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Proof of efficacy in stroke rehabilitation for a novel home-based technology

Submission date
19/03/2025

Recruitment status
Recruiting

Registration date
28/03/2025

Overall study status
Ongoing

Last Edited
19/03/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
After a stroke, many people find that the hand on their affected side is weak and poorly coordinated. This study aims to test a new approach to improving hand function after stroke.

Who can participate?
Participants should be more than 6 months after a stroke, and have moderately or mildly affected hand function.

What does the study involve?
Participants will attend our laboratory three times, with each visit separated by four weeks. On each visit, we will perform a number of assessments to determine how good hand function is, and to measure the strength of connections in the brain which control the hand. In between two of the visits (either visit 1 and 2, or visit 2 and 3, chosen randomly for each participant), participants will be issued a device which can measure hand grasp, and deliver weak electrical stimuli to a nerve in the arm. Participants will be asked to play a mobile phone game each day, using repetitive grasping movements to control the game. Electrical stimuli will be given synchronised to these movements.

What are the possible benefits and risks of participating?
If the new therapy is effective, it could enhance hand function. However, this is not certain – we are performing the trial to find this out. There are no risks of participating: the methods used are safe, and routinely used to measure hand function and motor pathways.

Where is the study run from?
The Faculty of Medical Sciences, Newcastle University (UK)

When is the study starting and how long is it expected to run for?
October 2024 to December 2026

Who is funding the study?
Newcastle University (UK)

Who is the main contact?
Prof. Stuart Baker, stuart.baker@ncl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Stuart Baker

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Improving hand function in mild-moderate chronic stroke survivors: a mobile phone game pairing repetitive movements with nerve stimulation.

Study objectives
Playing a mobile phone game involving making repetitive grasp movements paired with nerve stimulation over a 4 week period will improve hand function, measured by the following tests:
· Box and block test.
· Action Research Arm Test
· Fugl Meyer measurement
· Power and pinch grasp strength
· An objective measure of finger individuation, obtained by measuring finger flexion forces using a custom device

This intervention will also increase the strength of specific neural circuits, assessed by the following electrophysiological tests:
· Motor evoked potentials (MEPs) evoked by transcranial magnetic brain stimulation (TMS)
· Intracortical inhibition and facilitation measured using TMS
· Short-latency afferent inhibition measured using TMS
· The StartReact effect

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/12/2024, Ethics Committee of the Faculty of Medical Sciences (Newcastle University, Newcastle Upon Tyne, NE1 7RU, United Kingdom; +44 (0)1912086000; fmsethics@ncl.ac.uk), ref: 2934/52110

Study design
Interventional randomized cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improvement of hand function in stroke survivors

Interventions
All participants will make three visits to the laboratory, separated by 4 weeks each (i.e. visits at week 0, week 4 and week 8). On each visit, the following measurements of hand function and neurophysiological assessments of pathways will be made:
· Box and block test
· Action Research Arm Test
· Fugl Meyer measurement
· Power and pinch grasp strength
· An objective measure of finger individuation, obtained by measuring finger flexion forces using a custom device
· Motor evoked potentials (MEPs) evoked by transcranial magnetic brain stimulation (TMS)
· Intracortical inhibition and facilitation measured using TMS
· Short latency afferent inhibition measured using TMS
· The maximal M wave

Participants will be randomised into two arms of the study. One group will receive the intervention between visit 1 and visit 2. The second group will receive the intervention between visit 2 and visit 3. Oddly recruited patients are to have device between visits 1 and 2, even recruited patients are to have device between visits 2 and 3.

The intervention will be to play a game on a mobile device. The game will require participants to perform repetitive hand grasp movements, squeezing a custom manipulandum which will register each grasp with a switch closure. The game gives regular auditory cues; participants are required to synchronise their movements to these cues, making performance highly reliable in

timing. Movements will be made in set of four; on the fourth movement, an electrical stimulus to the ulnar nerve will be given, precisely timed relative to the movement. A custom device will register the grasp movements, and deliver the electrical stimuli; it will connect to the mobile device over a Bluetooth connection, allowing input/output to and from the game.
Participants will be requested to perform around 200 sets of four repetitive movement each day for the four weeks that they are allocated the game to play.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
The Movemend Stimulator

Primary outcome(s)
Hand function will be assessed using the Box and Block Test, which counts the number of wooded blocks which can be transported across a barrier in one minute. This will be measured at each visit. Measures will be made in both most affected and least affected hand.

Key secondary outcome(s))
1. Hand function measured using Action Research Arm Test at each visit
2. Impairment measured using the Fugl-Meyer score at each visit
3. Power grip strength measured using a Jamar dynamometer at each visit
4. Pinch grip strength measured using a pinch grip dynamometer at each visit
5. Finger individuation measured using a custom device which measures digit flexion force at each visit
6. Motor evoked potentials in the first dorsal interosseous and flexor digitorum superficialis muscles measured using TMS over the motor cortex at a range of intensities above resting motor threshold, at each visit
7. Intracortical inhibition and facilitation in the first dorsal interosseous muscle measured using TMS over the motor cortex and electrical stimulation of the ulnar nerve at the wrist, at each visit
8. Short-latency afferent inhibition in the first dorsal interosseous muscle measured using TMS over the motor cortex and electrical stimulation of the ulnar nerve at the wrist, at each visit

Measures 3, 4 and 5 will be assessed in both the most affected and least affected hands. All other measures will be assessed only in the most affected side.
The improvement in all measures from visit 1 and visit 2 will be compared between those patients who used the game over this time, and those who did not.
For patients who used the game between visit 1 and 2, the improvement from visit 1 to visit 3 will be used to assess whether there is a long-term benefit of the therapy.
For patients who used the game between visit 2 and visit 3, the improvement from visit 2 to visit 3 will provide supplementary information on the efficacy of the therapy.

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. Community based stroke survivor
2. More than 6 months after suffering an ischaemic or haemorrhagic cortical or subcortical stroke of mild or moderate severity (Upper Extremity Fugl-Meyer score 29 or greater)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Aphasia or other language problem making understanding the study and giving consent difficult (this only relates to medical difficulties caused by the stroke; for people with poor English language skills, a suitable translator will be arranged)
2. Cognitive impairment making understanding the nature of the study and giving informed consent difficult
3. Metal implants in the brain or skull, which would be a contraindication for transcranial magnetic brain stimulation (TMS)
4. A history of epilepsy (also a contraindication for TMS)
5. Shoulder subluxation, pain or other musculoskeletal difficulties such as contractures
6. An aversion to loud sounds

Date of first enrolment
31/03/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University of Newcastle Upon Tyne
Henry Wellcome Building
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
University/education

Funder Name
Faculty of Medical Sciences, Newcastle University

Alternative Name(s)
FMS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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 stored in a publicly available repository (data.ncl.ac.uk)

Shared data will comprise a spreadsheet containing individual measures for all participants. All data will be anonymised.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/03/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes