

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

Submission date 11/07/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 01/08/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/11/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Protocol serial number

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. Effectively 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

Study type(s)

Treatment

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 trial 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(s)

Mean daily step count compared to baseline

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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?
Results article	results	01/07/2014		Yes	No
Protocol article	protocol	29/05/2013		Yes	No