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RHOMBUS: Rehabilitation via HOMe Based gaming exercise for the Upper-limb post Stroke

Submission date
27/03/2018

Recruitment status
No longer recruiting

Registration date
10/04/2018

Overall study status
Completed

Last Edited
22/01/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Three quarters of people following stroke will experience problems with moving their arm. This can be weakness, stiffness or a combination of both. Lack of arm recovery after stroke can lead to an increased dependence on others for help and a reduced quality of life for some. We know that treatments that work best to help with recovery of arm require lots of practice and movements have to be repeated many times. This can make doing exercises challenging and boring.
Therefore the development of rehabilitation devices that can be used safely and easily at home, and are motivating, enjoyable and affordable is essential. Gameball is a device that can be used at home for rehabilitation of the arm and hand post stroke that has designed by engineers, stroke survivors and specialist stroke physiotherapists. The portable device allows all-in-one arm training through uniquely designed rehabilitation computer games displayed on an iPad or laptop. Feedback and tracking and sharing of progress are also features.
The Gameball device has been successfully tested with 18 stroke survivors in a university setting, and was found to be safe, enjoyable and easy to use. The main aim of the RHOMBUS study is to test if the Gameball can be safely used in the home setting and to assess if people like using it for exercising the arm and hand after stroke.

Who can participate?
People who are at least 12 weeks after their stroke and still have problems moving their arm.

What does the study involve?
This study is carried out in the participant's home, and seeks to recruit 30 stroke survivors. Once a participant's eligibility has been confirmed and informed consent given, a research assistant (a physiotherapist) will visit the participant at home to carry out baseline assessments, and complete a number of questionnaires. Participants will be taught how to use the Gameball during a familiarisation week and will be provided with an instruction handbook. After training the stroke survivor will be asked to exercise their arm using the Gameball and specially designed games, ideally each day for 6 weeks. Time spent using the device will be incrementally increased depending on levels of fatigue or how energetic the person may feel. The device will automatically capture the number of times the Gameball is used, and for how long and how many exercises are done each session. Technical and clinical help is available throughout this 6-

week period, the number of times, if accessed will be measured to determine if the device is feasible to use at home. Adverse events will be monitored to assess safety of use. Assessments and questionnaires are repeated at the end of the intervention and again at follow up four weeks later. 15 participants will also be invited for an interview to learn more about their experience of using the Gameball at home. Data collected from this study will help researchers decide if it is possible to carry out a large trial at a later date to investigate if the device is effective.

What are the possible benefits and risks of participating?
As we are still testing the Gameball we cannot say there are any direct benefits for you from taking part in this study. Participants may increase the amount of time spent exercising their arm and this may make your arm or hand feel better. You will have a total of 7 weeks access to the Gameball device. 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 Gameball inducing epilepsy (a fit), however 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. 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 post stroke, tiring or upsetting.

Where is the study run from?
Brunel University London

When is the study starting and how long is it expected to run for?
January 2018 to February 2019

Who is funding the study?
Innovate UK

Who is the main contact?
Dr Cherry Kilbride
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3463

Study information

Scientific Title
A non-randomised intervention trial to assess the feasibility and acceptability of Gameball, a novel gaming platform for upper-limb stroke rehabilitation at home.

Acronym
RHOMBUS

Study objectives
The aim of this study is to determine if the Gameball platform is safe, feasible and acceptable to use for home base rehabilitation of the upper-limb post stroke, and to test procedures to inform the design and delivery of a definitive randomised controlled trial (RCT) of using the Gameball (which will assess the clinical and cost effectiveness of the the Gameball intervention with stroke survivors).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee, College of Health and Life Sciences, Brunel University London, 27/03/18, 10249-MHR-Mar/2018-12322-2

Study design
Single-centre intervention study with a parallel process evaluation

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Stroke

Interventions
Current version as of 17/04/2018:
All participants will be provided with a Gameball, which consists of a specially designed device and software platform for gamification of upper limb rehabilitation after stroke. Gameball is a portable device that uses either a hand controller and/or easy-to-put-on arm bands (determined by the ability and arm movement of the stroke survivor) that allows all-in-one arm training through uniquely designed rehabilitation games displayed on a tablet.
In summary, our study will recruit 30 people who are at least 12 weeks after their stroke and have a problem with moving their arm. All assessments will be carried out in the home setting. Questions related to the arm, general activity and well- being will be asked; most of these will be repeated later at the end of the using the device and then again 4 weeks later.
In the first week we will teach the participant how to use the Gameball device independently (or with a little bit of help from someone at home). Participants will be asked to use the Gameball regularly (i.e. at least 5 days per week) over a 6 week period for about an hour a day when stamina has been improved). We would also like to talk to people who have taken part to ask what it was like to take part as this helps us to maximise our learning to take forward to the next stage and how to make further improvements to the device. The total Gameball intervention will last 7 weeks.
Week 1: Participants will undergo a familiarisation process on how to use the Gameball device at home. This will include home visit training delivered by a research assistant and a follow-up call to clear any technical or clinical queries. During this familiarisation process the individual will be asked to gradually increase their usage of the Gameball.

Week 2-7: The participant will be asked to train with the Gameball regularly for 6 weeks, gradually building their stamina with an aim to use the device at least 5 days per week for a minimum of 45 minutes a day (current guidance for stroke intervention) or a total dosage of 225 minutes per week.
Clinical and technical support available throughout the intervention phase.

Original version:
All participants will be provided with a Gameball, which consists of a specially designed device and software platform for gamification of upper limb rehabilitation after stroke. Gameball is a portable device that uses either a hand controller and/or easy-to-put-on arm bands (determined by the ability and arm movement of the stroke survivor) that allows all-in-one arm training through uniquely designed rehabilitation games displayed on a tablet.
In summary, our study will recruit 30 people who are at least 12 weeks after their stroke and have a problem with moving their arm. All assessments will be carried out in the home setting. Questions related to the arm, general activity and well- being will be asked; most of these will be repeated later at the end of the using the device and then again 4 weeks later.
In the first week we will teach the participant how to use the Gameball device independently (or with a little bit of help from someone at home). Participants will be asked to use the Gameball regularly (i.e. at least 5 days per week) over a 6 week period for about an hour a day when stamina has been improved). We would also like to talk to people who have taken part to ask what it was like to take part as this helps us to maximise our learning to take forward to the next stage and how to make further improvements to the device. The total Gameball intervention will last 7 weeks.
Week 1: Participants will undergo a familiarisation process on how to use the Gameball device at home. This will include home visit training delivered by a research assistant and a follow-up call to clear any technical or clinical queries. During this familiarisation process the individual will be asked to gradually increase their usage of the Gameball.
Week 2-6: The participant will be asked to train with the Gameball regularly for 6 weeks, gradually building their stamina with an aim to use the device at least 5 days per week for a minimum of 45 minutes a day (current guidance for stroke intervention) or a total dosage of 225 minutes per week.
Clinical and technical support available throughout the intervention phase.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Current version as of 17/04/2018:
All participants will be assessed at baseline (week 0), post intervention (week 8) and follow up (week 12).
Safety:
1. Pain is assessed in the upper limb (fingers, hand, wrist, forearm, elbow, upper arm and shoulder) and trunk using a visual analogue scale at each assessment point and by the pain related question on the EQ-5D-5L.
2. Fatigue is assessed by the 7-item Fatigue Severity Scale (FSS-7) at each assessment point.

3. Number and type of adverse events will be assessed by asking participants if they have experienced arm pain, a fall or other adverse event at each assessment point. Adverse events will be categorised as either expected or unexpected.

Acceptability of the intervention will be assessed by:
1. Participant reported experience using the post-intervention questionnaire and by conducting semi-structured interviews with 15 participants. Interview participants will be purposively sampled from the cohort.

Feasibility of delivering the intervention will be assessed by:
1. Diary logs from the research assistants and technicians of their experience of supporting the intervention.
2. The number and length of technical related calls
3. The number and length of clinical related calls

Feasibility of conducting a definitive tria will be assessed by:
1. Monitoring recruitment and retention rates
2. Identifying reasons for non-participation using a questionnaire distributed to people who did not wish to take part in the study
3. Identifying reasons for withdrawal from the study using a questionnaire distributed to people who withdrew from the study
4. Monitoring the completion rate of outcome measures related to the clinical and cost effectiveness of the trial

Original version:
All participants will be assessed at baseline (week 0), post intervention (week 7) and follow up (week 11).
Safety:
1. Pain is assessed in the upper limb (fingers, hand, wrist, forearm, elbow, upper arm and shoulder) and trunk using a visual analogue scale at each assessment point and by the pain related question on the EQ-5D-5L.
2. Fatigue is assessed by the 7-item Fatigue Severity Scale (FSS-7) at each assessment point.
3. Number and type of adverse events will be assessed by asking participants if they have experienced arm pain, a fall or other adverse event at each assessment point. Adverse events will be categorised as either expected or unexpected.

Acceptability of the intervention will be assessed by:
1. Participant reported experience using the post-intervention questionnaire and by conducting semi-structured interviews with 15 participants. Interview participants will be purposively sampled from the cohort.

Feasibility of delivering the intervention will be assessed by:
1. Diary logs from the research assistants and technicians of their experience of supporting the intervention.
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Feasibility of conducting a definitive tria will be assessed by:
1. Monitoring recruitment and retention rates
2. Identifying reasons for non-participation using a questionnaire distributed to people who did not wish to take part in the study
3. Identifying reasons for withdrawal from the study using a questionnaire distributed to people

who withdrew from the study
4. Monitoring the completion rate of outcome measures related to the clinical and cost effectiveness of the trial

Secondary outcome measures
Current version as of 17/04/2018:
The following outcome assessments will be assessed for all participants at baseline (week 0), post-intervention (8 weeks) and follow-up (12 weeks). These outcomes are the proposed outcomes that will be used to determine the clinical and cost effectiveness of the intervention if a definitive trial is conducted.
The following measures will be assessed at all time points.
1. Objective arm function assessed by the Action Research Arm Test (ARAT)
2. Arm impairment assessed by Fugl-Meyer (FMA – upper limb)
3. Passive Range of Movement (PROM) assessed by goniometry
4. Spasticity assessed by Modified modified Ashworth Scale (MMAS)
5. Self reported arm function assessed by the Motor Activity Log -14 (MAL)
6. Social integration (participation) assessed by the Subjective Index of Physical and Social Outcome (SIPSO)
7. Quality of life assessed by the EQ-5D-5L
8. Health service use assessed by the Adapted Client Service Receipt Inventory (CSRI)
9. Pain assessed by Visual Analogue Scale (VAS)
10. Fatigue assessed by Fatigue Severity Scale-7 (FSS-7)
11. Global disability assessed by the simplified modified Rankin Scale questionnaire (smRSq)

Original version:
The following outcome assessments will be assessed for all participants at baseline (week 0), post-intervention (6 weeks) and follow-up (10 weeks). These outcomes are the proposed outcomes that will be used to determine the clinical and cost effectiveness of the intervention if a definitive trial is conducted.
The following measures will be assessed at all time points.
1. Objective arm function assessed by the Action Research Arm Test (ARAT)
2. Arm impairment assessed by Fugl-Meyer (FMA – upper limb)
3. Passive Range of Movement (PROM) assessed by goniometry
4. Spasticity assessed by Modified modified Ashworth Scale (MMAS)
5. Self reported arm function assessed by the Motor Activity Log -14 (MAL)
6. Social integration (participation) assessed by the Subjective Index of Physical and Social Outcome (SIPSO)
7. Quality of life assessed by the EQ-5D-5L
8. Health service use assessed by the Adapted Client Service Receipt Inventory (CSRI)
9. Pain assessed by Visual Analogue Scale (VAS)
10. Fatigue assessed by Fatigue Severity Scale-7 (FSS-7)
11. Global disability assessed by the simplified modified Rankin Scale questionnaire (smRSq)

Overall study start date
02/01/2018

Completion date
28/02/2019

Eligibility

Key inclusion criteria
1. Capacity to consent
2. Unilateral stroke
3. Minimum of 12 weeks post-stroke and finished formal rehabilitation for their arm (ie NHS or private provider)
4. Mild to moderately severe reduction in arm function (9-25 on the Motricity Index)
5. Able to sit independently for up to 5 minutes before requiring rest
6. Aged 18 years or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Photosensitive epilepsy
2. Pain in the arm at rest
3. People with severe visual neglect/hemianopia (score >0 on NIHSS 'Visual' and 'Inattention and Extinction' subscales)
4. Unstable medical conditions e.g. angina not controlled by medication
5. Unable to understand or communicate in English (i.e. unable to follow instructions as assessed by 2-point command)
6. Fixed contracture or active disease (e.g. rheumatoid arthritis) affecting movement that will reduce the ability to use the Gameball.

Date of first enrolment
20/04/2018

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brunel University London
Kingston Lane, Uxbridge
Greater London
United Kingdom
UB8 3PH

Sponsor information

Organisation
Brunel University London

Sponsor details
Kingston Lane
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UB8 3PH

Sponsor type
University/education

Website
https//:brunel.ac.uk

ROR
https://ror.org/00dn4t376

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
This project will result in the publication of three articles in high impact peer-reviewed journals and four conference presentations between December 2018 and December 2019.

Intention to publish date
31/05/2019

Individual participant data (IPD) sharing plan
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
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/11/2018	25/11/2019	Yes	No
Results article		28/02/2022	27/10/2022	Yes	No
Results article	qualitative analysis	19/01/2024	22/01/2024	Yes	No