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A SMARTphone-based study to proMOte physical actiVity in primary carE

Submission date
11/07/2012

Recruitment status
No longer recruiting

Registration date
01/08/2012

Overall study status
Completed

Last Edited
27/11/2015

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Increasing levels of obesity and diabetes to name a few health concerns have prompted governments into promoting regular physical activity as an essential tool to improve your health. New accelerometer-based technology which is standard in smartphones facilitates the monitoring of physical activity, but as of yet there is no data to indicate whether it actually leads to increased levels of physical activity. The aim of this study is evaluate whether the use of smartphone technology promotes physical activity and improves associated health outcomes.

Who can participate?
Adults over the age of 16 with a sedentary (inactive) lifestyle, who are Android smartphone users.

What does the study involve?
A pedometer application is installed on the participants' smartphones to record their physical activity (e.g., step count). The first part of the study will consist of a 7-day run-in period during which the participants will be asked not to change their usual physical activity habits, allowing the team to calculate a baseline average step count. Participants are then randomly allocated to one of two groups: the intervention group or the control group. The control group is asked to carry on their daily activity as per normal but to walk an additional 30 minutes per day. The intervention group is told how to use the app and is instructed to reach the goal of 10,000 steps per day.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
North Clare Primary Care Network (Ireland).

When is the study starting and how long is it expected to run for?
August 2012 to August 2013.

Who is funding the study?
This study is funded as part of the Implementing Transnational Telemedicine Solutions (ITTS) research programme which is funded under the EU Northern Periphery Project (NPP).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of a smartphone-based intervention to promote physical activity in primary care

Acronym
SMART MOVE

Study objectives
Of all types of physical activity, walking is the most commonly encouraged, most commonly reported form of leisure physical activity. Pedometers which contain accelerometers have

become the most acceptable form of device for monitoring walking. This trial is investigating a pedometer-based walking intervention in combination with Smartphone-based technology and smartphone-based pedometer applications. Effectivily the Smartphone will replace the pedometer and is the primary source of data collection/step count during the trial period.

Aims:
1. An increase in step count per day compared to baseline step count.
2. Improved physiological and mental health scores i.e. reduction in weight BMI, blood pressure, resting heart rate and improved mental health results using Hospital Anxiety and Depression Scale (HADS) and Quality of Life (EQOL) questionnaire.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee, Galway, Health Service Executive of Ireland

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Smartphone for positive behavioural change/promotion of physical activity

Interventions
Screening/Baseline visit and run in period

All potential participants will be screened by a GP. The clinician will deem that a participant is in suitable physical health to undertake moderate physical activity. The participant will be invited to attend a screening/baseline meeting with 2 researchers. After obtaining a written informed consent, baseline data will be gathered by a research nurse.

Eligible participants will meet with a research engineer where the software app will be installed on the persons privately owned Smartphone with their consent. During the run in baseline period the pedometer application will be set to record and store physical activity e.g. step count. No widget (Smartphone screen display) or step count will be displayed or visible. In order to

standardize the recordings participants are asked to position the Smartphone in there trouser /pants pocket or on their waistband or belt and only remove it during times of sleep and showering.

The run in period will allow the team to identify a baseline average step count and confirm if the participant has sufficient Smartphone and computer literacy to successfully complete the trail period. The initial part of the protocol will consist of a 7-day baseline period during which the participants will be asked not to change their usual physical activity habits

Control Group
The control group will be contacted by mobile phone and asked to email their run in step count data. Once week one run in is deemed successful. Each member of the control group will be contacted by phone and:
1. Instructed to carry on daily activity as per normal but in addition instructed to walk an additional 30 minutes per day.
2. Advised on how to maintain the performance of the phone such as charging and constant carrying of the phone on their person.
3. Issued by post or electronically with Irish Heart Foundation 'Be Active' promotional brochure.
4. Contacted mid study session by telephone/text or email and asked to forward step count details. This is an attempt to reduce data/user error whereby the step count can be verified and the application confirmed to be working effectively.

Intervention Group
The intervention group will be contacted by mobile phone and asked to email their run in step count data. Once week one run in is deemed successful,
Each member of the control group will be contacted by phone and:
1. Instructed how to turn on the Accupedo widget or display and how to position the display on the home screen providing up to minute information of step count to date.
Instructed on usability of the Accupedo settings, graphs, and email and user interface.
2. Encouraged to interact with the smartphone pedometer app.
3. Instructed to achieve 10000 steps per day goal.
4. Issued by post or electronically with Irish Heart Foundation 'Be Active' promotional brochure.
5. Contacted mid study session by telephone/text or email and asked to forward step count details. This is an attempt to reduce data/user error whereby the step count can be verified and the application confirmed to be working effectively.

Intervention Type
Behavioural

Primary outcome measure
Mean daily step count compared to baseline

Secondary outcome measures
Physiological and mental health scores, i.e. weight, body mass index (BMI), blood pressure, resting heart rate, and mental health results using HADS and EQOL questionnaire.

Overall study start date
07/08/2012

Completion date
07/08/2013

Eligibility

Key inclusion criteria
1. Adults over the age of 16 with sedentary lifestyle
2. Are active Android smartphone users

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80 (40 intervention and 40 control)

Key exclusion criteria
1. People with learning disabilities
2. Acute psychiatric illness
3. Pregnant women
4. People with mobility issues

Date of first enrolment
07/08/2012

Date of final enrolment
07/08/2013

Locations

Countries of recruitment
Ireland

Study participating centre
National University of Ireland Galway
Galway
Ireland
N/A

Sponsor information

Organisation

Implementing Transnational Telemedicine Solutions [ITTS] (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.transnational-telemedicine.eu/

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Research organisation

Funder Name
Northern Periphery Programme (Denmark)

Funder Name
Implementing Transnational Telemedicine Solutions [ITTS] (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/05/2013		Yes	No
Results article	results	01/07/2014		Yes	No