BMJ Open

Rehabilitation using virtual gaming for Hospital and hOMe-Based training for the Upper limb post Stroke (RHOMBUS II): protocol of a feasibility randomised controlled trial

Cherry Kilbride ,[1] Alyson Warland,[1] Victoria Stewart ,[2] Basaam Aweid,[3,4] Arul Samiyappan,[5] Jennifer Ryan ,[1,6] Tom Butcher,[1] Dimitrios A Athanasiou,[7] Karen Baker,[7] Guillem Singla-Buxarrais,[7] Nana Anokye,[1] Carole Pound,[8] Francesca Gowing,[1] Meriel Norris[1]

To cite: Kilbride C, Warland A, Stewart V, *et al*. Rehabilitation using virtual gaming for Hospital and hOMe-Based training for the Upper limb post Stroke (RHOMBUS II): protocol of a feasibility randomised controlled trial. *BMJ Open* 2022;**12**:e058905. doi:10.1136/bmjopen-2021-058905

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-058905).

Received 11 November 2021
Accepted 05 April 2022

For numbered affiliations see end of article.

Correspondence to
Dr Cherry Kilbride;
Cherry.Kilbride@brunel.ac.uk

ABSTRACT

Introduction Upper limb (UL) rehabilitation is most effective early after stroke, with higher doses leading to improved outcomes. For the stroke survivor, the repetition may be monotonous. For clinicians, providing a clinically meaningful level of input can be challenging. As such, time spent engaged in UL activity among subacute stroke survivors remains inadequate. Opportunities for the stroke survivor to engage with UL rehabilitation in a safe, accessible and engaging way are essential to improving UL outcomes following stroke. The NeuroBall is a non-immersive virtual reality (VR) digital system designed for stroke rehabilitation, specifically for the arm and hand. The aim of the Rehabilitation using virtual gaming for Hospital and hOMe-Based training for the Upper limb post Stroke study is to determine the safety, feasibility and acceptability of the NeuroBall as a rehabilitation intervention for the UL in subacute stroke.

Methods and analysis A feasibility randomised controlled trial (RCT) will compare the NeuroBall plus usual care with usual care only, in supporting UL rehabilitation over 7 weeks. Twenty-four participants in the subacute poststroke phase will be recruited while on the inpatient or early supported discharge (ESD) stroke pathway. Sixteen participants will be randomised to the intervention group and eight to the control group. Outcomes assessed at baseline and 7 weeks include gross level of disability, arm function, spasticity, pain, fatigue and quality of life (QoL). Safety will be assessed by recording adverse events and using pain, spasticity and fatigue scores. A parallel process evaluation will assess feasibility and acceptability of the intervention. Feasibility will also be determined by assessing fidelity to the intervention. Postintervention, semistructured interviews will be used to explore acceptability with 12 participants from the intervention group, four from the usual care group and with up to nine staff involved in delivering the intervention.

Ethics and dissemination This trial has ethical approval from Brunel University London's Research Ethics Committee 25257-NHS-Oct/2020-28121-2 and the Wales Research Ethics Committee 5 Bangor (Health and Care Research Wales) REC ref: 20/WA/0347. The study is sponsored by Brunel University London. Contact: Dr Derek Healy, Chair, University Research Ethics committee (Derek.healy@brunel.ac.uk). Trial results will be submitted for publication in peer-reviewed journals, presented at national and international conferences and distributed to people with stroke.

Trial registration number ISRCTN11440079; Pre-results.

Strengths and limitations of this study

- ⇒ The Rehabilitation using virtual gaming for Hospital and hOMe-Based training for the Upper limb post Stroke trial will investigate the feasibility, acceptability and safety of delivering a virtual reality intervention in the early subacute stroke pathway in hospital and home settings.
- ⇒ To be maximally inclusive, stroke survivors with mild, moderate and severe arm impairment can participate in the study.
- ⇒ The feasibility of conducting a definitive randomised controlled trial of clinical and cost-effectiveness of the intervention will be determined.
- ⇒ Fidelity to the intervention will be objectively measured by the NeuroBall device and supported by qualitative data from participant and staff interviews.
- ⇒ In keeping with rehabilitation studies, it was not possible to blind the therapists or study participants.

INTRODUCTION

Stroke is a leading global cause of adult severe disability,[1] resulting in one person suffering a stroke every 5 min in the UK.[2] Nearly three-quarters of stroke survivors have persistent problems in using their hand and arm.[3 4]

Motor improvements and self-reported capacity of upper limb (UL) function by stroke survivors have been shown to be greatest in

the first 6 weeks following stroke and remain significant for up to 2 years.[5] This may be because there is a period of increased neural plasticity in the acute and early subacute poststroke period.[6 7] This suggests that rehabilitation interventions for the hemiplegic UL should exploit the early window of neural plasticity in the acute poststroke period and continue into the chronic phase. Practice and intense repetition of movement are recognised as key elements of physical interventions aimed at improving UL impairment and function poststroke.[8 9] Despite this, time spent moving the haemiplegic UL in subacute stroke rehabilitation settings has been found to be limited.[10]

More rehabilitation in the early stages after stroke is needed to drive improvements in recovery and arm function.[11–13] With National Health Service (NHS) staffing and resources limited,[14] time spent rehabilitating the upper limb in the subacute stroke phase is insufficient. Additionally, asearly supported discharge (ESD) pathways for stroke survivors can reduce length of inpatient stay,[15] the development of motivating, enjoyable and affordable rehabilitation devices that can be used safely and easily in the inpatient rehabilitation setting and at home are essential in implementing the required dose and intensity.

For the last 3 years, a team of clinical researchers, stroke survivors and bioengineers (www.neurofenix.com) have been undertaking a programme of iterative research to provide a possible solution. The NeuroBall is a portable device that allows all-in-one arm training through a uniquely designed rehabilitation gaming app, displayed on a tablet computer. The device (https://neurofenix.com) was purposely developed in line with the Medical Research Council Complex Interventions Framework.[16] It was initially tested in a proof-of-concept study,[17] and later, its feasibility and acceptability for use among community dwelling chronic stroke survivors was evaluated in a non-randomised intervention study.[18] Findings showed the device to be safe, enjoyable and easy to use, but it has yet to be evaluated in the subacute inpatient and ESD stroke pathways.

Study aims and objectives

The aim of the Rehabilitation using virtual gaming for Hospital and hOMe-Based training for the Upper limb post Stroke (RHOMBUS II) study is to determine the safety, feasibility and acceptability of the NeuroBall for UL rehabilitation in subacute stroke survivors.

The study objectives 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 healthcare professionals.
5. To explore factors that may impact adoption of the NeuroBall.
6. To determine the feasibility of conducting a definitive trial.

METHODS AND ANALYSIS

Study design

The RHOMBUS II trial is a feasibility RCT with a parallel process evaluation comparing the use of the NeuroBall plus usual care, with usual care only to support UL rehabilitation. A timeline and summary of all participant events and data collection points is provided in table 1.

Study setting

The study will take place in the Hillingdon Hospitals' NHS Foundation Trust (THH) Acute Stroke Unit (ASU) and the homes of participant stroke survivors on Central and North West London NHS Foundation Trust (CNWL) ESD stroke team.

Trial status

At the time of submission of this study protocol, data collection is ongoing.

Participants

Participants are eligible to be included in the trial if they meet the following inclusion criteria:

1. Aged 18 years or over.
2. Clinically confirmed stroke with new unilateral weakness.
3. Able to provide consent to take part in the study.
4. Mild to severe reduction in arm and/or hand function poststroke (as measured by the Motricity Index 9–25, ie, participants need a flicker of activity in the shoulder or elbow as a minimum to take part).
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.

Potential participants will not be eligible according to the following exclusion criteria:

1. Unstable medical conditions.
2. Unable to follow a two-stage command.
3. Uncontrolled photosensitive epilepsy.
4. Shoulder/arm pain exacerbated on movement.
5. Fixed contracture, active disease or orthopaedic conditions affecting the haemiplegic arm.
6. Current participation in an UL rehabilitation trial.
7. Significant cognitive impairment and inability to comprehend and follow all instructions relating to participation in the study.
8. Care home residents.

Sample size

Twenty-four stroke survivors will be recruited based on recommendations that between 24 and 50 participants are sufficient for feasibility studies.[19 20] The data collected from this study will be used to determine the primary outcome and outcome measure to use in a definitive trial. In addition to stroke survivors, nine healthcare staff will be invited to participate in an interview to explore the acceptability of the intervention.

Table 1 Participant timeline and schedule of assessments

Time point	Study set-up	Screening	Baseline	Randomisation/ allocation	Intervention	Postintervention
Preregistration checklist		×				
Consent		×				
Eligibility		×				
Sociodemographics			×			
smRSq			×			×
Self-report pain			×			×
PROM UL			×			×
MMAS			×			×
FMA-UE			×			×
ARAT			×			×
MAL-14			×			×
SEHEP			×			×
FSS-7			×			×
SIPSO			×			×
EQ-5D-5L			×			×
GAD2 & PHQ2			×			×
QUEST						×
Adapted CSRI						×
Training healthcare staff	×					
Randomisation and allocation				×		
Intervention plus usual care or usual care only					×	
Clinical and technical support					×	
Fidelity to the intervention					×	
Record AEs			×	×	×	×
Interviews with participants						×
Interviews with healthcare staff						×

AE, adverse event; ARAT, Action Research Arm Test; CSRI, client service receipt inventory; EQ-5D-5L, EuroQol 5 Dimensions 5 Levels; FMA-UE, Fugl-Meyer Assessment-upper extremity; FSS-7, seven-item Fatigue Severity Scale; GAD2, Generalised Anxiety Disorder-2 item; MAL, Motor Activity Log; MMAS, Modified modified Ashworth Score; PHQ-2, two-item Patient Health Questionnaire; PROM UL, passive range of movement upper limb; QUEST, Quebec User Evaluation of Satisfaction with Assistive Technology; SEHEPS, Self-efficacy for Home Exercise Program Scale; SIPSO, Subjective Index of Physical and Social Outcome; smRSq, simplified modified Rankin Scale questionnaire.

Recruitment

Participants will be recruited from the THH ASU and the CNWL ESD stroke pathway. Each clinical team will identify potential participants and complete the screening checklist. Potential participants will be introduced to the study by the site principal investigator or a member of the multidisciplinary team, provided with a summary information sheet and a more detailed participant information sheet (PIS). Interest in participation will be confirmed by a member of the clinical team before the person is approached by the research assistant (RA). The RA will answer any questions about the study, outline the procedures and obtain informed consent if the person wishes to take part. Recruitment will take place across a 10-month period. Participants' general practitioners will be informed of their involvement in the trial. Stroke survivors who participate in interviews will receive another PIS before the RA seeks consent for this part of the study.

Reasons for non-participation

A non-participation questionnaire will be distributed to stroke survivors who are eligible but do not wish to take part in the study. This will help identify reasons for refusal so future studies can be tailored to maximise inclusivity. The survey will take approximately 5 min to complete.

Randomisation and allocation

Following baseline assessments, participants will be randomly allocated to the intervention or usual care group in a 2:1 ratio. A person independent to the delivery

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 RA who will inform the participant if they are in the intervention or control group.

Intervention

Participants in the intervention group will receive the following interventions:

- The NeuroBall.
- Usual care for the UL as determined by the ASU or ESD therapy team.

The intervention is described in detail elsewhere using the Template for Intervention Description and Replication.[21] In summary, the NeuroBall is a non-immersive VR digital platform in the form of an app, designed for UL 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 enabled analytics dashboard. The device can be used to promote specific practice of unilateral or bilateral movements in the shoulder, elbow, wrist and hand through uniquely designed games displayed on a tablet computer and is supported by an instruction handbook, a QuickStart guide and short instructional videos. The NeuroBall software measures activity data, including game played, duration of play and the number of repetitions performed and is automatically sent via secure transmission to bioengineers at Neurofenix.

Each participant in the intervention group will be provided with their own NeuroBall for personal use for 7 weeks. The device can be used 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 and beyond the minimum national daily target of 45 min as able (this may be achieved in multiple sessions of less than 45 min). Participants will be advised to self-limit use based on fatigue and to stop and seek advice from the RA or their treating therapist if they experience discomfort or pain.

Participant training

Stroke survivors will receive initial training from the RA (a registered physiotherapist with experience in neurorehabilitation) on how to use their device. If interested, family members can also be trained so they can help the participant if required. A brief training questionnaire will be completed at the start of the first session about the participant's prior experience with technology and video games, and their confidence in using new technology will be assessed with a visual analogue scale (VAS). This information will be used to tailor the pace and content of teaching to each participant's confidence level and experience. Training will include advice on physical requirements for using the device including maintaining good posture, avoiding compensatory movements and how to don and doff the device. If the participant is recruited from the ASU and discharged home with the device, the RA will visit them at home within two working days of discharge to check the set-up of the device. Participants will be asked to only use the NeuroBall and not use any other video gaming technology involving their affected arm for the 7 weeks of the study intervention. They may however continue to use their unaffected arm for other gaming technology for the duration of the intervention.

Healthcare staff training

Healthcare staff from the ASU and ESD teams will have the option to attend a 1 hour training session on use of the NeuroBall. This will be provided by the study team and will be supported with online recordings, a handbook and access to the study team for queries and follow-up training sessions if needed. Neurofenix engineers will be available remotely for technical support if required.

Control group

Participants allocated to the control group will receive usual care for the UL as determined by the ASU or ESD teams and informed by national guidelines.[22 23] Usual care will be recorded throughout the 7 weeks using a standardised form.

Assessments

Baseline assessments will be undertaken within two working days of entry to the study, where possible. The time between entry to study and baseline assessment will be recorded. Follow-up assessments will be completed within two working days of the end of the 7week intervention, where possible. All participants who withdraw or are withdrawn from the intervention will be requested to complete follow-up assessments.

At baseline, sociodemographic information, relevant medical history and stroke details including the National Institute of Health Stroke Scale (NIHSS) will be obtained from the individual's healthcare records. If the NIHSS has not been recorded by the medical team, the assessment will be undertaken by the RA. If participants do not consent to the research team accessing their healthcare records, the RA will engage with the participant to gather the information as best able.

Outcomes

All outcome measures will be assessed by the RA following a standardised operating procedure. The participants will receive standardised instructions. Assessors will not be blind to group allocation as we are not examining effectiveness in this study.

Arm impairment

The Fugl-Meyer Assessment-upper extremity motor, coordination/speed and sensation sections[24 25] will be used to assess impairment. Performance of each item is scored on a three-point ordinal scale. Scores for each item are summed to give a possible score of between 0 and 60 for

the motor section (including coordination/speed) and 0–12 for the sensation section. The minimal clinically important difference (MCID) for the motor section is 10.[26 27] The MCID for the sensory section has not been established.

Arm function

Arm function will be assessed using the Action Research Arm Test (ARAT).[28] The ARAT consists of 19 items divided into subscales of grasp, grip, pinch and gross movement and is scored between 0 and 57, with a higher score indicating a better performance. The MCID is 12 or 17 in acute stroke if the dominant or non-dominant side is affected, respectively.[29] Self-reported arm function will be assessed using the 14-item Motor Activity Log (MAL-14).[30] Fourteen daily functional tasks are scored on a six-point ordinal scale rating from 0 (the weaker arm is never used for that activity) to 5 (the ability to use the arm is the same as before the stroke). A mean MAL-14 score is calculated for both scales by adding the rating scores for each scale and dividing by the number of items asked.[31] Higher scores signify better function. A MCID is yet to be determined for the MAL-14.

Spasticity

The Modified Modified Ashworth Scale[32] will be used to assess resistance to passive movement in the shoulder adductors, internal rotators, elbow flexors, wrist flexors and finger flexors. Performance is rated on a five-point ordinal scale (from 0 to 4) with a higher score indicating more marked spasticity.

Fatigue

Fatigue will be assessed using the seven-item Fatigue Severity Scale,[33] with each of the items rated on a seven-point Likert scale. The total score is obtained by summing the score on each item; scores range from 7 to 49, with higher scores indicating greater fatigue.

Self-efficacy

Self-efficacy for Home Exercise Programme is a validated and reliable self-report 12-item questionnaire to assess self-efficacy for prescribed home exercises in the musculoskeletal population;[34] as yet there is no validated measure in stroke. Participants rate their confidence on a seven-point scale ranging from 0 (not confident) to 6 (very confident). Total score is obtained by summing the score on each item; higher total score indicates higher self-efficacy. Participants who score below 59 points on the measure are twice as likely to be non-adherent to their prescribed home exercise programme.

User satisfaction

The eight-item QUEST[35] will be completed postintervention to assess user satisfaction of the device. Scores range from 0 to 40 with higher scores indicating greater satisfaction.

Anxiety and depression

GAD-2[36] is based on the first two questions of the GAD-7[37] and assesses the frequency of anxiety disorders, with a score ranging from 0 to 6. Two-item Patient Health Questionnaire[38] is based on the first two question of the PHQ-9[39] and assesses the frequency of depressed mood, with a score ranging from 0 to 6. Higher scores indicate higher frequency of anxiety and depression.

Quality of life

QoL will be assessed using the EuroQol 5 Dimensions 5 levels questionnaire (EQ-5D-5L)[40] and will be completed by participants preintervention and at the 7-week follow-up. Each dimension has five response categories rated from 1 (no problems) to 5 (extreme problems). A higher score indicates greater the perceived problems. The EQ-5D-5L has an MCID of 0.10 in people with stroke.[41] In line with National Institute for Health and Care Excellence[42] recommendation, utility weight based on the cross walk function[43] was used to assign utility weights.

Participation

Participation will be assessed using the 10-item Subjective Index of Physical and Social Outcome,[44] which is divided into three sections: (1) physical functioning, (2) mobility and social and (3) emotional functioning. Each question is scored from 0 to 4. The total score is obtained by summing scores on each item; range is 0–40 with a higher score indicating an increased ability to reintegrate with the community.

Gross level of disability

The simplified modified Rankin Scale questionnaire[45] will be used to measure the individual's self-reported level of disability. Yes or no responses are required from the participant or caregiver. Disability level is rated on a seven-point scale, ranging from 0 (no symptoms) to 5 (cannot sit up in bed without help).

Health service use

Client services receipt inventories (CSRI)[46] has been developed to measure use of health, social care and broader community resources. The CSRI is a self-reported tool, which can be adapted to record inpatient costs, outpatient services, accommodation, medications and local authority services. Information on service utilisation will be captured using an adapted CSRI. We previously used an adapted CSRI to collect information on health service use during the community RHOMBUS study.[18 21] For this study, we further refined the adapted CSRI based on our experience of using it and incorporated aspects of the Stroke Receipt of Services Questionnaire.[47]

Economic evaluation

This study will examine the feasibility of conducting an economic evaluation in a definitive RCT where the cost-effectiveness of the NeuroBall will be compared with usual care and determined using the participant, NHS

and personal social services perspective.[48] Resource use data will include: (A) cost of the NeuroBall device, (B) training of the therapy and healthcare staff, (C) training of stroke survivors, for example, duration and frequency of sessions required, (D) the number and length of visits for stroke survivors, (E) any out-of-pocket expenses such as purchase of equipment and maintenance costs associated with the device and (F) use of health and personal social services by participants. Unit costs will be taken from the NHS reference costs,[49] standard unit costs and the published literature.[14] The main outcome of the economic analysis will be an incremental cost per quality-adjusted life year, based on EQ-5D-5L. In addition, feasibility of conducting an economic evaluation will be determined by examining the completeness and quality of data collected using the EQ-5D-5L and adapted CSRI.

Process evaluation

Process evaluations aim to explain how complex interventions work.[50] A parallel process evaluation will be conducted alongside the trial to determine the safety, feasibility and acceptability of the intervention.

The safety of using the NeuroBall will be assessed by comparing pain, fatigue, spasticity and adverse events between the intervention and control group at follow-up. The feasibility of the intervention for stroke survivors will be determined by recording the number, length and frequency of training sessions received by the participants, the number of additional clinical or technical inpatient session requests for assistance, the number, frequency and length of phone calls and/or the clinical or technical home visits required. Post-training confidence with the NeuroBall will be assessed with a 10-point VAS (higher score equates to more confidence).

Feasibility will be determined by assessing fidelity to the intervention. Fidelity will be assessed as time spent training the UL with the NeuroBall, number of days training and number of UL movements performed, in addition to qualitative data from participant and staff interviews. Sensors are used to automatically collect data from the NeuroBall, which is stored on the participant's tablet until remotely downloaded by a member of the research team.

Feasibility of delivering the intervention will be assessed by recording the number of healthcare staff who attend training sessions and the number of requests for clinical and/or technical assistance related to the use of the NeuroBall with participants. In addition, semistructured interviews will be undertaken to gather subjective data with up to nine staff members.

Response rate, retention and outcome measure completion, reasons for missing data and acceptability of the intervention will be used to determine the feasibility of a definitive trial.

Assessment of the acceptability of the intervention will be informed by the Theoretical Framework of Acceptability (TFA),[51] which consists of seven component constructs: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy. The acceptability of the intervention will be explored through semistructured interviews with 12 of the 16 participants from the intervention group and with up to nine staff who deliver the intervention. Interviews will be conducted in person or over the phone (if social distancing restrictions are in place). In person interviews will be held, with permission, in the stroke survivor's home. Twelve participants receiving the intervention will be purposively sampled to include key criteria such as gender, age, amount of use, confidence with technology and level of UL impairment and function. The acceptability of allocation to the control group will be explored in four participants along with their experience and acceptance of not receiving the intervention. The interviews will be conducted by the RA following topic guides developed from the TFA, relevant literature and specific aims of the process evaluation.

Acknowledging the limitation of the RA being involved in the data collection and training and delivery of the intervention, a reflexive diary will be kept by the RA. An experienced qualitative researcher will oversee this stage of the study.

Data management

Personal data collected during the trial will be handled and stored in accordance with the Data Protection Act (2018) and the UK General Data Protection Regulation (GDPR) (2018). To preserve participant anonymity, only their allocated trial number will be recorded on trial documentation (with the exception of the consent forms and contact details). Consent forms will be kept separate from other data in site trial master files at Brunel University London in a locked, secure environment. Contact details will be stored electronically. Qualitative interviews will be audio recorded and will be stored electronically and identified by trial number only. Contact details and audio recordings will be stored using password-protected files. Transcripts will be anonymised or assigned a pseudonym. Only non-identifiable clinical data will be shared with Neurofenix. Data generated by the NeuroBall will adhere to a Data Privacy Protocol, informed by Information Commissioners' Office guidelines and comply with UK GDPR. Anonymised aggregated data will be made available in a public repository following publication of findings.

Patient and public involvement

People with stroke have been involved in the ongoing development of the device since its inception. Specifically, two community stroke groups have provided input to the development of this protocol and have provided key feedback on the study design especially around the challenge of randomisation and delivering a novel intervention in a ward setting. Three members of the community stroke groups have provided advice on the trial documentation including the participant information sheets and consent forms. Two stroke survivors will be on the Trial Steering

Committee and will be reimbursed for their time and expertise. The six principles of the UK Standards for Public Involvement[52] will be drawn on throughout the study.

Data analysis

Qualitative data

To determine the feasibility, acceptability and safety of the intervention, interviews will be analysed using the five iterative stages of the Framework Analysis method (familiarisation, thematic framework identification, indexing, charting, mapping and interpretation).[53] This method incorporates both deductive and inductive coding and provides a strong audit trail of the analytical process from original transcripts to final themes, including illustrative quotations.[54] It enables trial processes and positive as well as negative participant experiences to be explored and reported. Deductive trial factors will include factors relating to feasibility, acceptability and adoption of technology, which will be informed by the TFA[51] and the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) framework.[55]

Quantitative data

A person independent to the study will apply anonymous codes to all data sheets before analysis to ensure the research team and the statistician are blinded to group allocation when processing and analysing the data. Distribution of data will be explored using Q–Q plots, histograms and cross-tabulations. Data relating to participant characteristics, outcome measures, recruitment, retention, fidelity (ie, active game play and numbers of repetitions of movements) and feasibility of delivering the intervention (eg, the number and duration of clinical and technical visits and calls) will be summarised using descriptive statistics such as mean, SD, median, IQR and frequencies as appropriate. Pain, fatigue and spasticity will be compared between the intervention and control group at follow-up using analysis of covariance adjusting for baseline values. The incidence of adverse events in each group will be compared at follow-up using a negative binomial model.

Timeline

The trial is funded for a period of 12 months. Recruitment commenced in April 2021 and is projected to continue until February 2022. Data analysis and report writing will be conducted from February 2022 onwards.

ETHICS AND DISSEMINATION

Ethics

This study is sponsored by Brunel University London and has been approved by the University's Research Ethics Committee (Ref: 25257-NHS-Oct/2020-28121-2) and the Health Research Authority and Health and Care Research Wales (REC ref: 20/WA/0347). The trial will be conducted in full conformance with the principles of the Declaration of Helsinki and to the Medical Research Council Good Clinical Practice (GCP) guidelines. All researchers working on the trial will receive training in GCP guidelines. The trial will also comply with all applicable Brunel University Research integrity guidance. All participants will freely give their informed consent to participate in the trial. Additional informed consent will be obtained from individuals sampled to participate in semi-structured interviews.

Monitoring

As this intervention is low risk and potential harm is not anticipated, there will be no Data Monitoring Committee, interim analysis or stopping rules.

Administrative structures

The trial will be run by the Trial Management Group, which consists of the chief investigator, the two principal investigators, coinvestigators and RA. The conduct of the trial will be supervised by a trial steering committee and externally monitored by funders The Stroke Association with MedCity.

Dissemination

A detailed dissemination plan will be developed in the early stage of the trial in collaboration with the Trial Steering Committee. Study findings will be disseminated to all participants (stroke survivors and healthcare staff) and to those who wanted to participate but did not meet the inclusion criteria and requested feedback on results. The results of the trial will be submitted for publication in a peer-reviewed journal and presented at national and international stroke and virtual reality conferences. The trial will be reported in line with the Extended Consolidated Standards of Reporting Trials statement for pilot and feasibility studies. Authorship will be based on the International Committee of Medical Journal Editors criteria.

Author affiliations
[1]College of Health, Medicine and Life Sciences, Brunel University London, Uxbridge, UK
[2]Alderbourne Unit, Hillingdon Hospital, Uxbridge, Middlesex, UK
[3]Stroke Unit, Hillingdon Hospitals NHS Foundation Trust, Uxbridge, UK
[4]Early Supported Discharge (Stroke), Central and North West London NHS Foundation Trust, London, UK
[5]Adult Services, Central and North West London NHS Foundation Trust, London, UK
[6]Department of Epidemiology and Public Health Medicine, Royal College of Surgeons in Ireland, Dublin, Ireland
[7]Neurofenix, London, UK
[8]Faculty of Health and Social Sciences, Bournemouth University, Poole, UK

Twitter Cherry Kilbride @KilbrideCherry and Tom Butcher @TomDbutcher

Contributors All authors listed meet the International Committee of Medical Journal Editors criteria for authorship. CK and DAA conceived the study. JR, AW, MN, TB, BA and NA designed the study. DAA, TB, KB and CK designed the intervention. CK will lead the running of the trial as chief investigator, BA and AS are site-specific principal investigators. CP is the study specialist communication advisor. VS will lead the data collection and data management and analysis of the qualitative data. MN will lead the process evaluation. JR will lead the statistical analysis. NA will lead the evaluation of the feasibility of the economic evaluation. FG oversees

data management and reporting. All authors have read and approved the final manuscript.

Funding This work was supported by The Stroke Association and MedCity grant number SA MC 21\10001.

Competing interests DAA, KB and GS-B are employed by Neurofenix (UK), a digital therapeutics company developing a therapy platform and sensor-based devices to augment rehabilitation. Neurofenix provided the Neurofenix platforms and technical support to the research therapists. Neurofenix had no influence on the design of the study, data collection, analysis and interpretation of the data or manuscript preparation.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Cherry Kilbride http://orcid.org/0000-0002-2045-1883
Victoria Stewart http://orcid.org/0000-0003-4077-8848
Jennifer Ryan http://orcid.org/0000-0003-3768-2132

REFERENCES

1 Feigin VL, Norrving B, Mensah GA. Global burden of stroke. *Circ Res* 2017;120:439–48.
2 Stroke Association, 2020. Available: https://www.stroke.org.uk/ [Accessed 19 Jul 2020].
3 Kong K-H, Chua KSG, Lee J. Recovery of upper limb dexterity in patients more than 1 year after stroke: frequency, clinical correlates and predictors. *NeuroRehabilitation* 2011;28:105–11.
4 Kwakkel G, Kollen B. Predicting activities after stroke. In: Dietz V, Ward N, eds. *Oxford textbook of neurorehabilitation*. Oxford: Oxford University Press, 2015: 24–34.
5 Borschmann KN, Hayward KS. Recovery of upper limb function is greatest early after stroke but does continue to improve during the chronic phase: a two-year, observational study. *Physiotherapy* 2020;107:216–23.
6 Hordacre B, Austin D, Brown KE, *et al*. Evidence for a window of enhanced plasticity in the human motor cortex following ischemic stroke. *Neurorehabil Neural Repair* 2021;35:307–20.
7 Bernhardt J, Hayward KS, Kwakkel G, *et al*. Agreed definitions and a shared vision for new standards in stroke recovery research: the stroke recovery and rehabilitation roundtable Taskforce. *Int J Stroke* 2017;12:444–50.
8 Bernhardt J, Hayward KS, Dancause N, *et al*. A stroke recovery trial development framework: consensus-based core recommendations from the second stroke recovery and rehabilitation roundtable. *Int J Stroke* 2019;14:792–802.
9 Ward NS, Brander F, Kelly K. Intensive upper limb neurorehabilitation in chronic stroke: outcomes from the Queen square programme. *J Neurol Neurosurg Psychiatry* 2019;90:498–506.
10 McLaren R, Signal N, Lord S, *et al*. The volume and timing of upper limb movement in acute stroke rehabilitation: still room for improvement. *Disabil Rehabil* 2020;42:3237–42.
11 Langhorne P, Coupar F, Pollock A. Motor recovery after stroke: a systematic review. *Lancet Neurol* 2009;8:741–54.
12 Veerbeek JM, van Wegen E, van Peppen R, *et al*. What is the evidence for physical therapy poststroke? A systematic review and meta-analysis. *PLoS One* 2014;9:2.
13 Hubbard IJ, Carey LM, Budd TW, *et al*. A randomized controlled trial of the effect of early upper-limb training on stroke recovery and brain activation. *Neurorehabil Neural Repair* 2015;29:703–13.
14 Curtis L, Burns A. *Unit costs of health and social care 2019. personal social services research unit, University of Kent, Canterbury*, 2019: 176.
15 Langhorne P, Baylan S, Early Supported Discharge Trialists. Early supported discharge services for people with acute stroke. *Cochrane Database Syst Rev* 2017;7:CD000443.
16 O'Cathain A, Croot L, Duncan E, *et al*. Guidance on how to develop complex interventions to improve health and healthcare. *BMJ Open* 2019;9:8.
17 Kilbride C, Nowicky A, Scott D, *et al*. GameBall: the development of a novel platform to provide enjoyable and affordable hand and arm rehabilitation following stroke. *Physiotherapy* 2019;105:e192–3.
18 Kilbride C, Nowicky A, Warland A, *et al*. Rehabilitation using a novel home based digital therapy device for the upper-limb post stroke (RHOMBUS): an intervention study. *Arch Phys Med Rehabil* 2021;102:e67.
19 Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharm Stat* 2005;4:287–91.
20 Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301–8.
21 Kilbride C, Scott DJM, Butcher T, *et al*. Rehabilitation via home based gaming exercise for the upper-limb post stroke (RHOMBUS): protocol of an intervention feasibility trial. *BMJ Open* 2018;8:11.
22 National Institute of Clinical Excellence. Stroke rehabilitation in adults: clinical guideline [CG162] 2013.
23 Royal College of Physicians. *National clinical guideline for stroke*. 5th edition, 2016.
24 Deakin A, Hill H, Pomeroy VM. Rough guide to the Fugl-Meyer assessment. *Physiotherapy* 2003;89:751–63.
25 Fugl-Meyer AR, Jääskö L, Leyman I, *et al*. The post-stroke hemiplegic patient. 1. a method for evaluation of physical performance. *Scand J Rehabil Med* 1975;7:13–31.
26 Arya KN, Verma R, Garg RK. Estimating the minimal clinically important difference of an upper extremity recovery measure in subacute stroke patients. *Top Stroke Rehabil* 2011;18 Suppl 1:599–610.
27 Shelton FD, Volpe BT, Reding M. Motor impairment as a predictor of functional recovery and guide to rehabilitation treatment after stroke. *Neurorehabil Neural Repair* 2001;15:229–37.
28 Lyle RC. A performance test for assessment of upper limb function in physical rehabilitation treatment and research. *Int J Rehabil Res* 1981;4:483–92.
29 Lang CE, Edwards DF, Birkenmeier RL, *et al*. Estimating minimal clinically important differences of upper-extremity measures early after stroke. *Arch Phys Med Rehabil* 2008;89:1693–700.
30 Uswatte G, Taub E, Morris D, *et al*. Reliability and validity of the upper-extremity motor activity Log-14 for measuring real-world arm use. *Stroke* 2005;36:2493–6.
31 Motor Activity Log (MAL) Manual. Available: https://www.uab.edu/citherapy/images/pdf_files/CIT_Training_MAL_manual.pdf [Accessed 19 Jul 2020].
32 Naghdi S, Ansari NN, Azarnia S, *et al*. Interrater reliability of the modified modified Ashworth scale (MMAS) for patients with wrist flexor muscle spasticity. *Physiother Theory Pract* 2008;24:372–9.
33 Lerdal A, Kottorp A. Psychometric properties of the fatigue severity Scale-Rasch analyses of individual responses in a Norwegian stroke cohort. *Int J Nurs Stud* 2011;48:1258–65.
34 Picha KJ, Jochimsen KN, Heebner NR, *et al*. Measurements of self-efficacy in musculoskeletal rehabilitation: a systematic review. *Musculoskeletal Care* 2018;16:471–88.
35 Demers L, Weiss-Lambrou R, Ska B. Development of the Quebec user evaluation of satisfaction with assistive technology (quest). *Assist Technol* 1996;8:3–13.
36 Kroenke K, Spitzer RL, Williams JBW, *et al*. Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection. *Ann Intern Med* 2007;146:317–25.
37 Spitzer RL, Kroenke K, Williams JBW, *et al*. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–7.
38 Kroenke K, Spitzer RL, Williams JBW. The patient health Questionnaire-2: validity of a two-item depression screener. *Med Care* 2003;41:1284–92.
39 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606–13.
40 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
41 Chen P, Lin K-C, Liing R-J, *et al*. Validity, responsiveness, and minimal clinically important difference of EQ-5D-5L in stroke patients undergoing rehabilitation. *Qual Life Res* 2016;25:1585–96.
42 Developing NICE guidelines: the manual. Available: https://www.nice.org.uk/process/pmg20/chapter/incorporating-economic-evaluation [Accessed 20 Jul 2020].
43 van Hout B, Janssen MF, Feng Y-S, *et al*. Interim scoring for the EQ-5D-5L: mapping the EQ-5D-5L to EQ-5D-3L value sets. *Value Health* 2012;15:708–15.

44 Trigg R, Wood VA. The validation of the subjective index of physical and social outcome (SIPSO). *Clin Rehabil* 2003;17:283–9.
45 Bruno A, Akinwuntan AE, Lin C, *et al*. Simplified modified Rankin scale questionnaire: reproducibility over the telephone and validation with quality of life. *Stroke* 2011;42:2276–9.
46 Beecham J, Knapp M. Costing psychiatric interventions. In: Thornicroft G, ed. *Measuring mental health needs. Gaskell*. London, 2001: 200–24.
47 Donnelly M, Power M, Russell M, *et al*. Randomized controlled trial of an early discharge rehabilitation service: the Belfast community stroke trial. *Stroke* 2004;35:127–33.
48 Developing NICE guidelines: the manual. Available: https://www.nice.org.uk/process/pmg20/chapter/incorporating-economic-evaluation [Accessed 23 Sep 2020].
49 NHS reference costs. Available: https://www.gov.uk/government/collections/nhs-reference-costs [Accessed 23 Sep 2020].
50 Process evaluation: evaluation in health and wellbeing. Available: https://www.gov.uk/guidance/evaluation-in-health-and-wellbeing-process [Accessed 23 Sep 2020].
51 Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17:88.
52 Better public involvement for better health and social care research. Available: https://www.invo.org.uk/wp-content/uploads/2019/11/UK-standards-for-public-involvement-v6.pdf [Accessed 24 Sep 2020].
53 Ritchie J. *Qualitative research practice: a guide for social scientists students and researchers*. London: SAGE Publishers, 2009.
54 Gale NK, Heath G, Cameron E, *et al*. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;13:117
55 Greenhalgh T, Abimbola S. The NASSS Framework – A Synthesis of Multiple Theories of Technology Implementation. In: Scott P, Georgiou A, De Keizer N, eds. *Applied interdisciplinary theory in health informatics*. IOS Press, 2019: 193–204.