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Multicentre pilot randomised control trial of a self-directed exergaming intervention for poststroke upper limb rehabilitation: research protocol

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ABSTRACT

Introduction Technology-facilitated, self-directed upper limb (UL) rehabilitation, as an adjunct to conventional care, could enhance poststroke UL recovery compared with conventional care alone, without imposing additional resource burden. The proposed pilot randomised controlled trial (RCT) aims to assess whether stroke survivors will engage in self-directed UL training, explore factors associated with intervention adherence and evaluate the study design for an RCT testing the efficacy of a self-directed exer-gaming intervention for UL recovery after stroke.

Methods and analysis This is a multicentre, internal pilot RCT; parallel design, with nested qualitative methods. The sample will consist of stroke survivors with UL paresis, presenting within the previous 30 days. Participants randomised to the intervention group will be trained to use an exergaming device and will be supported to adopt this as part of their self-directed rehabilitation (ie, without formal support/supervision) for a 3-month period. The primary outcome will be the Fugl Meyer Upper Extremity Assessment (FM-UE) at 6 months poststroke. Secondary outcomes are the Action Research Arm Test (ARAT), the Barthel Index and the Modified Rankin Scale. Assessment time points will be prior to randomisation (0–1 month poststroke), 3 months and 6 months poststroke. A power calculation to inform sample size required for a definitive RCT will be conducted using FM-UE data from the sample across 0–6 months time points. Semistructured qualitative interviews will examine factors associated with intervention adoption. Reflexive thematic analysis will be used to code qualitative interview data and generate key themes associated with intervention adoption.

Ethics and dissemination The study protocol (V.1.9) was granted ethical approval by the Health Research Authority, Health and Care Research Wales, and the London- Harrow Research Ethics Committee (ref. 21/LO/0054) on 19 May 2021. Trial results will be submitted for publication in peer-reviewed journals, presented at national and international stroke meetings and conferences and disseminated among stakeholder communities.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This work follows gold-standard research design guidelines for stroke rehabilitation and recovery research.
⇒ This work will include a heterogeneous sample, through broad inclusion criteria, including those with cognitive and/or communication impairments poststroke.
⇒ This work is novel in its evaluation of a self-directed intervention in a free-living context, using innovative, low-cost technology.
⇒ The quantification of intervention dose poses challenges, due to the complexity of the concept of dose.
⇒ The variability of 'conventional care' poses challenges to understanding the conventional care characteristics and dose.

Trial registration number NCT04475692

INTRODUCTION

Understanding how to improve upper limb (UL) recovery after stroke is a growing scientific, clinical and patient priority.[1–3] A recent Cochrane review of over 500 trials failed to yield high-quality practice recommendations for interventions for the UL.[4] Generally, higher exercise doses are associated with superior UL outcomes in animal stroke models[5 6] and clinical trials,[7] with a dose-response emerging at approximately 2 hours of daily UL training and 300–500 repetitions. Meaningful dose enhancement, however, faces significant challenges in translation to clinical practice.

At present, conventional poststroke rehabilitation dose is subtherapeutic,[8] with stroke survivors on average engaging in 17 minutes of UL training and 32 UL exercise repetitions in the critical early recovery period after stroke.[9] Reasons for this are multifaceted, including barriers such as rehabilitation costs and staffing,[10 11] as well as reduced capacity of

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stroke survivors to initiate and engage in self-directed exercise[12] (defined as when >50% of training occurs outside of direct professional supervision[13]). To date, traditional self-directed rehabilitation approaches (ie, paper-based programmes) have shown modest improvements in UL outcomes.[14] Such interventions are often limited by the severity of motor impairment, low motivation and lack of guidance or performance feedback.[15–17] Compliance is typically self-reported,[18] leaving little clarity around actual intervention dose. Rehabilitation technologies pose a pragmatic solution to optimising UL rehabilitation dose.[19] Technology-based rehabilitation platforms may offer enhanced accessibility and motivational incentive, facilitate real-time and longitudinal performance feedback, as well dose quantification, to promote high doses of UL training for stroke survivors.[20] However, while technologies provide the means to supplement exercise dose, their clinical adoption, thus far, has been underwhelming.[21] Little is known about the adoption of self-directed rehabilitation technologies among the heterogeneous stroke survivor cohort, with much research focusing on homogenous, 'high-functioning' groups.[13 22–27] Furthermore, self-directed interventions, thus far, have leveraged on significant 'hands-on' support to maintain adherence.[13 28 29] The extent to which an intervention will be effective (ie, produce measurable gains), depends on the degree of adherence. This begs the question: if patients are truly left to their own devices (in both senses), with low levels of supervision and support found in the public healthcare inpatient and community services, will they engage with technology-based interventions to the extent prescribed and/or modelled in clinical trials. Bridging this 'translational gap' is a much-needed focus of rehabilitation research.[30–32]

Here, we trial a simple, low-cost, exergaming system (GripAble) (figures 1 and 2) designed to promote intensive self-directed UL exercise (repetitive, task-specific training), through interactive gaming activities within a non-immersive virtual environment. The platform has been adapted to optimise accessibility and engagement in a stroke context. The system consists of a flexible, hand-held device that senses both grip force and rigid acceleration, enabling measurement of finger, wrist and arm movements. Through individualised calibration, training is tailored to the user's ability and can be adapted over time. The device houses an inbuilt motor, enabling haptic feedback and communicates wirelessly with a tablet on which there is a suite of UL exergames within an app. Once participants select an activity, the app provides instructions to guide the user through the activity.



Figure 1 GripAble tablet and hand controller: demonstrates the components of the rehabilitation technology employed in this research, that is, the electronic tablet on which the software is stored (GripAble App) and the hand-held sensor which is used to interact with App-based activities during training.

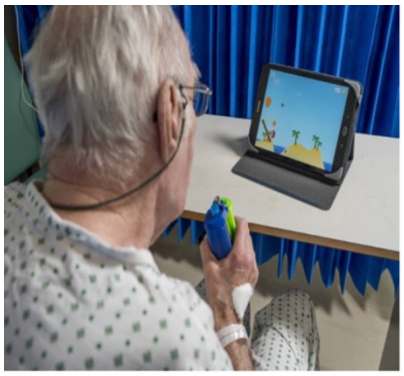


Figure 2 Stroke patient using GripAble, single player grasp and release activity: demonstrates a stroke survivor engaged in upper limb rehabilitation activities using the technology employed in this research. *The person depicted is not a research participant and image was captured with the participant's knowledge.

Prior work investigated the feasibility of this intervention for self-directed rehabilitation in a heterogeneous, inpatient and stroke survivor cohort.[33] Participants (n=30) increased daily UL exercise duration twofold, and repetitions eightfold, compared with standard care, without requiring additional professional supervision. The proposed pilot randomised controlled trial (RCT) addresses an important focus for stroke rehabilitation: the capacity to increase exercise dose, without imposing an additional resource burden on stroke rehabilitation stakeholders. The protocol is based on gold-standard clinical trial development and reporting guidelines.[34–36]

The primary aim is to evaluate the study design for an RCT testing the efficacy of a self-directed exergaming intervention for UL recovery after stroke. Secondary aims are to (a) assess whether stroke survivors will engage in self-directed UL training and (b) explore factors associated with intervention adherence.

The objectives are to:

- Assess recruitment, retention and data completeness within both intervention and control groups.
- Evaluate adherence with the intervention.
- Examine the usability, acceptability and adoption of the intervention among stroke survivors and identify factors associated with this.
- To estimate the sample size for an RCT.

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As this is an internal pilot study, progression criteria have been established[37]; progression criteria will be assessed using a traffic light system of green (go), amber (amend) and red (stop). Progression criteria will include recruitment and retention (length of recruitment period—opening of proposed centres, attrition rate), data completeness, incidence of research-related adverse or serious adverse events, protocol non-adherence, changes to the protocol such that would indicate further feasibility or pilot testing.

METHODS AND ANALYSIS

A single-blinded, mixed-methods pilot RCT, parallel design, will compare an intervention group (self-selected dose of self-directed UL exergaming as an adjunct to conventional care) with a control group receiving conventional care only. This is an internal pilot study; if no changes are made to the protocol, data will be included in the subsequent definitive trial. Published and unpublished prior work has informed this intervention design and research protocol.[38]

Patient and public involvement

All research design was undertaken through consultation and collaboration with patient and public representatives, who formed part of the research team, as well as independent expert clinical and academic stakeholders. A steering group will oversee the study implementation/progress and support interpretation and dissemination of findings. All time and travel associated with ongoing patient and public involvement (PPI) will be reimbursed according to the National Institute for Health Research INVOLVE guidelines.[39]

Study setting

Participants will be recruited from hyperacute and acute stroke units at four stroke centres in the UK. Participants will continue to receive the intervention/follow-up within the community when discharged from hospital.

Participants

Inclusion criteria:

- Adults, aged 18 or over.
- Stroke diagnosis (first or subsequent stroke, haemorrhagic or ischaemic) within 30 days of onset at point of recruitment.
- UL motor deficit poststroke (bilateral/unilateral)
  1. Distal UL power >1/5 on the Oxford Rating Scale (Medical Research Council Manual Muscle Testing scale).

  Or

  2. Voluntary finger extension of the thumb and/or two or more fingers of the affected hand (to 10° or more).[40]

The presence of sensory impairment (including neglect syndrome) or movement disorder (apraxia) is not a contraindication to enrolment, permitting there is a concurrent motor deficit (as described above).

- Cognitively able to use the intervention (±support) and engage in protocol-related trainings/assessments; to be indicated by treating clinician at point of screening.
- Can communicate and understand sufficient English, for completion of intervention and outcome measures. English language translation services may be used for consenting procedures. A decision to include or exclude those with significant expressive or receptive communication impairment will only be made following consultation with the treating speech and language therapist to ensure all reasonable accommodations are made to support participation.

Exclusion criteria:

- Patients concurrently enrolled in an interventional or observational neurorehabilitation trial.
- Patients concurrently enrolled in clinical trials that contraindicate co-enrolment (to be discussed with respective chief investigators on a case-by-case basis). The burden of assessment milestones will be considered for any co-enrolled participants.
- Patients presenting with unstable medical conditions/medical contraindications as determined by treating medical consultant (these patients may be approached at a later date should their condition improve).
- Patients with uncontrolled photosensitive epilepsy/other neurological symptoms that may be exacerbated by a required focus on light-emitting diode (LED) screen/moving object on screen.
- Those registered blind or with uncompensated/uncorrected visual deficits.
- Behavioural/affective dysfunction (eg, relating to alcohol dependence or untreated psychological comorbidities) which could influence the ability of the person to engage with the research protocol and/or pose risk to researchers (in circumstances such as follow-up community visits).
- Other concomitant neurological disorders affecting upper extremity motor function (multiple sclerosis, spinal cord injury, brachial plexus or radial nerve injury).
- Unremitting arm pain at rest.
- Pre-existing UL impairment with known and significant disruption to range of motion, motor or functional performance (fracture, arthritic changes, other known musculoskeletal problems).

Recruitment

Delegated healthcare practitioners or clinical research network practitioners (co-investigators) will screen for and identify appropriate participants on a daily/weekly basis (as relevant to their setting). Potential participants will be provided with information about the study, including being shown the technology. They will be given at least 24 hours to consider this information and ask any questions;

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those willing to participate will be asked to provide informed, written consent. Participants lacking capacity to consent to research participation will be recruited based on the declaration of a personal consultee.

Site-specific electronic recruitment logs will be maintained to record all identified patients, eligible patients, patients provided with a Participant Information Sheet (PIS) and patients consenting to participate. Missed opportunities and reasons for dissent (where provided) will also be recorded. Screening and recruitment data will be logged on DOCUMAS or EDGE (site-specific). The study recruitment phase will open for a total of 12 months, participants' enrolment in the study will last 6 months.

Sample size calculation

Feasibility study data are not used to guide recruitment/retention estimates for this work, as this feasibility work was non-randomised, did not have a fixed enrolment duration and took place at a single centre. In a systematic review of the efficiency of recruitment to neurorehabilitation trials, authors found that on average, sites recruited 1.5 participants per site per month (IQR 0.71–3.22), and 1 in 20 (6% (IQR 0–13) dropped out during the RCTs.[41] Estimating recruitment of 1.5 participants per month at 4 sites over a 12-month recruitment period, we set a target sample size of 72 (68, allowing a 6% dropout rate). Guidelines advocate a sample size of 12–30 participants per group for pilot testing.[42 43] Due to the long timespan and multicentre setting of this study, a greater risk of loss to follow-up was anticipated, Consequently, a slightly increased target sample size was set to ensure sufficient power for analysis of results.

To guide estimations for ongoing work, a formal power calculation was conducted, using open source software[44] on R-Studio, implementing methods described by Jones *et al*.[45] Baseline data from our feasibility sample were used, assuming the proportional recovery rule,[46] to detect a minimum clinically important difference (MCID) of 4.9 on the primary outcome measure (FM-UE). The distribution of FM-UE scores was examined in the target population; the Shapiro-Wilk normality test ($p<0.05$) was used to verify data normality. The standard deviation (SD) of baseline FM-UE scores was 15.608. At 80% power (1–β) and with an unpaired two-sided t-test with significance level 0.05 (α) this would require an estimated sample size of 176. We retrospectively estimate that a sample size of 72 (36 in each group) will power our pilot work at 50% (0.49398) power (1–β). Data collected during pilot testing will enhance the rigour of a power calculation for the definitive trial.

Intervention

Participants will be allocated to a treatment group using a 1:1 ratio, using computer-generated block randomisation, stratified for participants' location (site), National Institutes of Health Stroke Scale (NIHSS) score and FM-UE score. The primary researcher will perform allocation for all sites. Intervention will commence directly after randomisation.

Intervention group

Participants randomised to the intervention group will be trained to use the technology in a single session using a standardised education and training protocol. Where appropriate/available, a relative, carer or friend will be included in this session. Participants (and a relative, carer or friend where appropriate) will have a follow-up session the next day to review and rate their performance in using the device (independent/support for set up only (modified independence)/supervision and support required (assistance)/unable). The intervention group will be provided with the device from randomisation up until 3 months poststroke. Intervention group participants will be encouraged to train daily, implementing a self-selected UL training dose, in addition to conventional care. User adherence data (UL exercise dose: duration of active time on task daily/weekly, number and frequency of training episodes, number of movement repetitions per training episode/day/week, type of exercises completed and force exerted/calibration of training resistance) will be automatically captured electronically and may be accessed by researchers throughout the intervention period. Throughout the intervention period, researchers will screen for intervention support needs or equipment malfunction via phone calls fortnightly (or as required), and offer individualised coaching using the Topic, Goal, Reality, Options and Way forward (T-GROW) model,[47] either in person or remotely. Participants will also have access to a dedicated technical support helpline. All contact time with intervention participants will be logged.

Control group

The control group will continue to receive conventional care. Aside from collection of data, they will not have any direct or additional input from the research team. Conventional care norms for participants across both groups will be reported by recording whether or not participants had an UL rehabilitation goal set, whether or not they were provided with an UL self-exercise programme and the frequency and duration of occupational therapy and physiotherapy input received as part of conventional care (as logged in local Sentinel Stroke National Audit Programme (SSNAP) databases).

Outcomes

All participant data will be securely stored in hardcopy case record files, duplicate data will be stored on an electronic data capture system; Research Electronic Data Capture (REDCap). All data will be stored and accessed in line with General Data Protection Regulation guidelines.

Clinical and demographic data collected for sample description and subgroup/correlation analysis

Clinical data collected at baseline will support subgroup analysis and enhance interpretation of associations between intervention outcomes and relevant clinical/

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Table 1 Baseline demographic and clinical data

Patient age (years)
Sex (male/female/other)
Ethnicity (white British/ white other, mixed/multiple ethnic groups, Asian/Asian British, black/ African/Caribbean/black British, other ethnic group)
Comorbidities (medical history)
Previous stroke (Y/N)
Capacity to consent/personal consultee declaration provided
Baseline cognitive score (Montreal Cognitive Assessment)
Mood at 0, 3 and 6 months (Hospital Anxiety and Depression Scale)
Pain 0, 3 and 6 months (Faces Pain Rating Scale)
Fatigue 0, 3 and 6 months (Fatigue Severity Scale)
Premorbid function (modified Rankin Scale)
Prior technology exposure (select one) - Does not own or use a mobile phone - Owns a mobile phone (does not use) - Owns and uses a mobile phone (calls/texts) - Owns and uses a smart phone (apps/internet)
Stroke Severity (24 hours NIHSS)
Stroke type (ischaemic/haemorrhagic), stroke subtype (lacunar/large artery/other, eg, carotid dissection/undetermined)
Stroke location (cortical: internal capsule, middle cerebral artery (MCA), frontal lobe/subcortical: thalamus, basal ganglia/ midbrain: pons, medulla, cerebellum/brainstem)
Thrombolysis/thrombectomy/N/A
Stroke diagnosis confirmed on imaging: Y/N—If 'N' ensure clinical diagnosis documented
Time since stroke (weeks)
Clinical course (normal, repeat neurological event, aspiration, sepsis, delirium, falls, other medical deterioration)
Handedness: Edinburgh Handedness Scale (Left/Right/Both)
Affected UL: Right/Left/Bilateral (L/R/BL)
UL goal set (documented in charts)
UL self-exercise programme provided (ie, Graded Repetitive Arm Supplementary Programme (GRASP)) (documented in charts)
Average daily OT/PT rehabilitation (SSNAP data) (7-day average from enrolment)
Length of hospital admission (days)
Subsequent discharge outcome (home, Early Supported Discharge (ESD), onsite inpatient rehabilitation, other)
Frequency of community rehabilitation (nil, fortnightly or less, weekly, more than weekly)
Location at 3-month follow-up (home, inpatient rehabilitation, nursing home, residential home, supported living, other)
Location at 6-month follow-up (home, inpatient rehabilitation, nursing home, residential home, supported living, other)
Social Deprivation Index (based on postcode of home address) (standardised rank of 1–10)

It presents the clinical and demographic data which will be collected to describe the research sample, explore associations between sample characteristics and outcomes, and understand relevant context for interpreting results.
NIHSS, National Institutes of Health Stroke Scale; OT, occupational therapy; PT, physiotherapy; SSNAP, Sentinel Stroke National Audit Programme; UL, upper limb.

demographic features. These assessments and data points are listed in table 1.

Research design evaluation

- Recruitment efficiency—Percentage of stroke survivors: screened, eligible, approached and consented.
- Retention and completion rates—Percentage of participants who complete the intervention period, attend all data collection visits/engage in all data collection items. Drop-out rates and details of participant withdrawals.
- Protocol implementation—Time taken to collect and analyse data. Standardisation of assessment protocols and inter-rater variance on primary and secondary outcome measures will be audited based on video recordings of assessment sessions and remote assessment scoring by a second, blinded researcher.

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- Adverse events—A log will be maintained in which all adverse events will be categorised (serious/non-serious and related/unrelated to research participation), recorded and reported in line with Good Clinical Practice protocol.
- Acceptability of the protocol—Number of participants who withdraw or decline participation, along with reasons for dissent or withdrawal. An end-point research survey composed of a 3-point Likert scale (agree/disagree/neutral) will be used to evaluate participants' experience of the research protocol, materials and implementation.
- Power calculation—Primary and secondary outcome measures will be administered at baseline, intervention end-point and 6-month follow-up. These data will inform a power calculation to estimate parameters for a robust sample size within a definitive RCT. See the Clinical assessments section for further details.

Usability, acceptability and adoption of the intervention

- Usability—A 4-point user performance rating scale formulated for the purposes of this study will be administered within the intervention group; rating users' performance with the technology as (4) independent (3) support for set up only (modified independence); (2) supervision and support required (assistance); (1) or unable to use meaningfully (unable). Performance ratings will be allocated, by the researchers, based on the following device functionalities: physical set up; turning on; accessing the activity platform; selecting and executing exercise software; executing the physical exercise requirements; device charging. Amount of time per participant required for education, intervention training and technical or other support will be logged throughout the study and analysed at study end-point.
- Acceptability of the intervention—A survey examining participants' experience with the intervention will be administered at the intervention end-point (3 months poststroke). This will comprise a 5-point Likert Scale, with items and subcategories based on domains of the Capability Opportunity Motivation-Behaviour (COM-B) model.
- Adoption of the intervention—Measure of UL training dose per participant, as recorded by system analytics, will provide an objective indicator of adoption.
  Participants' views and experience—Semistructured interviews will be conducted with a purposive sample of 10 intervention group participants at the intervention end-point, to explore the barriers and facilitators to engagement with the intervention from the perspective of participants.

Clinical outcomes

A standardised assessor training package will be undertaken by all researchers participating in clinical data collection. Interrater reliability will be assessed between the researchers as part of protocol training, to ensure a consensus is achieved in administration and scoring of all outcome measures. Baseline assessments will be completed by delegated researchers prior to randomisation. Primary and secondary outcome measures will be video recorded for 3-month and 6-month assessment points; a local researcher will administer and score the assessment, a random sample of assessment recordings will then be scored by a blinded assessor to ensure consensus between blinded and unblinded scores. If a discrepancy is identified between blinded and unblinded scores on review of this initial sample of recordings, assessor-blinded scores will be applied to the whole sample to negate risk of assessor bias. This method of remote assessment has been widely validated for both the FM-UE and the ARAT.[48]

- UL impairment: The primary outcome will be the between-group difference on the FM-UE at 6 months poststroke, based on intention to treat analysis. This will be used to estimate parameters for a sample size calculation for an RCT. The FM-UE measures change at the impairment level, assessing UL impairment in terms of synergistic motor control. It has three categories, comprised 22 subquestions scored on a 3-point ordinal scale (0=unable, 1=partial, 2=near normal). The sum of the categories ranges between 0 and 66 points (66=normal function). The MCID on the FM for acute–subacute stroke patients is an increase of >4 points.[49] In a similar population, Hiragami *et al* suggest a change of 4.9 points, which is consistent with participant perceptions of meaningful change in UL impairment among stroke survivors.[38] The FM-UE has shown excellent inter-rater reliability[50 51] moderate to good responsiveness and good concurrent validity when compared with similar tests of UL motor impairment.[49]
- UL function: The secondary outcome measure is the ARAT (Lyle, R.C 1981). The ARAT assesses upper-extremity deficits at the activity level. The ARAT is an UL capacity test which assesses the ability to grasp, move and release objects of various sizes, weights and shapes. It has 19 subquestions scored on a 4-point ordinal scale, adding up to a total score between 0 and 57 points (57=normal capacity).
- Functional performance: The Barthel Index is an ordinal scale used to measure performance in activities of daily living (ADLs). Ten variables describing ADL and mobility are scored, a higher number being a reflection of greater ability to function independently following hospital discharge. We will use self-reported or proxy-reported ratings for this scale.[52] A further assessment of function will include the modified Rankin Scale (mRS); a clinician-reported measure of global disability. Six statements describe subjects' overall level of ability/disability, with a lower score reflecting a greater functional ability.

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Data analysis

Quantitative data

Data collected via research logs, survey items and clinical/demographic data (sample characteristics) will be analysed and reported as descriptive statistics. Intervention dose will be interpreted from electronic user analytics for the intervention group. This will encompass users' activity patterns by day and hour of day over the course of the intervention period. These will be analysed to establish daily training dose, overall intervention training dose, as well presented as usage patterns/change in usage behaviour over time. We will compare the results on each clinical outcome measure for intervention and control groups. We will implement subgroup analysis based on premorbid and baseline characteristics and explore correlations between characteristics and outcomes. To control for attrition bias, an intention-to-treat approach will be taken and all data will be used in final analysis. Missing data points will be imputed using individual curve fitting for subjects with two available assessments by estimating the recovery curves using multivariate imputation.

Qualitative data

Interview recordings will be transcribed verbatim. The primary researcher will familiarise themself with the dataset, undertaking to read/re-read transcripts several times and review all footnotes. An explorative, inductive approach will be employed, from a relativist, ontological stance. Reflexive thematic analysis will be used to code interview data and generate key themes. Codes, and subsequently themes, will be reviewed and agreed by second and third researchers to ensure consistency in interpretation of the dataset. To enhance the practical application of findings, themes will subsequently be mapped onto the COM-B model[53] and Theoretical Domains Framework[54] to identify targeted mechanisms to inform future intervention design and support intervention adoption.

Ethics and dissemination

The study was granted ethical approval by the Health Research Authority, Health and Care Research Wales, and the London-Harrow Research Ethics Committee (ref. 21/LO/0054). Local site capacity and capability approval has been granted by participating NHS trusts. The current approved protocol version is V.1.9 dated 21 May 2021 and has been published on the clinical trial registry (ClinicalTrials.gov identifier: NCT04475692). Any changes to the protocol will be submitted as amendments to the Research Ethics Committee and approved by local research boards prior to implementation.

Participants are free to withdraw from the study at any time, data collected prior to participant withdrawal will be used in final analysis. In addition to a participant's decision to withdraw, withdrawal criteria are included in the research protocol to guide researchers when observing/interpreting participants for contraindications to continued participation in the research; these include medical deterioration, neurological deterioration or change in mental capacity. The day-to-day management of the study will be coordinated by the CI and local principal investigators. A study steering committee formed of the independent stroke clinicians, PPI representatives and research support staff from the participating sites will meet at regular intervals throughout the study.

Regular updates about the trial will be made available through social media, blog posts and electronic newsletters. Trial results will be submitted for publication in journals, presented at national and international stroke meetings and conferences and disseminated among stroke community stakeholders. The results of this trial will inform development of subsequent research.

Contributors In order of authorship as listed previously: MB: contributed to the research idea, developed the research protocol and protocol materials, managed research approvals and registry processes, prepared the protocol manuscript for publication. PB and JBu (equally contributed): conceived the research idea, obtained the research grant, contributed to the research protocol development, oversaw research approvals and reviewed the protocol manuscript. SD: supervised and contributed to design of the qualitative research methodology, as well as associated research materials and reviewed the protocol manuscript. JBe and LJ: contributed to the research protocol development and review and and reviewed the protocol manuscript. RO'S: contributed to data analysis plan and reviewed the protocol manuscript.

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Competing interests PB was involved in the Imperial College London research group who developed and conducted initial testing of the technology (GripAble) used in this study. Grip Able has since spun-out of Imperial College to form a limited company, PB does not hold a paid role within GripAble.

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.

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REFERENCES

1 Pollock A, St George B, Fenton M, *et al*. Top 10 research priorities relating to life after stroke-consensus from stroke survivors, caregivers, and health professionals. *Int J Stroke* 2014;9:313–20.
2 Winstein C, Varghese R. Been there, done that, so what's next for arm and hand rehabilitation in stroke *NeuroRehabilitation* 2018;43:3–18.
3 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.
4 Pollock A, Farmer SE, Brady MC, *et al*. Interventions for improving upper limb function after stroke. *Cochrane Database Syst Rev* 2014;2014:CD010820.
5 Jeffers MS, Corbett D. Synergistic effects of enriched environment and task-specific reach training on poststroke recovery of motor function. *Stroke* 2018;49:1496–503.
6 Nudo RJ, Wise BM, SiFuentes F, *et al*. Neural substrates for the effects of rehabilitative training on motor recovery after ischemic infarct. *Science* 1996;272:1791–4.

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7 Lohse KR, Lang CE, Boyd LA. Is more better? Using metadata to explore dose-response relationships in stroke rehabilitation. *Stroke* 2014;45:2053–8.
8 Clark B, Whitall J, Kwakkel G, *et al*. The effect of time spent in rehabilitation on activity limitation and impairment after stroke. *Cochrane Database Syst Rev* 2021;10:CD012612.
9 Hayward KS, Brauer SG. Dose of arm activity training during acute and subacute rehabilitation post stroke: a systematic review of the literature. *Clin Rehabil* 2015;29:1234–43.
10 Clarke DJ, Burton L-J, Tyson SF, *et al*. Why do stroke survivors not receive recommended amounts of active therapy? Findings from the react study, a mixed-methods case-study evaluation in eight stroke units. *Clin Rehabil* 2018;32:1119–32.
11 Lynch EA, Cadilhac DA, Luker JA, *et al*. Inequities in access to inpatient rehabilitation after stroke: an international Scoping review. *Top Stroke Rehabil* 2017;24:619–26.
12 Meadmore KL, Hallewell E, Freeman C, *et al*. Factors affecting rehabilitation and use of upper limb after stroke: views from healthcare professionals and stroke survivors. *Top Stroke Rehabil* 2019;26:94–100.
13 Da-Silva RH, Moore SA, Price CI. Self-directed therapy programmes for arm rehabilitation after stroke: a systematic review. *Clin Rehabil* 2018;32:1022–36.
14 Connell LA, McMahon NE, Harris JE, *et al*. A formative evaluation of the implementation of an upper limb stroke rehabilitation intervention in clinical practice: a qualitative interview study. *Implement Sci* 2014;9:90.
15 Poltawski L, Boddy K, Forster A, *et al*. Motivators for uptake and maintenance of exercise: perceptions of long-term stroke survivors and implications for design of exercise programmes. *Disabil Rehabil* 2015;37:795–801.
16 Barker RN, Gill TJ, Brauer SG. Factors contributing to upper limb recovery after stroke: a survey of stroke survivors in Queensland Australia. *Disabil Rehabil* 2007;29:981–9.
17 Harris JE, Eng JJ, Miller WC, *et al*. A self-administered graded repetitive arm supplementary program (GRASP) improves arm function during inpatient stroke rehabilitation. *Stroke* 2009;40:2123–8.
18 Levy T, Laver K, Killington M, *et al*. A systematic review of measures of adherence to physical exercise recommendations in people with stroke. *Clin Rehabil* 2019;33:535–45.
19 Domínguez-Téllez P, Moral-Muñoz JA, Salazar A, *et al*. Game-based virtual reality interventions to improve upper limb motor function and quality of life after stroke. *Games Health J* 2020;9:1–10.
20 Parker J, Powell L, Mawson S. Effectiveness of upper limb wearable technology for improving activity and participation in adult stroke survivors: systematic review. *J Med Internet Res* 2020;22:e15981.
21 Thomson K, Pollock A, Bugge C, *et al*. Commercial gaming devices for stroke upper limb rehabilitation: a survey of current practice. *Disabil Rehabil Assist Technol* 2016;11:454–61.
22 Chi N-F, Huang Y-C, Chiu H-Y, *et al*. Systematic review and meta-analysis of home-based rehabilitation on improving physical function among home-dwelling patients with a stroke. *Arch Phys Med Rehabil* 2020;101:359–73.
23 Wittmann F, Held JP, Lambercy O, *et al*. Self-directed arm therapy at home after stroke with a sensor-based virtual reality training system. *J Neuroeng Rehabil* 2016;13:75.
24 Nijenhuis SM, Prange GB, Amirabdollahian F, *et al*. Feasibility study into self-administered training at home using an arm and hand device with motivational gaming environment in chronic stroke. *J Neuroeng Rehabil* 2015;12:89.
25 Slijper A, Svensson KE, Backlund P, *et al*. Computer game-based upper extremity training in the home environment in stroke persons: a single subject design. *J Neuroeng Rehabil* 2014;11:35.
26 Dodakian L, McKenzie AL, Le V, *et al*. A home-based telerehabilitation program for patients with stroke. *Neurorehabil Neural Repair* 2017;31:923–33.
27 Zondervan DK, Friedman N, Chang E, *et al*. Home-based hand rehabilitation after chronic stroke: randomized, controlled single-blind trial comparing the music glove with a conventional exercise program. *J Rehabil Res Dev* 2016;53:457–72.
28 Chen Y, Abel KT, Janecek JT, *et al*. Home-based technologies for stroke rehabilitation: a systematic review. *Int J Med Inform* 2019;123:11–22.
29 Rémy-Néris O, Le Jeannic A, Dion A, *et al*. Additional, mechanized upper limb self-rehabilitation in patients with subacute stroke: the REM-AVC randomized trial. *Stroke* 2021;52:1938–47.
30 Morone G, Cocchi I, Paolucci S, *et al*. Robot-assisted therapy for arm recovery for stroke patients: state of the art and clinical implication. *Expert Rev Med Devices* 2020;17:223–33.
31 Laver KE, Lange B, George S, *et al*. Virtual reality for stroke rehabilitation. *Cochrane Database Syst Rev* 2017;11:CD008349.
32 Glegg SMN, Levac DE. Barriers, facilitators and interventions to support virtual reality implementation in rehabilitation: a scoping review. *PM R* 2018;10:1237–51.
33 Broderick M, Almedom L, Burdet E, *et al*. Self-directed exergaming for stroke upper limb impairment increases exercise dose compared to standard care. *Neurorehabil Neural Repair* 2021;35:974–85.
34 Eldridge SM, Chan CL, Campbell MJ, *et al*. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
35 Chan A-W, Tetzlaff JM, Altman DG, *et al*. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
36 Bernhardt J, Borschmann K, Boyd L, *et al*. Moving rehabilitation research forward: developing consensus statements for rehabilitation and recovery research. *Int J Stroke* 2016;11:454–8.
37 Avery KNL, Williamson PR, Gamble C, *et al*. Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. *BMJ Open* 2017;7:e013537.
38 Hiragami S, Inoue Y, Harada K. Minimal clinically important difference for the Fugl-Meyer assessment of the upper extremity in convalescent stroke patients with moderate to severe hemiparesis. *J Phys Ther Sci* 2019;31:917–21.
39 UK Standards for Public Involvement. Working together. 2023. Available: https://sites.google.com/nihr.ac.uk/pi-standards/standards/working-together
40 Persson HC, Parziali M, Danielsson A, *et al*. Outcome and upper extremity function within 72 hours after first occasion of stroke in an unselected population at a stroke unit. A part of the SALGOT study. *BMC Neurol* 2012;12:162.
41 McGill K, Sackley CM, Godwin J, *et al*. A systematic review of the efficiency of recruitment to stroke rehabilitation randomised controlled trials. *Trials* 2020;21:68.
42 Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract* 2004;10:307–12.
43 Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharm Stat 2005;4:287–91. 10.1002/pst.185 Available: https://onlinelibrary.wiley.com/toc/15391612/4/4
44 Champely S. PWR: basic functions for power analysis. 2020. Available: https://cran.r-project.org/package=pwr
45 Jones SR, Carley S, Harrison M. An introduction to power and sample size estimation. *Emerg Med J* 2003;20:453–8.
46 van der Vliet R, Selles RW, Andrinopoulou E-R, *et al*. Predicting upper limb motor impairment recovery after stroke: a mixture model. *Ann Neurol* 2020;87:383–93.
47 Whitmore J. *Coaching for Performance: A Practical Guide to Growing Your Own Skills*. 1st ed. Nicholas Brealey, 1992.
48 Amano S, Umeji A, Uchita A, *et al*. Reliability of remote evaluation for the Fugl–Meyer assessment and the action research arm test in hemiparetic patients after stroke. *Top Stroke Rehabil* 2018;25:432–7.
49 Lundquist CB, Maribo T. The Fugl–Meyer assessment of the upper extremity: reliability, responsiveness and validity of the Danish version. *Disabil Rehabil* 2017;39:934–9.
50 Sullivan KJ, Tilson JK, Cen SY, *et al*. Fugl-Meyer assessment of sensorimotor function after stroke standardized training procedure for clinical practice and clinical trials. *Stroke* 2011;42:427–32.
51 Duncan PW, Goldstein LB, Matchar D, *et al*. Measurement of motor recovery after stroke outcome assessment and sample size requirements. *Stroke* 1992;23:1084–9.
52 Hsieh Y-W, Wang C-H, Wu S-C, *et al*. Establishing the minimal clinically important difference of the Barthel index in stroke patients. *Neurorehabil Neural Repair* 2007;21:233–8.
53 Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.
54 Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* 2012;7:37.

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