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Can smartphone technology be used to support an effective home exercise intervention to prevent falls amongst community dwelling older people?

Submission date
20/08/2018

Recruitment status
No longer recruiting

Registration date
21/08/2018

Overall study status
Completed

Last Edited
03/02/2023

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Falls lead to injury, loss of independence and death for older adults. Targeted home exercise, including exercises to strengthen muscles and improve balance, is proven to prevent falls. However, older adults do not always maintain their exercises nor do them regularly enough to gain the benefits. Many healthcare services do not offer adequate support to enable older adults to carry out the exercises regularly or for a long enough period of time. Technology can provide feedback and support to people trying to become more active but has not used for falls prevention exercise in this way. The aim of this study is to find out whether smartphone technology can be used to support patients to adhere to a evidence-based falls exercise programme.

Who can participate?
Older adults aged 50+ who are at risk of falls

What does the study involve?
Two motivational smartphone applications (health professional and patient) based on goal setting and personalised feedback are used to support patients to adhere to their prescribed exercise programme. Two community services who deliver falls rehabilitation identify patients who normally require a strength and balance programme and deliver the intervention. Patients are randomly allocated to either the standard service provided or the standard service and the use of the smartphone apps. All patients use the smartphone as a falls detector/alarm and report their exercises using the smartphone. This study assesses the acceptability of the study design and procedures before a full-scale trial looking at the effectiveness of the technology.

What are the possible benefits and risks of participating?
The intervention may increase support/motivation which should lead to increased adherence and increased exercise. It could therefore assist maintenance of health, reducing long-term falls risk and re-access to services. Taking part will take up participants' time (about 20 hours in total)

and participants will have to charge the smartphone every night. However, those who receive the intervention will receive the same services with the addition of technology. They will receive additional visits from the research team and if participants are in the group using the smartphone application they will also receive additional feedback from their health professional. Participants will learn how to use the technology if they do not already have a smartphone. They will also have a study smartphone with access to a limited amount of data, calls and text messages. Their feedback will help to design a larger study to test whether using this technology can improve strength and balance and reduce falls risk more than just receiving what is currently provided, and whether it is value for money. It will also help to improve the technology so that it is easier to use.

Where is the study run from?
1. Alexandra Park Health Centre (UK)
2. Partington Health Centre (UK)
3. Seymour Grove Health Centre (UK)
4. George H Carnall Leisure Centre (UK)
5. North Community Rehabilitation Services (UK)
6. South Manchester Falls Team (UK)
7. Doncaster Falls Team (UK)

When is the study starting and how long is it expected to run for?
April 2018 to July 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Helen Hawley-Hague
helen.hawley-hague@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Helen Hawley-Hague

ORCID ID
http://orcid.org/0000-0002-2451-4482

Contact details
University of Manchester
Division of Nursing, Midwifery and Social Work
School of Health Sciences
Faculty of Biology, Medicine and Health
Jean McFarlane Building
Floor 6, Room 332
Oxford Road
Manchester
United Kingdom

M13 9PL
+44 (0)7810358568
helen.hawley-hague@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38273

Study information

Scientific Title
Can smartphone TechnolOGy be used to support an EffecTive Home ExeRcise intervention to prevent falls amongst community dwelling older people? The TOGETHER feasibility randomised controlled trial

Acronym
TOGETHER

Study objectives
This study explores whether smartphone technology can be used to support patients to adhere to a evidence-based falls exercise programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester East Research Ethics Committee, 09/07/2018, ref: 18/NW/0457

Study design
Randomised; Interventional; Design type: Treatment, Process of Care, Education or Self-Management, Device, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation, Active Monitoring

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Falls in older people

Interventions
Usability testing has already been carried out to assess whether the technology is usable and acceptable to both health professionals and patients. Following the Medical Research Council's guidance for developing a complex intervention the trialists will now use a feasibility randomised trial, this will test the study procedures and whether it is feasible to introduce this intervention alongside standard service. Qualitative focus group and interviews are also used both to improve the technology and further understand health professional and patients' experience of the study procedures.

This will be a pragmatic trial (it will test whether the intervention will work in existing services) and therefore participants will be recruited through two different types of falls service. There are two commonly used types of service delivery for falls rehabilitation exercise, an 'everybody's business model' where a range of community services deliver falls rehabilitation, and a specific community falls team. Older adults at risk of falls (aged 50+) and assessed as requiring a falls exercise programme, will be identified through current community falls rehabilitation services in both Central Manchester (already engaged in previous study) and Pennine Care NHS Trust (Trafford Community Services). Each site will recruit 36 patients (as recommended by Lancaster et al (2004) for feasibility trials) and will deliver both the intervention and control arm of the trial. Study participants will be randomised using the Manchester Academic Health Science Centre -Clinical Trials Unit (MAHSC-CTU) randomisation service using block randomisation (2, 4 or 6 blocks) into either an intervention group (INT1- standard service plus the smartphone apps) or a control (CON- standard service). Randomisation is based on a computer-generated randomisation algorithm at sealedenvelope.com. Assessments will be carried out at baseline, 12 weeks and then at 24 weeks. Baseline and follow-up assessments will be carried out by an experienced clinician within each NHS Trust (not within the clinical teams participating) who is blinded to which intervention the participants will receive.

All participants will be offered an interview (even those who withdraw from the trial) in their own home after the final follow-up to assess their experiences of the intervention and the trial processes, family members or carers may also attend the interview at the participants' request. Health professionals from Trafford and Central Manchester community services (N=10) who are involved in the study will be recruited to participate in a focus group at the end of the study (after 24 weeks follow-up). Participants can choose to be part of a one to one interview if they prefer not to be interviewed with colleagues or if for staffing reasons it is not feasible for them to attend the focus group.

The intervention
The Samsung Galaxy S5 phone will be used by participants and the S4 or S5 will be used by health professionals as this is the phone which has undergone usability testing, as well as testing as part of previous research projects.

The ‘motivate me’ app is the health professional application. This app will be used by the health professional with the patient to:
1. Set patients' long-term goals (outcomes/aspirations) e.g. I want to improve my ability to go up and down stairs
2. Set patients' behavioural goals (which exercises they will do and how often, when they will exercise with the health professional or alone)

The health professional can also use the app to:
1. Access the patients self-report data and see what exercises they have been doing and when
2. To give the patient bespoke feedback
3. To check that patients have been receiving messages

My activity programme
My activity programme is the patient's application. This app will be used by the patient to:
1. Report the exercises they have done (exercise type, duration, intensity)
2. Receive prompts when they have scheduled to exercise (via the health professional app)
3. Receive automated motivational messages based on the long-term goals they have set (with a focus on strengthening outcome expectations e.g. these exercises strengthen your feet and upper legs so you can walk up and down steps)
4. Receive bespoke feedback from health professionals e.g. well done Edith, I see that you have been carrying out your exercises, keep going and you will achieve your goal!
5. Confirm they have received messages and also say whether they like them

Behaviour change techniques adopted include goal setting (behaviour and outcome), action planning (recording plan to exercise in diary on smartphone/reminder text messages when it is time to start the programme), and feedback on behaviour (providing feedback on what they have done/benefits).

Control application for self-reporting exercise
The control arm will receive an app very similar to the ’my activity programme’ application, but they will only be able to report their exercises, they will receive no messages or feedback on the phone.

Assessments
Data such as demographics (age, gender, health conditions) and physical tests will be recorded on the Case Report Forms (CRF) and the original copies kept in the site file. Participants will be asked if the assessment data can be shared with the health professional and kept with their patient notes (as requested by the health professionals).

Interviews and focus groups
The interview and focus group schedules are based on FARSEEING guidelines (developed through systematic review/stakeholder consultation/usability testing, FARSEEING, 2014). The following key areas will be explored in relation to the smartphone, the Motivate me app, my activity programme app, the falls alarm, and the uTUG:
Ease of use
Clarity of screen (smartphone Apps)
Demonstration of use
Wearing comfort
Adaption of use
Reliability
Choice and Control
Home and lifestyle

This feedback will be considered and any required changes to the technology set-up, applications and intervention will be made prior to the full RCT. The trialists will also ask additional questions about the research process including: general expectations and views; experiences of recruiting patients (health professional), and of being recruited and randomised (patients), suggestions of methods for recruiting participants; likely uptake and retention of participants (see interview and focus group schedules).

Analysis
Quantitative data will be analysed using SPSS Release 22.0. Data will be stored on the smartphone and will be downloaded onto an encrypted laptop. Data will be shared with Dr Sabato Mallone at the University of Bologna (UNIBO) for assessment (e.g. falls data) and assistance with analysis. Data will be shared through dropbox for business (recommended for confidential data sharing by the University of Manchester's IT services). Data will be double-entered into SPSS for analysis, with the two data files cross-checked in SPSS for errors. The main analyses will be descriptive, involving the estimation of recruitment rates, attrition rates, non-compliance rates, means and standard deviations of outcomes by group at baseline and end trial, and 95% confidence intervals for differences of means of outcomes between groups at end trial.

Follow-up interviews/focus groups will be analysed using thematic analysis (Braun & Clark, 2006). The research will be inductive and although will seek to further understand the quantitative findings, this approach will also generate categories and explanations directly from the data rather than based on previously set aims and objectives, reducing risk of bias (Braun & Clark, 2006). QSR International's NVivo 10 qualitative data analysis software will be used to manage the data. The validity of the analysis will be checked by returning to the data once themes have been identified and also through the use of a second researcher who will check samples of analysis. Findings will be reviewed by both health professionals and participants to check for interpretation and accuracy.

Timescales
Training of staff: May 2018
Due to previous experience of recruitment to the usability testing we aim to run recruitment for 9 to 12 months starting in May/June 2018.
Interviews will take place with each participant after their six months follow-up has taken place and the focus groups will be carried out with health professionals at the end of the last 6 month follow-up (likely December 2019 at the latest).
Analysis of qualitative data will be ongoing following interviews but trial data will be examined December 2019- January 2020.
Report submitted to NIHR: May 2020.

Updated 24/01/2020:
Timescales
Training of staff: May 2018
Due to previous experience of recruitment to the usability testing we aim to run recruitment for 9 to 12 months starting in May/June 2018.
Interviews will take place with each participant after their six months follow-up has taken place and the focus groups will be carried out with health professionals at the end of the last 6 month follow-up (likely March 2020 at the latest).
Analysis of qualitative data will be ongoing following interviews but trial data will be examined March 2020-May 2020.
Report submitted to NIHR: June 2020.

Intervention Type
Device

Primary outcome measure
The feasibility and acceptability of the design and procedures including:
1. Willingness of participants to be randomised (selected to go into either the intervention or control group)
2. Willingness of clinicians to recruit participants
3. Number of eligible patients
4. Characteristics of the proposed outcome measures e.g. reliability of falls detector, Instrumented Timed up and Go
5. Follow-up rates, adherence/compliance rates
6. Time needed to collect and analyse data
7. Determine effect sizes for use in sample-size calculations at 3 months and 6 months., enabling power calculations for the reduction in falls for a definitive large scale RCT (allowing the trialists to estimate how many patients need to be recruited to show a difference between the standard service and the intervention)
This will be assessed through data collected on the CRF and through interviews (at 6 months).

Secondary outcome measures
Measured at at baseline, 3, and 6 months:
1. Falls: The primary outcome for any future definitive trial would be falls, expressed as the fall rate per person per months of follow-up. For this study falls will be detected via the falls alarm. All participants will wear the smartphone in their pocket or on a waistband and this will act as a falls detector. This will be used as an outcome measure for the study. If the patient chooses then they can also use the app on the phone as a falls alarm. The fall detection system application allows the user to identify a list of formal/informal caregivers who will receive an SMS if a fall is detected. Patients are given an opportunity to de-active the falls alarm through an application on the smartphone if there is a false alarm, enabling the user to maintain control and prevent unwanted intrusion. Data collected through the smartphone will be downloaded from the phone at the end of the intervention period. Participants will be asked if we can use their anonymised falls data for further development of the app and in the Farseeing real-world falls database (http://farseeingresearch.eu/the-farseeing-real-world-fall-repository-a-large-scale-collaborative-database-to-collect-and-share-sensor-signals-from-real-world-falls/). However, to validate this as an outcome measure the trialists will also use the internationally agreed ProFaNE falls definition (Lamb et al 2005). Patients are asked to record falls as they happen on a falls calendar completed daily and returned by mail monthly. If a person does not return their fall calendar, they are telephoned to determine whether they have fallen and if they report a fall they are contacted to record the circumstances of fall, whether any injuries occurred and whether any help was sought as a result of the fall.
2. Fear of falling, measured using the Short Falls Efficacy Scale-International (Short FES-1) (Kempen et al., 2008). This is a measure often used by UK falls services as part of standard outcome measures.
3. Function, assessed using the Timed Get Up and Go test (TGUG). The TGUG will be applied as described by Podsiadlo and Richardson (1991). Participants will be asked to perform the TGUG at their self-selected walking speed. An application developed by the University of Bologna implements an instrumented (on the smartphone) version of the TGUG called the mTUG. The application is able to automatically provide guidance to the user for administering the test, capture and process the data, and generates summary reports of function for the health professional. The mTUG is registered as a type 1 medical device and is CE marked. mTUG includes a certified external sensor for accuracy. The health professional will carry out a

standard mTUG at baseline and follow-up with a sub-sample of 10 patients at each site to assess their experiences of its use. The blinded assessor will complete the normal TUG and the mTUG as outcome measures (the standard TUG as a validation measure).
4. Balance, assessed using the Berg balance scale. This has good validity and sensitivity in this population (Berg et al, 1991) and is an assessment tool that has been used before by falls services. This will be used to estimate the number of patients needed for a full trial.
5. Strength, assessed using the 30 seconds chair stand test (Jones et al, 1999).
6. Adherence, measured in a number of ways:
6.1. Self-report app will be used for both control and intervention group (which exercises from their programme they have done and intensity). The health professional will be asked to provide a copy of the participants prescribed exercise plan, any changes to it and the dates any changes were made (both sites record this as part of standard intervention). For any group based exercise or face to face home based exercise offered, the health professional will be asked to report what is delivered (this will be used to validate the self-report from participants). The participants in the intervention arm will have their programme set on the 'motivate me' and 'my activity programme' applications as part of behavioural goals. Adherence will be classed as the participant carrying out 80% of their prescribed programme. This percentage is based on the evidence base for effective strength and balance (Nyman and Victor, 2011; Osho et al, 2017). During follow-up if participants move on to other strength and balance provision (e.g. community based strength and balance exercises) they will be encouraged to report this through the self-report app. The trialists will record any transitions between group exercise and only home exercise within the CRF. They will also ask the follow-up groups (delivered by leisure services, AgeUK and NHS exercise referral service) for a copy of what was delivered the day any of our participants attended.
6.2. Exercise Adherence Rating Scale (EARS, Newman-Benairt et al, 2017). This is a validated 16 question tool with a 6 question subscale specifically measuring adherence (the remaining questions measure reasons for adherence/non-adherence).
7. Health economics: The health economics analysis is focussed on informing relevant measures and means of collection of health related quality of life and resource use for the future definitive study. No formal tests of cost-effectiveness will be conducted, for all measures we will report mean values and sample variability alongside information on missing values. The health-related quality of life measures will include the European Quality of Life 5 Dimensions (EQ-5D-5L, 2009) and an additional measure used in previous trials related to falls prevention (the ICEpop CAPability measure for Older people (ICE-CAP-O) Davis et al, 2012; Grewal et al, 2006). Costs of delivering the intervention will be observed based on staff training, delivery costs and equipment costs. Additional resource use measures will be captured via a Resource Use Questionnaire which will seek to measure costs related to an NHS and social care perspective (secondary, primary, and community care service use), and a patient perspective (costs related to informal care, see Resource Use Questionnaire).

Overall study start date
01/04/2018

Completion date
03/07/2020

Eligibility

Key inclusion criteria
1. Older adults at risk of falls
2. Older adults aged 50+

3. Older adults assessed as requiring a falls exercise programme
4. Identified through current community falls rehabilitation services in both Central Manchester and Pennine Care NHS Trust (Trafford Community Services)
5. Good 3G/4G reception in their home or wifi available

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 86; UK Sample Size: 86

Total final enrolment
52

Key exclusion criteria
1. Older adults who are unable to follow instructions (unless they have support from a family member or carer)
2. Older adults who are unable to read written English (unless they have support from a family member or carer)
3. Severe visual impairment
4. Long-term residential or nursing care or expected shortened lifespan, defined as less than 6 months

Date of first enrolment
04/09/2018

Date of final enrolment
20/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester University NHS Foundation Trust
Falls Service
Alexandra Park Health Centre
2 Whitswood Close

Manchester
United Kingdom
M16 7AP

Study participating centre
Community Rehab Team
Pennine Care NHS Foundation Trust
Partington Health Centre
Partington
United Kingdom
M31 4FL

Study participating centre
Community Rehabilitation Team (Old Trafford)
Seymour Grove Health Centre
70 Seymour Grove
Old Trafford
United Kingdom
M16 0LW

Study participating centre
STAMP Rehabilitation Groups
George H Carnall Leisure Centre
Kingsway Park
Davyhulme
United Kingdom
M41 7FJ

Study participating centre
North Community Rehabilitation Services
Newton Health Health Centre
2 Old Church Street
Manchester
United Kingdom
M40 2JF

Study participating centre
South Manchester Falls Team
Wythenshawe Offices
1 Stancliffe Road
Wythenshawe

Manchester
United Kingdom
M22 4PJ

Study participating centre
Doncaster Falls Team
Rotherham, Doncaster and South Humber NHS Foundation Trust
Tickhill Road Site
Balby
Manchester
United Kingdom
DN4 8QN

Sponsor information

Organisation
The University of Manchester

Sponsor details
c/o Lynne MacRae
Faculty of Biology, Medicine and Health
Room 1.21a Simon Building
Brunswick Street
Manchester
United Kingdom
-
+44 (0)161 275 5436
fbmhethics@manchester.ac.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: PDF-2015-08-012

Results and Publications

Publication and dissemination plan
The trial protocol will be published within the next 6 months. Results will be reported at conferences and in peer-reviewed publications within a year of trial end. A dissemination event will also be held in Manchester just before trial end to present the results of the trial to participants and a wider audience.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the fact that this is a feasibility study and therefore of limited use to other researchers. However, the falls signals collected as part of the study will be available as part of the Farseeing real-world fall repository and can be accessed via the following link: http://farseeingresearch.eu/the-farseeing-real-world-fall-repository-a-large-scale-collaborative-database-to-collect-and-share-sensor-signals-from-real-world-falls/. This will include the study data from January 2021.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/09/2019	24/01/2020	Yes	No
Results article		05/12/2022	03/02/2023	Yes	No
HRA research summary			26/07/2023	No	No