BMJ Open

EvolvRehab–MoveWell telerehabilitation for stroke survivors: study protocol for a feasibility with embedded initial proof-of-concept study

Jemma Perks [ID],[1,2] Philip McBride,[1,2] Maedeh Mansoubi [ID],[2] Philip Clatworthy,[3] Claire Hulme,[4] Gordon Taylor,[5] Martin Warner,[6] Helen Dawes [ID][2]

[1]University of Exeter, Exeter, UK
[2]Medical School, University of Exeter, Exeter, UK
[3]North Bristol NHS Trust, Southmead, UK
[4]Health Economics Group, University of Exeter, Exeter, UK
[5]College of Medicine and Health, University of Exeter, Exeter, UK
[6]University of Southampton, Southampton, UK

Correspondence to
Dr Jemma Perks;
jperksphd@gmail.com

ABSTRACT

Introduction Stroke is a leading cause of disability throughout the world. Unilateral upper limb impairment is common in people who have had a stroke. As a result of impaired upper limb function, people who have had a stroke often employ abnormal 'compensatory' movements. In the short term, these compensatory movements allow the individual to complete tasks, though long-term movement in this manner can lead to limitations. Telerehabilitation offers the provision of rehabilitation services to patients at a remote location using information and communication technologies. 'EvolvRehab' is one such telerehabilitation system, which uses activities to assess and correct compensatory upper body movements, although the feasibility of its use is yet to be determined in National Health Service services. Using EvolvRehab, we aim to assess the feasibility of 6 weeks telerehabilitation in people after a stroke.

Methods and analysis A multisite feasibility study with embedded design phase. Normally distributed data will be analysed using paired samples t-tests; non-normally distributed data will be analysed using related samples Wilcoxon signed rank tests. Thematic content analysis of interview transcripts will be used to investigate the usability and perceived usefulness of the EvolvRehab kit.

Ethics and dissemination This study has received ethical approval from Solihull Research Ethics Committee (REC reference: 23/WM/0054). Dissemination will be carried out according to the dissemination plan co-written with stroke survivors, including academic publications and presentations; written reports; articles in publications of stakeholder organisations; presentations to and publications for potential customers.

Trial registration number NCT05875792.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The multicentre study design will improve the generalisability of the results.
⇒ The use of comprehensive assessments of performance-based impairment alongside clinical outcome measures may provide valuable additional insight into the health profiles of people who have suffered a stroke.
⇒ Data of compliance and adherence to training protocols will inform rehabilitation prescription following stroke in relation to outcomes.
⇒ Without a control group, we cannot be sure that any potential differences observed are a result of the exposure.

INTRODUCTION

Stroke is a leading cause of disability throughout the world. In 2019, it was estimated that there were around 12.2 million new cases of stroke, 101 million cases of prevalent stroke, and 142 disability-adjusted life-years as a result of stroke.[1] In England, Wales and Northern Ireland, between 80,000 and 100,000 people are admitted to hospitals with stroke each year.[2] The ongoing effects of stroke are various and may include sensory, motor, and cognitive impairment, as well as reduced ability to engage in social activities and perform activities of daily living (ADLs).[1 3] Unilateral upper limb impairment is common in people who have had a stroke, with 40% of people still having severe impairment of arm function, 40% having mild-to-moderate impairment, and only 20% having 'normal' function 3 months after a stroke.[4 5] As a result of impaired upper limb function, people who have had a stroke often employ abnormal 'compensatory' movements of the trunk, and scapula, during reaching movements, and/or replace the use of the paretic arm with additional use of the less impaired side.[6] In the short term, these compensatory movements allow the individual to complete tasks; though long-term movement in this manner can lead to limited range of motion, joint contractures, muscle weakness, impingement syndromes, and 'learnt non-use' of muscles involved in more 'normal' patterns of movement.[7–11]

The COVID-19 pandemic forced many healthcare systems, including stroke services,

to re-examine how care can be delivered; lessons which should be carried forward post-COVID-19.[2] One such opportunity is the potential for telerehabilitation—the provision of rehabilitation services to patients at a remote location using information and communication technologies[12]—to aid in the delivery of home-based rehabilitation programmes for people who are recovering from stroke.[13] A recent Cochrane review considered whether the use of telerehabilitation leads to improved ability to perform ADLs in people who have experienced stroke.[14] Within the review, three randomised controlled trials (RCTs) were pooled to compare in-person care to computer software, to rehabilitate upper limb function (170 participants in total). One study compared the same intervention delivered in-person versus virtually,[15] one compared virtual reality telerehabilitation to conventional in-person therapy,[16] and one investigated comparable doses and modes of therapy delivered either in-clinic or through telerehabilitation.[17] Within the review, a further three RCTs compared telerehabilitation to usual care to rehabilitate upper limb function, one using written and video instructions,[18] one using phone and messaging systems,[19] and one using a computer-based system.[20] The report suggests telerehabilitation is not inferior to in-person care, however these pooled analyses were reported as low-quality evidence. The review also notes that while some of the included studies report telerehabilitation being less expensive, there was a lack of information about cost-effectiveness. In a follow-up article, Laver *et al*[21] highlighted the potential benefits of telerehabilitation for improving access to services for people for whom travel is less convenient, as well as the potential for easier prescription of exercises from the healthcare provider. However, they also highlight that it is not currently possible to discern whether the economic savings in, for example, travel time will account for factors such as inefficiencies due to technical difficulties, and investment in hardware, software, ongoing technical support and maintenance.[21]

Based on a preliminary search of the PubMed database using "telerehabilitation" and "stroke" as search terms, reports on at least 20 RCTs have been published since 2018. The robustness of these studies varies, sample sizes range from 10[22] to 124[17 23] participants. An example of these from the USA, reported on 124 people who had experienced a stroke in the preceding 4–36 weeks who were randomised to either a usual care group (within an outpatient rehabilitation therapy clinic) or a home-based telerehabilitation group.[17] Over 6 weeks, each group received thirty-six, 70 minute sessions of upper limb rehabilitation, with intensity, duration, and frequency matched across groups. Post-intervention, results were comparable between the two groups, with participants in the telerehabilitation and usual care groups making substantial gains in upper limb function. A more recent expansion of this trial assessed the feasibility of various additional components, including the use of augmented reality-based games that emphasised movements integral to ADLs.[24] The study successfully incorporated augmented reality elements in the form of video-based motion tracking and sensors attached to real-world objects. Participants continued to make improvements over the 12-week intervention, and the augmented reality telerehabilitation systems were well accepted. However, the telerehabilitation system used in the study seemingly only tracks accumulation of movements and does not offer feedback to users on the quality of movement. Additionally, the study lacked a qualitative element, and therefore, could not explore the perspectives of patients and caregivers involved. Although the studies by Cramer *et al*[17 24] did not report on cost-effectiveness of interventions, another intervention evaluating the effectiveness of a virtual reality-based telerehabilitation system for balance recovery post-stroke proved promising.[25] Compared with in-clinic care, the telerehabilitation intervention resulted in US$654.72 fewer expenses per participant over 12 weeks.

The 'EvolvRehab' system is a telerehabilitation tool that incorporates an Azure Kinect 3D sensor camera, which uses artificial intelligence for body tracking. The system has been developed and evaluated in collaboration with the University College London, Queen Square Upper Limb Neurorehabilitation Programme clinical team. The system runs a complimentary programme 'EvolvRehab MoveWell' which uses activities to assess and correct compensatory upper body movements at the shoulder, trunk, and head which can be used in people who have had a stroke. In this way, the system uses augmented reality to deliver repetitive, 'gamified' exercises with the aim of increasing patient access and adherence to rehabilitation exercises. The system is not designed to act as a replacement for usual care, but as part of a rehabilitation programme, offering healthcare providers an adjunct tool to meet rehabilitation targets without adding to the burden on delivery teams.

Previous iterations of the system have shown to have good adherence rates and are potentially useful in the context of home-based specialised upper-limb rehab, for people late after stroke.[26] In the aforementioned study by Ellis *et al*, eight participants completed the 12-week intervention, reporting an 88% adherence rate (1710–9377 repetitions performed using the kit).[26] Additionally, there was some evidence of potential improvement in functional capacity, for example, performance on the Wolf Motor Function Test improved in both time (−7.9 to −27.2 s per item across three participants) and function (0.2–1.1 points per item across four participants).

However, before EvolvRehab MoveWell can be widely adopted into clinical practice, evidence of the feasibility of using the system implemented in services needs to be established; alongside the efficacy of use. Feasibility metrics including recruitment, completion of measures, compliance and adherence to the rehabilitation programme, potential for effect in measures of interest, cost benefits, and barriers and facilitators for the use of the system need to be established to inform the need for a full efficacy trial. Using EvolvRehab MoveWell, we aim

to assess the feasibility of 6 weeks telerehabilitation in people who have suffered a stroke. In line with feasibility studies, there will be no primary outcome, rather a range of measures will be described and used to plan the need for a follow-on trial and primary outcome measure.

METHODS AND ANALYSIS
Study design: using a feasibility study with embedded design phase

This study is carried out under the MRC framework for developing complex interventions and extensions for feasibility studies.[27] Under this framework, person-based methods underpin intervention development with an initial literature review followed by stakeholder interviews and proof-of-concept pilot phases. The study is also reported in line with the template for intervention description and replication guidelines outlined in online supplemental table 1. This study is split into two stages, an initial design phase (stage 1), followed by feasibility phase (stage 2).

Within stage 1, stages 1.2 (iterative proof of concept) and 1.4 (service user interviews) will be conducted by the University of Exeter (UofEx) unless problems with recruitment would require additional sites to be involved. All other tasks in stage 1 will be conducted by the following research sites: UofEx (site 1); Sirona care and health; St George's University hospitals National Health Service (NHS) trust and Solent NHS trust. The results from stage 1 of the study will be used to inform stage 2, following a protocol amendment to incorporate any changes required. All participants will give informed consent as outlined in the ethics section.

Stage 1: co-design development phase
Stage 1.1: review of product and processes for the preliminary pilot

This project has adopted a Person-Based Approach throughout (implementing PPIE as key stakeholders) to co-develop/refine the technology and clinical processes for use in stroke services (n=15). Work within this feasibility phase will include working with stroke survivors, occupational therapists, stroke clinicians, and carers to explore the capabilities of the EvolvRehab kit, and ask participants pre-specified questions relating to the system's usability, acceptability, and usefulness. These events will also help to refine the study design and gain general insight into key opinions of health technology, and its potential for providing rehabilitation at home.

Stage 1: co-design development phase continued
Stage 1.2: iterative proof-of-concept pilot work

This study will begin recruiting in June 2023 and will be completed by June 2024. EvolvRehab/MoveWell will be iteratively piloted in five stroke survivors' homes (n=5). Consent and recruitment procedures are described in detail later. Briefly, participants will be identified by their treatment team. If happy to hear more about the study, participants will complete a contact details form, will be offered a participant information sheet and informed consent form, and have a chance to discuss the study in more detail with the research team. Potential participants will be screened against inclusion/exclusion criteria and read a participant information sheet before consent will be taken. Participants will use EvolvRehab/MoveWell kit for 1 week, as well as wear bilateral activity monitors for up to 8 days prior to the intervention, and up to 8 days during the intervention (described later). The research team will visit participants' homes to provide initial support, and the team will monitor home safety during the implementation phase. A log of issues and feedback will be compiled, and system data will be collected to finalise system requirements. Data on outcome measure completion, safety and adherence, and compliance with the training programme will be collected and considered.

Stage 1.3: staff focus group

Rehabilitation team staff (eg, clinicians, carers, managers; n=5) will be asked to take part in semi-structured focus groups, in order to capture their opinions, regarding how EvolvRehab will be deployed in community stroke services. This project will explore barriers and facilitators to deployment and report how these will be identified and addressed. This will be advertised via poster and sent via email to stakeholders already involved in the study.

Stage 1.4: service user interviews

Semi-structured interviews will be held with stroke survivors participating in stage 1.2 (n=5) to explore issues experienced when using the system in their homes. We will explore support structures (eg, social networks) and barriers/facilitators to engagement. Potential software, hardware, support, and training changes will be mapped and reported. Instruction materials and a digital inclusion packages will be created. Participants will be contacted to organise this via telephone and/or email.

Stage 1.5: service specification

A final service and product specification, including reference to the materials above, will be prepared to inform the second stage of the study.

Stage 2 will include at least 6 weeks of study intervention, and up to 6 months follow-up, where possible, which is described next.

Stage 2 feasibility study phase
Stage 2.1: site engagement and setup

The study will initially be set up at four sites and will include staff training. Recruitment sites will be rolling, adding additional sites (with appropriate approvals) until the recruitment target is reached.

Stage 2.2: recruitment n=70

Consent and recruitment procedures are described in detail below. Briefly, participants will be identified by the site. If happy to hear more about the study, participants will complete a contact details form, will be offered

a participant information sheet, and informed consent form, and have a chance to discuss the study in more detail with the research team. Potential participants will be screened against inclusion/exclusion criteria and read a participant information sheet before consent will be taken. Participants will be shown how to use the system by their treating therapist, and/or a member of the research team, during the baseline visit, after consent has been taken.

Stage 2.3: overview of study flow n=70

For the duration of the study, participants will continue to use EvolvRehab as directed by the research team, alongside a prescribing therapist. Use and progression will be recorded by the system. Participants will continue to be provided with support by the research team as required, which will be recorded, the research team will be in contact with the participant via telephone, post or email to organise the baseline visit and any further visits in line with the study. Participants will be contacted, at a minimum within the first 2 weeks of their participation to discuss their progress. Support requirements will be logged.

Stage 2.4: data collection and management n=70

Outcome measures will be recorded by a member of the research team, at the baseline and follow-up visit as follows:
- ► Health economic outcomes: Health-related quality of life (European quality of life assessment: EQ-5D-5L).
- ► Service utilisation: Measures the utilisation of resources during the study for the health economic analysis (eg, number and duration of staff visits; requirement for technical support and training required).
- ► Feasibility of intervention use in stroke services: Acceptability (amount of use, process interview of intervention measure: intervention appropriateness, feasibility of intervention measure); safety (adverse events) and System Usability Scale (SUS).
- ► Feasibility of potential future clinical trial (recruitment and retention rate; data completeness).
- ► Clinical effectiveness: disability (WHO Disability Assessment Schedule: WHODAS); physical function (shoulder abduction finger extension: (SAFE), grip strength, timed up and go (TUG), Fugl-Meyer); physical activity (gait analysis, accelerometers).
- ► Process measures: time in EvolvRehab activities; number of repetitions using EvolvRehab kit; range of motion using EvolvRehab kit and goniometer measured range of motion; compensation/quality of movement using the EvolvRehab kit (described later in 'medical device'); pain and fatigue recorded in the EvolvRehab kit. Subjective reports of effectiveness. Carer strain index.

Stage 2.5: process interviews n=15

Interviews with clinicians, stroke survivors, and carers post-trial will explore potential improvements and user experience, including testimonials for dissemination. This will be advertised via poster which will be sent via email to stakeholders already involved in the study.

Stage 2.6: data analysis

Analyses will be conducted under headings:
- ► Health economics (including service utilisation).
- ► Feasibility of intervention use in stroke services.
- ► Feasibility of future clinical trial: variability of clinical outcomes will allow estimation of sample size for a future trial of system clinical effectiveness. Recruitment and retention rates will be used to estimate necessary recruitment; data completeness.
- ► Clinical effectiveness: analysis will focus on improvement over the course of the study, particularly compensatory movements and disability.

Stage 2.7: dissemination

Dissemination activities will be carried out according to the dissemination plan co-written with stroke survivors. We will use a variety of means to disseminate the results to a range of stakeholders. Methods include academic publications and presentations; written reports; articles in publications of stakeholder organisations; presentations to and publications for potential customers. Stakeholders include stroke survivors and the general public; health professionals (individuals and organisations); clinical academics; voluntary sector organisations; health and care commissioners; and healthcare providers.

Intervention

Principal research objective stage 2

Assess the feasibility of delivering EvolvRehab in clinical services for improving upper limb function in people who have suffered a stroke with functional arm and hand impairments and associated disability.

Secondary objectives stage 2

1. To identify the priorities for further evidence development for relevant future research.
2. To report changes in carer strain, grip strength, Fugl-Meyer, EQ-5D-5L, WHODAS, SAFE, acceptability, range of motion (EvolvRehab and goniometer), movement quality and quantity (EvolvRehab), session duration and equipment use (EvolvRehab), recruitment and retention rates, physical activity, describe service utilisation, acceptability and usability.

Sample size stage 2.2

The choice of this sample size for the main trial (n=70, 50 with complete data) reflects a balance between a large enough sample to represent population diversity and provide estimates of variability, while ensuring that recruitment is achievable (participant drop-out and approximately 50% of eligible participants recruited). Statistician (Gordon Taylor) is a member of the study team and has advised on sample size. 20–30 people is generally sufficient to estimate SD of outcome measures that can then be used to estimate the sample size for a definitive

clinical trial based on known estimates of minimal clinically important differences.

Sample (stage 1.2 and stage 2.2)
Stroke survivors will be approached and screened against the inclusion and exclusion criteria to assess their suitability to take part in the study.

Inclusion/exclusion criteria (stage 1.2 and stage 2.2)
Inclusion criteria:
► Experiencing motor difficulties in using the paretic arm, with some use of hand/arm as determined by therapist.
► Able to safely participate and complete EvolvRehab activities as determined by treatment team.
► Male/female ≥18 years old.
► Recently had a stroke requiring upper limb intensive rehabilitation.
► Capacity to consent to participate.
► The participant is expected to be able to use equipment for a minimum of 6 weeks.**
► Able to communicate adequately in English with the research team.

Exclusion criteria will be:
► Participating in another intervention which the researchers deem could interfere with study outcomes.
► Any medical condition compromising the safety or the ability to take part in the study (such as insufficient vision or hearing, upper limb condition not linked to stroke, uncontrolled blood pressure, uncontrolled diabetes, comorbidity).
► History of more than one epileptic seizures since stroke onset or uncontrolled epileptic seizure.
► Cognitive or communication impairment such that the participant is unable to follow a two-stage command.
► Moderate to severe hemispatial neglect compromising the ability to take part in the study, as determined by research team.

**Stage 1.2=minimum of 1 week.

Measures
Baseline and follow-up data will be recorded using paper copies of case report forms and/or Research Electronic Data Capture (REDCap). These will be collected at the participants' homes in line with their usual-care visits where possible. Interviews will be audio recorded and transcribed. The schedule of events is available in online supplemental table 2.

Baseline
► Carer strain index.[28]
► Hand grip strength.
► Fugl-Meyer.[29]
► European quality of life questionnaire (EQ-5D-5L).[30]
► WHODAS[31 32]
► Demographic Data: current treatments, clinical scores, comorbidities, age, sex, ethnicity, handedness.
► SAFE.[33]

► Instrumented TUG.[34]
Automatic measures:
► Free-living activity monitoring bilateral (up to 8 days) described later in this section.
► EvolvRehab outcomes; for example, compensation/quality of movement, number of repetitions, time in EvolvRehab activities, pain and fatigue.
► Range of motion (from the EvolvRehab system and in-person goniometer).

Follow-up at 6 weeks and up to 6 months:
► Carer strain index.
► Hand grip strength.
► Fugl-Meyer.
► EQ-5D-5L.
► WHODAS.
► Semistructured process interviews: Interviews will be led by researchers from UofEx (interviews with clinicians, stroke survivors, and carers post-trial will explore potential improvements and user experience, including testimonials for dissemination).
► Acceptability (amount of use, process interviews of intervention measure, of intervention appropriateness, feasibility of intervention measure) and safety (monitoring of any adverse events).
► Health resource use questionnaire: Measures the utilisation of resources during the study for the health economic analysis (number and duration of staff visits; requirement for technical support and training required); plus participant use of other NHS and social care services.
► SUS (Usability will be assessed through successful establishment of a usability SUS target >68 and through the number of therapy support sessions required).
► Instrumented TUG.
Automatic measures:
► Free-living activity monitoring bilateral (up to 8 days) described later in this section.
► EvolvRehab outcomes; for example, compensation/quality of movement, number of repetitions, time in EvolvRehab activities, pain and fatigue.
► Range of motion (from the EvolvRehab system and in-person goniometer).

Recruitment
Participants for stage 1.2, and stage 2.2 will be identified by the site. If happy to hear more about the study, participants will complete a contact details form and will be offered a participant information sheet and informed consent form, and have a chance to discuss the study in more detail with the research team. Potential participants will be screened against inclusion/exclusion criteria and read a participant information sheet before consent will be taken online. A screening log will be kept, including reasons why participants were ineligible or declined to participate (anonymously recorded).

Recruitment for stage 1.3 (staff focus group), and stage 2.5 (process interviews), will include advertisement via

poster which will be sent via email to stakeholders already involved in the study.

Consent

Any participants recruited at stage 1.2 and 2.2 will have to complete the decisional capacity form (form C) before consenting which determines whether they are capable of consenting.

Before any study-related procedure can take place, the participant must sign and date the latest approved version of the informed consent form. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal. If a participant withdraws from the study, the data already obtained will still be used in the study. This will be made clear on the participant information sheet and consent form. If a participant has withdrawn due to a serious adverse event (SAE), a general practitioner or managing clinician will follow up as appropriate. Potential participants will be given time before consenting to participate to go through the study information sheet and ask any questions. Participants are given full contact details of relevant investigators for the study.

If a participant, who has given informed consent, loses capacity to consent during the study, the participant will be withdrawn from the study. No further data would be collected or any other research procedures carried out on or in relation to the participant.

Electronic consent ('E-consent') forms will be completed online using REDCap and initialled, signed, and dated based on an informed decision from this information. REDCap is a secure, web-based platform for building and managing online surveys and databases. It is widely used in the medical and research fields to collect and store data and is particularly useful for data that needs to be collected in a standardised way. REDCap features include the ability to create surveys and forms, import and export data, and generate reports. It is highly customisable and can be used to support a wide range of research and data collection activities. The system security is being managed by the UofEx IT service. Consent will be obtained by someone who has received generic consent training and will be included in the Delegation of Authority Log and has been authorised by the chief investigator to do so. The original signed form will be retained at the study site within the site Master File, a copy will be kept in REDCap and placed in the eTMF at UofEx. Participants can download a copy of the consent form from REDCap or request it from named study researchers.

Medical device

The EvolvRehab kit has a CE mark and UKCA marking in the UK. The kit will be further developed with participants in stage 1 and will consist of initial staff training. Exercise prescription will be in line with their usual care.

The EvolvRehab kit includes a Kinect box with a TV screen, which requires internet connection. The participant performs virtual exercises and 'exergames' (games that incorporate movements that need to be practised). Using these, participants practice movements which are vital in their daily lives such as hand to head (bringing the hand to mouth, eyes and ears) and reaching forward. Within the EvolvRehab kit is a module called MoveWell, in which the goal is to help reduce impairment and improve overall quality of movement of the paretic limb, based on the best practices of neurorehabilitation currently being used in the NHS and other providers of stroke rehabilitation. To do so, the rehab kit detects common 'compensatory movements' performed by stroke survivors using kinematic analysis, while moving their paretic limb.

These are as follows:
► Shoulder abduction.
► Shoulder elevation.
► Trunk forward flexion.
► Trunk lateral flexion.
► Trunk rotation.
► Head flexion (while bringing the hand to the head).

When a compensatory movement is detected, prompts are provided to the participant through their in-game avatar, alerting them to the abnormal movement. These include audio prompts (a virtual voice) and visual prompts (green dots on selected joints turn red if compensatory movement is detected). This allows patients to detect and correct compensation, which is important as patients are often unaware of compensatory movements.

To determine compensatory movements for each participant, the EvolvRehab kit also asks the participant to complete initial 'compensation assessments'. This involves completing common tasks such as shoulder flexion, elbow extension, and reaching activities with both the paretic and non-paretic limb so to establish a personal benchmark of normal. The information can be incorporated as part of the goal-setting process for participants and supports the kinematic compensation detection within the kit. Evolv plans to further explore the data collected on the non-paretic limb to improve the prescription and personalisation of EvolvRehab MoveWell activities and subsequent analysis of performance data.

Activity monitors

Participants will use bilateral physical activity monitors (accelerometers; Axivity3), which they will wear for up to 8 days, one on each wrist, prior to the start of the intervention (stages 1.2 and 2.2), to measure a period of 'free-living' at baseline as well as up to 8 days for follow-up. This will objectively measure participants' habitual physical activity level. Participants will be asked to continuously wear the monitors for 24 hours a day for up to 8 days. The devices will be initialised using the manufacturer's software under default settings.

The accelerometer and inertial motion unit (IMU) measuring three-dimensional acceleration and orientation at 100 Hz will be used to derive variables relating to motion quality, quantity, and timing on the functional

tasks. Pilot work has found good indicators of engagement, intensity, and motor control when instrumented with accelerometery and heart-rate sensors. IMU data will be analysed using a custom programme written in LabVIEW2019 (National Instruments, Ireland) using Data Gait software. Z-axis object frame accelerations will be transposed using quaternion rotation matrices, and double integrated to vertical centre of mass movement in the global reference frame, and used for both phase plot analysis and to calculate spatiotemporal gait parameters. Accelerometer data will be analysed within OMGUI (https://github.com/digitalinteraction/openmovement/blob/master/Docs/omgui/index.md).

Baseline visit

Participants will be shown how to use the EvolvRehab system by their treating therapist and/or a member of the research team at their baseline appointment, and provided with additional support as required by the research team, which will be recorded throughout.

During familiarisation with the rehab kit, a virtual assessment will be performed with the participants, with or without a therapist physically present; this does not replace any assessments which would routinely take place as part of usual care. This virtual assessment will measure how much the participant compensates when using their affected limb compared with their non-affected limb. This information is presented to the participant and therapist through the user interfaces, providing a goal of reducing their compensatory movements, for the participant to work towards while performing the activities.

Follow-up

Where possible, individuals will continue to use the EvolvRehab–MoveWell system beyond 6 weeks from stage 2.2, technical support will continue until the end of the study completion. The intervention will be supported by the clinical treatment team and/or research team in keeping with routine care. The research therapist will attend clinical visits and support as required. The number of visits will be recorded; in-person visits will only be carried out when support cannot be adequately provided remotely, for example, by telephone or video call, with the intention of reducing to zero over the first 6 weeks of use of the device.

Data analysis

Data will be graphically presented and summary statistics, including minimum and maximum, calculated. This will enable us to ensure data are in range, check normality and other assumptions where appropriate. The percentage of missing data will also be provided. Given this is a feasibility study, limited statistical testing will be performed and results will be appropriately interpreted. No adjustment for multiple testing will be performed. For the following outcomes: carer strain index, grip strength, Fugl-Meyer, EQ-5D-5L, WHODAS, SAFE, range of motion, movement quality and quantity (EvolvRehab),

session duration and equipment use (EvolvRehab), TUG, and physical activity outcomes (accelerometers). Data distributions between participants will be assessed for conformity to a normal distribution; normally distributed data will be analysed using paired samples t-tests; non-normally distributed data will be analysed using related samples Wilcoxon signed rank tests. Statistical analysis tests will be two sided, significance level will be set at 5% for the within-subject change from baseline to the end of the intervention (1 week (n=5), 6 weeks and up to 6 months follow-up (n=70)). Descriptive statistics including service utilisation, SUS, acceptability questionnaire score, and participant characteristics/demographics will be reported as frequency and (%) or mean±SD. All statistical analyses will be conducted using Microsoft Excel, SPSS V.28, R, and Stata V.18.

Thematic content analysis of interview transcripts will be used to investigate the usability and perceived usefulness of the EvolvRehab kit to support self-management and rehabilitation. It will also be used to explore participants' experiences. All qualitative data collection for the process evaluation will be carried out by a research team member with qualitative research experience. Interviews will be transcribed verbatim, and analysed using thematic analysis methods.[35] Interview transcripts will be coded using NVivo software (or similar software). Each interview will be independently coded by two reviewers. After coding four transcripts, reviewers will compare codes and discrepancies will be discussed and resolved prior to coding the remaining transcripts. The interim analysis will be conducted following an initial sample of 15 participants to determine whether saturation of themes has been reached.

Health economic modelling

Targeted reviews of the literature will be undertaken to identify current evidence on the effectiveness and cost-effectiveness of rehabilitation training for upper limb function in people early after stroke with functional arm and hand impairments; and to identify information describing the clinical care pathway and standard care. The findings will be synthesised to enable summary estimation of the relevant metrics outlined above. In line with established methods for model-based cost-effectiveness analysis, the first step in model development will be to define standard care. A decision model will be developed, based on the care pathway following methods for model-based economic evaluation. The analysis will take an NHS perspective. Input parameters will use data collected within the pilot. Uncertainty will be captured using probabilistic SBRIH-18 project summary sensitivity analysis. A value of information analysis will be conducted to assist with prioritisation and further research design.

For the service use data, descriptive statistics will be presented, for each of the services used. Unit costs will be assigned to each service using recognised UK sources. The mean and SD cost of the pathway will be presented.

ETHICS AND DISSEMINATION

This study has received ethical approval from Solihull Research Ethics Committee (REC reference: 23/WM/0054) and is a registered as a clinical trial (NCT05875792). The study sponsor is the University of Exeter and all their standard operating procedures will be followed ensuring this study complies with all relevant legislation and guidelines, including communicating protocol modifications. Direct access will be granted to authorised representatives from the sponsor, host institution, and regulatory authorities to permit study-related monitoring, audit and inspection. In addition, the study will be supported by a steering committee, made up of independent experts, lay representatives with lived experience of the condition, and the study chief/senior investigators. The steering committee will provide overall supervision for the study, concentrating on study progress, adherence to protocol, participant safety, and consideration of new information relevant to the research question. The steering committee will meet approximately on a quarterly basis at pertinent points in the progression of the study. The chief investigator (HD) will ensure that this study is conducted in full conformity with the Declaration of Helsinki (Fortaleza, Brazil, October 2013).

Assessment and management of risk

1. Information management
   - Information from the EvolvRehab kit will be pseudoanonymised and will be stored on the Azure cloud platform, their data server centre is located and stored in London, UK.
   - All other information will be securely stored on the UofEx SharePoint in a locked folder with access limited to named researchers in the study.
2. Disclosure of personal/identifiable harmful information
   - All personal and identifiable data will only be collected during the initial screening process and will only be stored in secure folders on UofEx-managed computers. This can only be accessed by named UofEx researchers.
   - No personal/identifiable information will be stored on the EvolvRehab kit.
   - Sharing of data between collaborators will be made securely through SharePoint. Access to this will be secure.
3. Discomfort during testing
   - Participants may feel discomfort during exercises. This should not be any more than would be expected during routine care, as exergames have been designed with physical therapists and treatment teams. The research therapist or clinical treatment team will approve any exergames for use by individual participants while advising participants of what action to take in the event of pain or discomfort during activities carried out as part of the study. If the participant reports discomfort during the session that is more than they have been told to expect by their treatment team, or if they experience pain triggered by any of the activities, activities will be paused and participants will be instructed not to restart use of EvolvRehab until their clinical treatment team or the research therapist have confirmed that it is safe to do so. Participants will be instructed to rest in between activities.
   - The therapist will approve any activities performed by the participant, in line with the participants capacity.
4. Potential health problems if participants are very unfit.
   - Participants will be screened by the inclusion questionnaire, which asks them to certify that they are generally fit and capable of undertaking the movements in the experiment.
5. Adverse events
   - SAEs are unlikely and highly unlikely to occur as a result of the programme being delivered in this study. Adverse events will be reported in line with the HRA reporting guidelines.[36] Given the age range of the study population and the nature of physical interventions, foreseeable occurrences (adverse events) that may occur during the study period which do not require specific time-critical reporting but may be collected as part of standard data collection are:
     - Acute infections (eg, viral) .
     - Medical instability (eg, diabetic control—becomes hypoglycaemic, deterioration in control of heart failure) .
     - Vestibular disorders and stroke.

However, if any of the above occur as the result of an incident during, or within 2 hours of completing, or are related to the intervention and categorised as an SAE they should be reported to chief investigator as a suspected SAE as below:

SAEs which occur as a result of an incident during, or within 2 hours of completing, and are considered related to the study, will be reported in a predefined and time-critical process. The site principal investigator or delegated team member and chief investigator must assess causality of any suspected SAEs within 24 hours of becoming aware of the event, using the Non-CTIMP safety report to REC form. Completed forms will be scanned and emailed to the REC. These should be sent within 15 days of the chief investigator becoming aware of the event.

Dissemination

The dissemination plan will be co-written with stroke survivors. We will use a variety of means to disseminate the results to a range of stakeholders. Methods include academic publications and presentations; written reports; articles in publications of stakeholder organisations; presentations to and publications for potential customers. Stakeholders include stroke survivors and the public; health professionals (individuals and organisations); clinical academics; voluntary sector organisations; health and care commissioners and providers. For each output, a

writing team will be convened from the study group and where necessary external collaborators.

► Information that is commercially sensitive or that might otherwise be considered confidential. If necessary, university research support offices or unit administrators should be contacted for guidance.

► All funding bodies will be acknowledged within any publications produced by this study.

► Research is registered on a ClinicalTrials.gov, as well as Open Research Exeter (ORE). This is the UofEx's open access repository for storing, preserving and disseminating the research outputs of the University. Each publication in ORE has a unique persistent identifier (URI or handle), providing secure and permanent access.

► We will disseminate the results widely through journals and conferences to enhance understanding of stroke rehabilitation and shape future research to benefit people living with stroke.

► The participants may be notified of the outcome of the study via a specifically designed newsletter that will be emailed or posted to them, where a link to the published papers will be given where possible.

► The anonymised dataset will be made available on reasonable request.

► For dissemination, data will not be shared on a personal level and individualised study results will be used for this reason. Data sharing statement will depend on the journal.

ORCID iDs
Jemma Perks http://orcid.org/0000-0003-3022-8893
Maedeh Mansoubi http://orcid.org/0000-0002-8829-2217
Helen Dawes http://orcid.org/0000-0002-2933-5213

REFERENCES

1 Collaborators GS. Global, regional, and national burden of stroke and its risk factors, 1990-2019: a systematic analysis for the global burden of disease study 2019. *Lancet Neurol* 2021;20:795–820.
2 Douiri A, Muruet W, Bhalla A, *et al*. Stroke care in the United Kingdom during the COVID-19 pandemic. *Stroke* 2021;52:2125–33.
3 Miller EL, Murray L, Richards L, *et al*. Comprehensive overview of nursing and Interdisciplinary rehabilitation care of the stroke patient: a scientific statement from the American heart Association. *Stroke* 2010;41:2402–48.
4 Parker VM, Wade DT, Langton Hewer R. Loss of arm function after stroke: measurement, frequency, and recovery. *Int Rehabil Med* 1986;8:69–73.
5 Vafadar AK, Côté JN, Archambault PS. Effectiveness of functional electrical stimulation in improving clinical outcomes in the upper arm following stroke: a systematic review and meta-analysis. *Biomed Res Int* 2015;2015:729768.
6 Bakhti KKA, Laffont I, Muthalib M, *et al*. Kinect-based assessment of proximal arm non-use after a stroke. *J Neuroeng Rehabil* 2018;15:104.
7 Ludewig PM, Cook TM. Alterations in shoulder Kinematics and associated muscle activity in people with symptoms of shoulder Impingement. *Phys Ther* 2000;80:276–91.
8 Lewis JS, Wright C, Green A. Subacromial Impingement syndrome: the effect of changing posture on shoulder range of movement. *J Orthop Sports Phys Ther* 2005;35:72–87.
9 Cirstea MC, Levin MF. Improvement of arm movement patterns and Endpoint control depends on type of feedback during practice in stroke survivors. *Neurorehabil Neural Repair* 2007;21:398–411.
10 Sunderland A, Tuke A. Neuroplasticity, learning and recovery after stroke: a critical evaluation of constraint-induced therapy. *Neuropsychol Rehabil* 2005;15:81–96.
11 Kerr AL, Cheng SY, Jones TA. Experience-dependent neural plasticity in the adult damaged brain. *J Commun Disord* 2011;44:538–48.
12 Brennan DM, Mawson S, Brownsell S. Telerehabilitation: enabling the remote delivery of Healthcare, rehabilitation, and self management. *Stud Health Technol Inform* 2009;145:231–48.
13 Itrat A, Taqui A, Cerejo R, *et al*. Telemedicine in Prehospital stroke evaluation and Thrombolysis: taking stroke treatment to the doorstep. *JAMA Neurol* 2016;73:162–8.
14 Laver KE, Adey-Wakeling Z, Crotty M, *et al*. Telerehabilitation services for stroke. *Cochrane Database Syst Rev* 2020;1:CD010255.
15 Piron L, Turolla A, Tonin P, *et al*. Satisfaction with care in post-stroke patients undergoing a Telerehabilitation programme at home. *J Telemed Telecare* 2008;14:257–60.
16 Piron L, Turolla A, Agostini M, *et al*. Assessment and treatment of the upper limb by means of virtual reality in post-stroke patients. *Stud Health Technol Inform* 2009;145:55–62.
17 Cramer SC, Dodakian L, Le V, *et al*. Efficacy of home-based Telerehabilitation vs in-clinic therapy for adults after stroke: A randomized clinical trial. *JAMA Neurol* 2019;76:1079–87.
18 Bizovièar N, Rudolf M, Javh M, *et al*. Effects of home exercise assisted by written and video instructions in patients after stroke. *Rehabilitacija* 2016;3:26–32.
19 Chumbler NR, Quigley P, Li X, *et al*. Effects of Telerehabilitation on physical function and disability for stroke patients: a randomized, controlled trial. *Stroke* 2012;43:2168–74.
20 Huijgen BCH, Vollenbroek-Hutten MMR, Zampolini M, *et al*. Feasibility of a home-based Telerehabilitation system compared to usual care: arm/hand function in patients with stroke, traumatic brain injury and multiple sclerosis. *J Telemed Telecare* 2008;14:249–56.
21 Laver K, Walker M, Ward N. Telerehabilitation for stroke is here to stay *Neurorehabil Neural Repair* 2022;36:331–4.
22 Garcia A, Mayans B, Margelí A, *et al*. A feasibility study to assess the effectiveness of Muvity: A Telerehabilitation system for chronic post-stroke subjects. *J Stroke Cerebrovasc Dis* 2022;31:S1052-3057(22)00485-2.
23 Asano M, Tai BC, Yeo FY, *et al*. Home-based TELE-rehabilitation presents comparable positive impact on self-reported functional outcomes as usual care: the Singapore TELE-technology aided

rehabilitation in stroke (STARS) randomised controlled trial. *J Telemed Telecare* 2021;27:231–8.

24 Cramer SC, Dodakian L, Le V, *et al*. A feasibility study of expanded home-based Telerehabilitation after stroke. *Front Neurol* 2020;11:611453.

25 Lloréns R, Noé E, Colomer C, *et al*. Effectiveness, usability, and cost-benefit of a virtual reality-based Telerehabilitation program for balance recovery after stroke: a randomized controlled trial. *Arch Phys Med Rehabil* 2015;96:418–25.

26 Ellis F, Hancock N, Kennedy N, *et al*. Consideration-of-concept of Evolvrehab-body for upper limb virtual rehabilitation at home for people late after stroke. *Physiotherapy* 2022;116:97–107.

27 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:e029954.

28 Robinson BC. Validation of a Caregiver strain Index1. *J Gerontol* 1983;38:344–8.

29 Fugl-Meyer AR. Post-stroke Hemiplegia assessment of physical properties. *Scand J Rehabil Med* 1980;7:85–93.

30 Devlin N, Pickard S, Busschbach J. The development of the EQ-5D-5L and its value SETS. In: Devlin N, Roudijk B, Ludwig K, eds. *Value Sets for EQ-5D-5L: A Compendium, Comparative Review & User Guide 2022*. Cham: Springer, 2022: 1–12.

31 World Health Organization. International classification of functioning, disability, and health: children & youth version: ICF-CY. 2007.

32 Hu H-Y, Chi W-C, Chang K-H, *et al*. The world health organization disability assessment schedule 2.0 can predict the Institutionalization of patients with stroke. *Eur J Phys Rehabil Med* 2017;53:856–62.

33 Stinear CM, Byblow WD, Ackerley SJ, *et al*. Prep2: A biomarker-based algorithm for predicting upper limb function after stroke. *Ann Clin Transl Neurol* 2017;4:811–20.

34 Podsiadlo D, Richardson S. "The timed "up & go": a test of basic functional mobility for frail elderly persons". *J Am Geriatr Soc* 1991;39:142–8.

35 Glaser BG, Strauss AL, Strutzel E. The discovery of grounded theory: strategies for qualitative research. *Nurs Res* 1968;17:364.

36 HRA N. Safety reporting, Available: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting