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Evaluating the ability to recover finger extension with a wearable treatment ('PowerBead')

Submission date
23/11/2025

Recruitment status
No longer recruiting

Registration date
24/11/2025

Overall study status
Completed

Last Edited
24/11/2025

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
This study is looking at a new wearable device designed to help people who have had a stroke and now find it very hard to move their fingers. Around 32,000 people in the UK each year are affected in this way. The device gives two gentle signals: a small tap on the forearm and a click sound in one ear. Researchers want to see if using this device can help the brain and nerves relearn movement, making finger extension easier. The study will also check if the device is safe and easy to use at home in the future.

Who can participate?
-Healthy volunteers aged 18–75, with normal or corrected vision, and fluent in English.
-Stroke survivors aged 18–75, fluent in English, with normal or corrected vision, who had a stroke more than six months ago, are no longer receiving NHS support, and have moderate arm function based on a standard assessment.

What does the study involve?
Participants will wear the device during a single session lasting about four hours. The device will give gentle taps and clicks as part of the stimulation process. Researchers will measure changes in muscle activity and hand function before and after the session. Participants will also be asked for feedback about how easy the device is to use.

What are the possible benefits and risks of participating?
The device may help improve hand movement, but this cannot be guaranteed. The main risk is mild discomfort from wearing the device or from the tests, but these will be monitored closely. There is no surgery or invasive procedure involved.

Where is the study run from?
University College London (UK).

When is the study starting and how long is it expected to run for?
The study will start in August 2025 and is expected to finish in February 2026.

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR) in the UK.

Who is the main contact?
Dr Laura Salisbury, laura@knitregen.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Dr Laura Salisbury

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Additional identifiers

National Institute for Health and Care Research (NIHR)
208959

Study information

Scientific Title
Evaluating reticulospinal plasticity in neural circuits from a novel wearable treatment ('PowerBead') as a potential method for regaining finger extension post-stroke.

Acronym
PowerBead

Study objectives
1. Understand if RST and CST connectivity are strengthened after device use, evaluating LLSR, StartReact, AP/PA TMS and muscle response to TMS, compared before and after device usage
2. Detect changes in hand function, evaluate finger strength and individuation using a 5 digit force transducer
3. Evaluate device useability via participant feedback
4. Optimise device, participant inclusion criteria thereafter

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 17/06/2025, UCL Ethics Committee (Academic Services, University College London, Gower Street, London, WC1E 6BT, United Kingdom; +44 203 108 8216; ethics@ucl.ac.uk), ref: 1378

Primary study design
Interventional

Study design
Single-centre interventional non randomized controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Recovery of finger extension post-stroke with survivors who are moderately to severely impaired

Interventions
Participants are randomized into a single-arm intervention study to receive the wearable device delivering non-invasive dual stimuli. The device delivers a two-step stimulation: a mechanical tap that activates the extensor digitorum muscle in the arm, followed by an auditory click delivered through a single earphone on the contralateral side of the body. Each treatment session consists of a four-hour stimulation cycle. The intervention is administered according to the device's standard operating procedures, and no placebo or sham control is included in the study. Participants receive a single treatment with monitoring for adherence and safety throughout the intervention period.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
PowerBead

Primary outcome(s)
Increased reticulospinal drive associated with startle reflex activation measured using custom StartReact code via EMG before and after the administration of the PowerBead treatment.

Key secondary outcome(s)
1. Neurostimulation data measured using AP/PA TMS with and without startle, before and after the administration of the PowerBead treatment.
2. Degree of finger extension measured using motion capture data collected via lab camera, before and after the administration of the PowerBead treatment.
3. Variances in pinch and grip strength measured using a digital pinch dynamometer and grip dynamometer respectfully, before and after the administration of the PowerBead treatment.
4. Variances in muscle tone in the bicep, wrist and fingers measured using the Modified Ashworth Scale, before and after the administration of the PowerBead treatment.

Completion date

28/02/2026

Eligibility

Key inclusion criteria
For healthy volunteers:
1. Fluent in English and able to understand the protocol and provide informed consent;
2. Aged between 18 to 75 years old;
3. Normal vision or corrected vision (using contact lenses or glasses if needed);

For stroke participants:
1. Fluent in English and able to understand the protocol and provide informed consent;
2. Aged between 18 to 75 years old;
3. Normal vision or corrected vision (using contact lenses or glasses if needed);
4. >6 months post-stroke;
5. Discharged from NHS support;
6. Fugl Meyer Assessment - Upper Extremity (FMAUE) scores between 23- 52 divided into three groups:
(a)poor, (b)limited and (c)notable functional capacity).

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
For healthy volunteers:
1. Are pregnant or possibly pregnant;
2. Have metal in the brain, skull or forearm;
3. Have any infectious diseases;
4. Have issues with dermatitis or sensitive skin;
5. Clinical history/ diagnosis of neurological, musculoskeletal, or mental disorders (including stroke);
6. Have a pacemaker;

7. Have any disorders relating to blood clotting or wound healing;
8. Have tinnitus or other hearing ailments;
9. Have a clinical history or diagnosis of epilepsy, cerebrovascular disease, dementia or increased intracranial pressure;
10. Have a history of repetitive or severe head trauma;
11. Have any primary or secondary tumours in the CNS.

For stroke participants:
1. Are pregnant or possibly pregnant;
2. Have metal in the brain, skull or forearm;
3. Have any infectious diseases;
4. Have issues with dermatitis or sensitive skin;
5. Clinical history/ diagnosis of neurological, musculoskeletal, or mental disorders (other than stroke);
6. Have a pacemaker;
7. Have any disorders relating to blood clotting or wound healing;
8. Have any lesions to the brain stem as a result of the stroke(s);
9. Have tinnitus or other hearing ailments;
10. Have a clinical history or diagnosis of epilepsy, cerebrovascular disease, dementia or increased intracranial pressure;
11. Have a history of repetitive or severe head trauma;
12. Have any primary or secondary tumours in the CNS.

Date of first enrolment
08/08/2025

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
33 Queen Square
London
England
WC1N 3BG

Sponsor information

Organisation

University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Laura Salisbury at: laura@knitregen.com

Data that will be shared includes:
- Participant characteristics: Age, self-identified gender, height, weight, BMI, subcutaneous fat levels in the forearm, date of stroke onset, type of stroke, impairment level (FMUEA score).
- Neurostimulation data: AP/PA TMS with and without startle, StartReact
- Participant's behaviour: Force data captured from a bespoke finger individuation device using force transducers to measure finger extension.
- Electrophysiology data: EMG data recording muscle activity.

Data will be available once the study has concluded, by request for up to 10 years.
Data will be shared with parties who have no conflict of interest to the research.

Consent from participants was obtained in all cases prior to data collection. Data will be anonymised and therefore not personally identifiable. Anonymised data will be stored by UCL for 10 years post project completion in accordance with UCL Records Management Policy.

IPD sharing plan summary

Available on request