dominant hand is assessed as 1 to 3 MAS.
3. Participants should have the cognitive ability to understand the study and provide informed consent, as well as the ability to communicate any discomfort or issues during the study.
4. The capacity to comprehend and adhere to the study's requirements, especially important for interacting with the exoskeleton and providing feedback.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Participants should not experience severe pain in the affected hand that could be aggravated by the use of the exoskeleton.
2. Ensuring there are no medical reasons, such as specific implants or severe deformities, that would contraindicate the use of the hand exoskeleton.

Date of first enrolment
01/02/2024

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Heriot-Watt University
Riccarton
Currie
Edinburgh
United Kingdom
EH14 4AS

Study participating centre
Astley Ainslie Hospital
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Edinburgh
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EH9 2HL

Sponsor information

Organisation
Engineering and Physical Sciences Research Council

Sponsor details
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Sponsor type
Government

Website
https://www.ukri.org/councils/epsrc/

ROR
https://ror.org/0439y7842

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 publications in high-impact peer-reviewed journals and conferences in the field of robotics and rehabilitiation.

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be published as a supplement to the resulting publications.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	18/03/2024	No	Yes