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Rehabilitation using virtual gaming for hospital and home-based arm and hand exercise post stroke

Submission date	Recruitment status	[X] Prospectively registered
05/01/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/01/2025	Circulatory System	

Plain English summary of protocol

Background and study aims

Problems with arm function are very common after a stroke. The best treatments for the arm and hand are those that help the stroke survivor practice moving their arm and hand, and that movement needs to be repeated many times. Stroke survivors say that this repetition of movement can be boring, so playing specially designed games with the NeuroBall maybe one way of increasing practice time, while at the same time being motivating and enjoyable. The NeuroBall is a device that has been designed by engineers (www.neurofenix.com), stroke survivors and therapists specifically for rehabilitation of the arm and hand following stroke. Researchers have safely used this device in the community with established stroke survivors (i.e. more than 6 months after stroke) with positive results. They now want to test if the device is safe, enjoyable and easy to use (and/or any challenges) for the stroke survivor in the earlier stage of their stroke recovery (i.e. while still on the stroke unit and/or during the early weeks at home). Results from the study will help decide if a future study is needed. The researchers will also test if participants are willing to be allocated to one of two different treatment groups.

Who can participate?

Patients who have had a recent stroke, are either an inpatient on the hospital stroke unit or transferred home with the early supported stroke discharge team) and have problems moving their arm and or hand.

What does the study involve?

This study takes place either in the hospital stroke unit and/or in the home; the research assistant (a specialist neuro-physiotherapist) will come to see the participants for all appointments. All participants will be asked to take part in a number of physical assessments for their arm and hand function and complete a range of questionnaires. These measures will be repeated again at the end of the study, and the research assistant will be available to help if needed. Participants will then be allocated by chance to one of two groups, either to receive the NeuroBall intervention alongside their usual care or continue with usual care. If they are allocated to the NeuroBall intervention group in addition to exercises given to them by the therapy team, they will be trained how to use the NeuroBall device and receive your own

NeuroBall device to help them practice moving their arm and hand for the next 7 weeks. Time spent using the device will be incrementally increased depending on levels of fatigue or how energetic you may feel. The device will automatically capture the number of times the NeuroBall is used, and for how long and how many exercises are done each session. Technical and clinical help is available if needed throughout the study period. If participants are in hospital when they start using the NeuroBall they will be able to take it home with them for the remainder of the 7-week training period. The research assistant will follow them up at home to check everything is set up for them to continue safely using the device. Participants allocated to the usual care group will continue with their normal treatment for the duration of the study.

What are the possible benefits and risks of participating?
As the researchers are still testing the NeuroBall they cannot promise that taking part will bring any direct benefits. Participants will have 7 weeks of access to the NeuroBall to help them exercise your arm and hand. Participants allocated to the usual care group will be given the opportunity to trial the NeuroBall if the study results indicate a positive outcome.
There is a small risk that participants may experience arm pain or discomfort as a result of using the device but this will be carefully monitored and advice provided as required. There is also a very small risk of the NeuroBall inducing epilepsy (a fit), but this has not been reported in any previous study using video game devices. Motion sickness, headache and eye strain are other possible but unlikely risks. Some people may feel tired or have muscle soreness from increasing the use of their arm, these are well-recognised effects of exercise. There is a small risk that people may find the data collection procedures, in particular, some aspects of the measures and questionnaires that discuss arm use or quality of life after stroke, tiring or upsetting.

Where is the study being run from?
Brunel University London (UK)

When is the study starting and how long is it expected to run for?
November 2020 to March 2022

Who is funding the study?
1. The Stroke Association (UK)
2. MedCity (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
282970

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 282970

Study information

Scientific Title

Rehabilitation using virtual gaming for Hospital and HOMe-Based Upper-limb exercise post Stroke (RHOMBUS II): a feasibility randomized controlled trial

Acronym
RHOMBUS II

Study objectives
This study aims to determine the safety, feasibility and acceptability of the NeuroBall as a rehabilitation intervention for training of the upper limb (UL) post-acute stroke for 7 weeks while on the acute inpatient and/or ESD stroke pathways.

The specific objectives of the study are:
1. To determine the safety of the intervention
2. To determine the feasibility of delivering the intervention
3. To determine the fidelity to the intervention
4. To explore the acceptability of the intervention to people with stroke, therapists, and other health care professionals
5. To explore factors that may impact the adoption of the technology
6. To determine the feasibility of conducting a definitive trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/12/2020, Wales Research Ethics Committee 5 Bangor (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 785708 / +44 (0)7920 565664; WalesREC5@wales.nhs.uk), REC ref: 20/WA/0347

Study design
Feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Interventions
Following baseline assessments participants will be randomly allocated to the intervention or usual care group in a 2:1 ratio. An individual independent of the study will generate a sequence using permuted blocks of randomly chosen size three or six. The allocation sequence will be placed in opaque, sealed envelopes. Following each baseline assessment, an envelope will be drawn sequentially by the research assistant who will inform the participant if they are in the intervention or control group.

NeuroBall + usual care study arm:
The NeuroBall intervention is described in detail elsewhere using the Template for Intervention Description and Replication (TIDieR) (Kilbride et al 2018b). In summary, the NeuroBall is a non-immersive virtual reality digital platform in the form of an app on a computer tablet designed for upper limb stroke rehabilitation. The device is a portable sensor-enabled hand controller that tracks arm and hand movements and provides extrinsic feedback on a stroke survivor's exercise session through an artificial intelligence (AI) enabled analytics dashboard. The device can be used to promote the specific practice of unilateral or bilateral movements in the shoulder, elbow, wrist and hand through uniquely designed games displayed on a tablet computer. The NeuroBall software automatically measures activity data including game played, duration of play and the number of repetitions performed. Data is automatically sent via secure transmission to the bioengineers at Neurofenix. Each participant in the intervention group will be provided with their own NeuroBall for personal use for 7 weeks (including training/familiarisation time). The device can be used both as an adjunct to therapy led rehabilitation and for self-directed exercise outside of timetabled therapy sessions. Participants will be encouraged to slowly increase their use of the device towards the minimum national daily target of 45 minutes (this can be achieved in short, frequent sessions), self-limiting use based on fatigue, and if they experience discomfort or pain to stop and seek advice from the research assistant or their treating therapist. Participants will be then be advised to further increase their training time as they are able. Usual care for the upper limb as determined by the respective stroke unit or early support stroke discharge therapy team. Usual care will be recorded on a data collection form

Usual care study arm:
Participants allocated to the control group will receive usual care interventions for the upper limb as determined by the respective stroke unit or early support stroke discharge therapy team. Usual care will be recorded on a data collection form.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome measure
In accordance with a feasibility RCT this study will test the following outcomes:

1. Outcomes relating to safety (measured at baseline and post 7-week intervention):
1.1. Fatigue measured by the Fatigue Severity Score -7 (FSS-7)
1.2. Pain measured with a 10 point Visual Analogue Scale (VAS)
1.3. Spasticity measured with the Modified Modified Ashworth Scale (MMAS)

2. Outcomes relating to feasibility and acceptability (measured through the study):
2.1. Feasibility of delivery of the intervention will be measured by recording the number of people who receive the training sessions, number of sessions received, the length and content of the training, and the number of clinical or technical phone calls and hospital/home visits required.
2.2. Fidelity to the use of the NeuroBall intervention will be objectively measured throughout the study by using the data collected via the sensors in the device and software on the tablet computer on time spent actively exercising in each game and the number of movement repetitions.
2.3. Fidelity to delivery of the intervention will be measured by recording attendance at training sessions, the number of requests for clinical or technical assistance from the research or technical team.
2.4. Acceptability:
2.4.1. Stroke survivor acceptability of the intervention, including factors that may impact adoption of technology will be assessed post intervention with through semi-structured interviews (n=12) and the Quest 2.0 (n=24)
2.4.2. Healthcare staff acceptability of the intervention (n=9), including factors that may impact adoption of technology, will be assessed through semi-structured interviews
2.4.3. Stroke survivor (n=4) acceptability of allocation to the control group will be assessed through semi-structured interviews

Secondary outcome measures
3. Feasibility of a definitive trial determined by measuring:
3.1. Recruitment and retention rates at the completion of the intervention phase
3.2. Outcome measure completion at baseline and post 7-week intervention (and reasons for missing data):
3.2.1. Arm Impairment measured using the Fugl-Meyer Upper-limb (FMA-UL)
3.2.2. Arm function measured using the Action Research Arm Test (ARAT)
3.2.3. Arm function self-report measured using the Motor Activity Log 14 (MAL-14)
3.2.4. Passive range of movement measured using a goniometer (PROM)
3.2.5. Self-efficacy for exercise measured using the Self-efficacy for home exercise programme questionnaire (SHEAPs)
3.2.6. Quality of life measured using the EuroQol 5 Dimensions 5 levels (EQ-5D-5L)
3.2.7. Participation measured using the Subjective Index of Physical and Social Outcome (SIPSO)
3.2.8. Gross level of disability measured using the simplified modified Rankin Scale questionnaire (smRSq)
3.2.9. Health Service Use measured using the adapted Client Service Receipt Inventories (adapted CSRI)
3.2.10. Depression and Anxiety measured using the combined General Anxiety Disorder (GAD-2) and Patient Health Questionnaire (PHQ-2)

Overall study start date
30/11/2020

Completion date
31/03/2022

Eligibility

Key inclusion criteria

Stroke survivors:
1. Aged 18 years or over
2. Clinically confirmed acute stroke with new unilateral weakness
3. Able to provide consent to take part in the study and to comply with the requirements of the protocol
4. Motricity Index score between 9-25 for elbow (from 90 flexion) and/or shoulder movement (shoulder abduction)
5. Ability to communicate in English, sufficient for completion of the trial intervention and assessment
6. Able to see the graphics and visual display on the screen

Members of the healthcare team (stroke unit or early stroke supported discharge team):
1. Aged 18 years and over
2. Participated in the delivery of the intervention
3. Provided informed consent

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24 stroke survivors plus 9 healthcare staff invited to interview to explore the acceptability of training and delivering the intervention

Total final enrolment
24

Key exclusion criteria
Stroke survivors:
1. Unstable medical conditions
2. Unable to follow a two-stage command
3. Uncontrolled photosensitive epilepsy
4. Shoulder/arm pain exacerbated on movement
5. Already participating in an upper limb rehabilitation trial
6. Patients with significant cognitive impairment and unable to comprehend and follow all instructions relating to participation in the study
7. Care home residents

Date of first enrolment
19/04/2021

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hillingdon Hospital
The Hillingdon Hospitals NHS Foundation Trust
The Stroke Unit
Pield Heath Road
Uxbridge
London
United Kingdom
UB8 3NN

Study participating centre
Central and North West London NHS Foundation Trust (Early Stroke Support Discharge team)
Trust Headquarters
350 Euston Road
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Sponsor information

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Sponsor type
University/education

Website
http://brunel.ac.uk

ROR
https://ror.org/00dn4t376

Funder(s)

Funder type
Charity

Funder Name
Stroke Association

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
MedCity

Results and Publications

Publication and dissemination plan
1. The protocol is in preparation for submission for publication
2. Planned publications in a high impact peer-reviewed journal

Intention to publish date
01/04/2023

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 24/02/2022:
Anonymised aggregated data will be made available in a public repository following the publication of findings.

Previous individual participant data (IPD) sharing statement:
The data-sharing plans for the current study are unknown and will be made available at a later date. This project is a collaboration with a SME company and this makes any IP produced a contractual matter.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/06/2022	08/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		28/01/2025	30/01/2025	Yes	No