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An innovative method for delivering functional strength training exercises for the upper limb

Submission date
03/04/2017

Recruitment status
No longer recruiting

Registration date
27/06/2017

Overall study status
Completed

Last Edited
06/11/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). Stroke is a major health problem with around 1.2 million stroke survivors living in the UK. The most common problem following stroke is weakness or complete loss of movement affecting one side of the body. In order to promote movement recovery guidelines say that stroke survivors should have at least 45 minutes of physiotherapy a day but this is more likely to be directed toward activities such as getting out of bed or walking. Published studies have shown that during a hospital stay patients receive as little as 4-23 minutes a day of therapy for the arm. Poor recovery of the arm leads to greater dependence on carers for activities of daily living and social isolation. Therapists currently provide patients with an exercise prescription which is delivered through paper drawings. These are often insufficient and rely on the stroke survivor remembering the instructions and demonstration provided by the physiotherapist. The study team has developed an app designed to deliver exercise demonstrations and provide motivational tools to increase adherence to a prescribed exercise programme. It works by incorporating a number of behaviour change techniques including demonstration videos of the exercises in real time performed by stroke survivors; recording of the length and frequency the stroke survivors engage in the exercises; and to deliver reminders in order to further motivate stroke survivors. Before being able to evaluate the effectiveness of this app, it is important to determine whether this method of delivery is acceptable to both therapists and stroke survivors. The aim of this study therefore is to test the feasibility and acceptability of this app to see if a larger effectiveness study would be possible.

Who can participate?
Stroke survivors receiving therapy for an arm impairment as a result of stroke

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive their exercise prescription for arm activities on paper (usual care). Those in the second group receive their exercise prescription via the app that has been specifically designed for this project. Participants take part in the project for four weeks and their exercises are updated and delivered via either method by the therapist responsible for their movement rehabilitation. Each

time participants complete their exercises they are asked to record how many they have done and how happy they feel about them. Before they receive their first exercise prescription as part of the project, participants complete an assessment to evaluate how well they can move their arm at that point in time. These assessments are repeated after four weeks when their participation in the study has finished. Some people who have received their exercises via the app are also asked to take part in a focus group to help the research team understand what they felt about using the app and also how they feel the app could be improved.

What are the possible benefits and risks of participating?
The delivery of an exercise prescription by therapists to stroke survivors with loss of arm movement is part of usual practice. Participants may experience minor pain as a result of the exercises. If the pain is infrequent and only occurs during or for up to 1 hour after the exercises, then the participant should alert their therapist who should alter the exercise programme as appropriate. If pain persists for three consecutive days then the participant is removed from the study. Participation in the project may however prove beneficial to the participant by encouraging them to engage in more exercise - evidence suggests that more exercise leads to greater movement recovery.

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
August 2016 to October 2017

Who is funding the study?
The Health Foundation (UK)

Who is the main contact?
Mrs Kathryn Mares
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32886

Study information

Scientific Title
FeSTivAPP – an innovative method for delivering Functional Strength Training exercises for the Upper Limb in people after stroke – a feasibility study

Study objectives
The aim of this study is to investigate the feasibility and acceptability of a bespoke designed app 'FeSTivAPP' in delivering functional strength training exercises for the upper limb in people after stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands – Coventry & Warwickshire Research Ethics Committee, 12/12/2016, ref: 16/WM /0481

Study design
Randomised; Interventional; Design type: Treatment, Process of Care, Education or Self-Management, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Specialty: Stroke, Primary sub-specialty: Rehabilitation; UKCRC code/ Disease: Stroke/ Cerebrovascular diseases

Interventions

Patients fulfilling the eligibility criteria for the trial and who have given written informed consent will complete the baseline clinical measures and then will be randomly allocated to one of two experimental groups. Group allocation will be randomised via randomly sorted opaque envelopes and managed by a member of the research team not involved in the day to day running of the trial. To ensure an even spread of participants from each geographical area the trialists will stratify for location and use block randomisation.

Intervention group: arm exercises prescribed via a bespoke designed 'app'. Therapists responsible for a participant's care prescribe an individually tailored exercise programme which is uploaded to the app. Participants in this group then carry out their exercise according to this prescription. Exercises are demonstrated on the app using videos. On every occasion that a participant has completed their exercises, they record how many of each they have done of each.

Control group: arm exercises prescribed via print outs on paper (usual care). They are also asked to record their feedback every time they complete their exercises.

Interventions will be administered by the clinical therapists working with the stroke survivors. Both groups are monitored by their therapist as per usual practice. Frequency of follow up is dependent on the participant and the therapist. This would involve a face to face contact with the therapist who may change the exercise prescription or keep it the same as governed by the progress the participant is making with their movement recovery.

Intervention Type

Other

Primary outcome measure

Impairment and activity limitations with arm movements is measured using the Action Research Arm Test at baseline and 4 weeks

Secondary outcome measures

1. Upper limb impairment is measured using the Motricity Index at baseline and 4 weeks
2. Satisfaction is measured using a visual analogue scale through the app or on paper by the participant each time they carry out their exercises
3. Adherence to exercise regime is measured by recording frequency of exercises and number of exercises completed each time the participant carry out their exercises between baseline and 4 weeks
4. Acceptability and satisfaction qualitative data from two focus groups - one from therapists involved in prescribing the app and the second from participants who received the app. Conducted after the final participant has been recruited.
5. Willingness to take part in study is measured by recording frequency of exercise completion between baseline and 4 weeks
6. Usability of the app is measured with one focus group including up to 10 participants who have been allocated to the intervention group at 12 months
7. Recruitment rate is recorded as the number of eligible participants who consent to participate in the study at 12 months
8. Attrition rate is recorded as the number of participants who consent to participate that remain in the study at 12 months

Overall study start date
01/08/2016

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Adults aged 18+ years, diagnosed with stroke (infarct or haemorrhage)
2. Presenting with an upper limb impairment and who would usually be prescribed an active exercise plan by therapists on the stroke pathway teams
3. Can follow a one-stage command, i.e. sufficient communication/orientation for interventions in this trial
4. Able to access the material on the app – i.e. sufficient vision to be able to see the video demonstrations

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
People unable to give informed consent

Date of first enrolment
07/02/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Norwich Community Hospital
Bowthorpe Road
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NR2 3TU

Sponsor information

Organisation
University of East Anglia

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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high impact journal.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The current 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?
HRA research summary			28/06/2023	No	No