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A feasibility trial to evaluate a digital system for arm rehabilitation after a stroke

Submission date
15/12/2023

Recruitment status
No longer recruiting

Registration date
21/12/2023

Overall study status
Completed

Last Edited
30/05/2024

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
OnTrack is an app (application) that works on a smartwatch and smartphone. It has been designed to help people who have had a stroke which has affected the use of their arm. The watch tracks arm movement by counting the minutes of movement – just like a step counter, but for your arm. The app sends messages to the watch and phone throughout the day to encourage the user to move their arm and use it for everyday activities. The user can monitor their progress by looking at the app on their phone.
Therapists, such as physiotherapists or occupational therapists, can also use the app to monitor how their patients are progressing with their arm rehabilitation. This study aims to find out if OnTrack is a useful treatment that can be added to the usual care that stroke patients receive. This study is the first step to help the researchers begin to assess how well the new treatment works and to help them shape future research.

Who can participate?
Adults aged 18 years and over who have had a stroke diagnosis with any associated arm weakness in the previous 6 months, and who are receiving rehabilitation care from the NHS at the point of recruitment.

What does the study involve?
The researchers would like to find out how people using OnTrack get on with their rehabilitation compared to those who don't use it. Participants will be randomly assigned to one of two groups at the start of the trial. Group A will be asked to use the OnTrack system (in addition to receiving their standard rehabilitation care) for 12 weeks. Patients in group B will receive their standard rehabilitation care only for 12 weeks. All participating patients will be asked to answer some questions at the beginning, in the middle, and at the end of the trial about how they have been feeling and how their stroke symptoms are. Patients in Group A will be asked how they found using the OnTrack system at the middle and end of the trial. Some patients will also be asked if they will be willing to be interviewed by a member of the research team to discuss their experiences of being involved in the trial.

What are the possible benefits and risks of participating?
Although unlikely, it is possible that taking part may make patients more aware of their situation

and talking about their stroke may cause feelings of distress. Patients could experience fatigue due to an increase in activity. Although unlikely, participants could experience pain in their arm due to overuse. They are advised to gradually build up their activity.
Being involved in the trial may help to focus participants' attention on their arm which could help their rehabilitation. Being involved in the trial can help researchers develop new ways of treating/helping people with arm rehabilitation after a stroke.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
December 2022 to September 2024

Who is funding the study?
Small Business Research Initiatives (SBRI) Healthcare

Who is the main contact?
Dr Jane Davies, upbeat@cardiff.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
323576

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 59352, IRAS 323576

Study information

Scientific Title
A randomised feasibility trial to evaluate a digital system for UPper limB rEhabilitation After sTroke - the UPBEAT trial

Acronym
UPBEAT

Study objectives
UPBEAT is a feasibility study so there is no hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/12/2023, London Surrey REC (2 Redman Place, Stratford, E20 1JQ, UK; +44 (0)207 1048 088; surrey.rec@hra.nhs.uk), ref: 23/PR/1251

Study design
Randomized; Interventional; Design type: Treatment, Process of Care, Education or Self-Management, Device, Complex Intervention, Rehabilitation

Primary study design
Interventional

Study type(s)

Treatment

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

Interventions
This trial will use a parallel group, non-blinded, randomized, feasibility methodology comparing the OnTrack™ system plus standard care versus standard care alone for the treatment of patients with a stroke diagnosis within the previous 6 months with any associated arm weakness. A nested process evaluation and economic evaluation will be included.

Participants:
Two types of participants will be recruited:
1. Patients: Individuals, aged ≥18 years who are English speaking and have had a stroke diagnosis in the previous 6 months with any associated arm weakness. Patients randomised to the intervention group will receive the intervention (OnTrack™) in addition to standard rehabilitation care. Patients randomised to the control group will receive standard rehabilitation care.
2. Therapists: therapists who are responsible for delivering intensive rehabilitation to stroke patients within each of the trial sites (including Occupational Therapists, Physiotherapists, Speech and Language therapists, and Rehab Assistants). These therapists will be responsible for delivering the intervention (OnTrack™) to the patient participants randomised to the intervention group. Up to eight therapist participants will be recruited for each trial site.

The trial will recruit participants from 3-5 English NHS sites including both acute and community settings which provide different services for post-stroke rehabilitation. Patients may be recruited whilst they are receiving stroke rehabilitation as a hospital inpatient, outpatient or in the home setting. The setting may change during the course of the trial as participants may begin the trial whilst an inpatient and then subsequently be discharged home.

Participants will remain in the trial for up to 16 weeks and this will incorporate a 12-week intervention period; during this time outcome data will be collected via:
1. Questionnaires (at weeks 0, 6 and 12 - these can be completed online by the participant independently, over the telephone with assistance from a trial researcher, or face-to-face with a researcher according to participant preference and ability)
2. Observations of OnTrack sessions between therapists participants and patient participants
3. Interviews with both therapist and patient participants (at the end of the intervention period)
4. The OnTrack system (information regarding usage)
5. Focus groups with participating therapists

The patient recruitment period will last 3 months with a target recruitment rate of 14 patients per month. Three NHS sites have agreed to participate in the study, with a further two identified sites that can be opened if recruitment delays are encountered.

A trial PPIE group consisting of four people who have suffered strokes has been established and has reviewed and approved the UPBEAT trial protocol and materials. The group will continue to meet and contribute to the oversight of the trial once it is open to recruitment.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Feasibility of trial procedures will be assessed via analysis of:
1. Patient recruitment (at the end of the trial)
2. Patient retention – including treatment-specific retention (at the end of the trial)

Intervention feasibility will be assessed via analysis of:
1. System Usability Scale (SUS) - this scale is a reliable tool for measuring usability and consists of a 10-item Likert Scale questionnaire (Strongly Agree to Strongly Disagree). This questionnaire will be completed by patient participants and therapist participants at weeks 6 and 12.
2. Patient and therapist interviews (conducted at the end of the intervention period)

Intervention fidelity will be assessed via analysis of:
1. Patient compliance with the prescribed intervention use (number of days that the patient activated/switched on the OnTrack™ system) – this will be assessed at the end of the intervention period

Key secondary outcome(s))
Preliminary evidence of clinical effectiveness will be assessed via:
1. Arm function measured using Motor Activity Log-14 at week 0, week 6 and week 12
2. Confidence for functional performance and aspects of self-management relevant for individuals recovering from stroke, measured using the Stroke Self-Efficacy Questionnaire (SSEQ) at week 0, week 6 and week 12
3. Disability and dependence in individuals who have suffered from a stroke or other neurological condition, measured using the Modified Rankin Scale at week 0, week 6 and week 12
4. Health-related quality of life measured using EQ-5D-5L at week 0, week 6 and week 12

Completion date
11/11/2024

Eligibility

Key inclusion criteria
1. Age >=18 years
2. All participants in the study will have had a stroke diagnosis with any associated arm weakness in the previous 6 months, and be receiving rehabilitation care from the NHS at the point of recruitment
3. Participants must be able to provide informed consent
4. Participants must be English speakers with a reliable communication method and be able to read short messages on screen

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Potential participants who at the time of recruitment (or during participation) present with any of the following will be excluded:
1. Unstable medical condition
2. Self-reported ‘severe’ pain in the arm affected either at rest or during movement
3. Severe oedema in the arm affected by their stroke, judged by the consenting therapist

Date of first enrolment
15/01/2024

Date of final enrolment
29/07/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
Richmond Rehabilitation Unit
22 Evelyn Rd
Richmond
United Kingdom
TW9 2TF

Study participating centre
Community Neuro-rehabilitation Team
Hammersmith & Fulham, Kensington and Chelsea and Westminster (CLCH)

15 Marylebone Road
London
United Kingdom
NW1 5JD

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
NHS England; Grant Codes: SBRIH18P2002

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes