ISRCTN11167977 https://doi.org/10.1186/ISRCTN11167977

Evaluating how feasible a new mobile phone application is for reducing sitting behaviour and improving blood sugar levels in Type 2 diabetes

Submission date
29/06/2017

Recruitment status
No longer recruiting

Registration date
06/07/2017

Overall study status
Completed

Last Edited
29/06/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetes is a lifelong condition that causes the blood sugar level to become too high. There are 4 million people in the UK living with diabetes and 90% of these have type 2 diabetes. In the past ten years the number of cases of type 2 diabetes has increased by 60% in the UK. Diabetes costs the NHS £9 billion each year and has become a public health epidemic. The American Diabetes Association recommends that adults with type 2 diabetes should decrease the total amount of time spent sitting and should interrupt prolonged sitting (sedentary behaviour) with bouts of at least light-intensity activity every 30 minutes for blood sugar benefits. The increasing prevalence of type 2 diabetes means that cost-effective self-management treatment strategies are needed. Technology is readily available and widely used in the modern society and has thus been identified as a potentially effective method to aid in self-management of type 2 diabetes. Mobile phone application self-management interventions for type 2 diabetes can improve blood sugar control. However, most mobile phone applications that have been developed for self-management of type 2 diabetes are focused on providing personalised feedback on self-monitoring data (e.g., blood sugar), food intake, and physical activity. The aim of this study is to assess the feasibility of the MyHealthAvatar mobile phone application for reducing prolonged sedentary behaviour and improving mood and blood sugar control in people with type 2 diabetes.

Who can participate?
Patients aged 18-65 diagnosed with type 2 diabetes within the last 4 years

What does the study involve?
Participants are randomly allocated to either the control group or intervention group and take part in the study for 8 weeks. Both groups of participants attend the University of Bedfordshire Sport and Exercise Science Laboratories in Bedford before and after the 8-week study period for a testing session. On both occasions they complete an Oral Glucose Tolerance Test (OGTT) to measure how their blood sugar levels respond to drinking a sugary drink, and also have their height, weight, body fat, waist circumference and blood pressure measured, and complete a questionnaire booklet. They are also provided with an activity monitor to wear for one week

before the study and during the last week of the study. Following the data collection session, the control group are asked to continue with their normal behaviour for the 8-week study period, while the intervention group download and use the MyHealthAvatar mobile phone application to use for 8 weeks and receive weekly motivational text messages.

What are the possible benefits and risks of participating?
Breaking up sitting time could help to improve blood sugar control, body fat and waist circumference. Participants receive a comprehensive assessment of their health and are compensated for their time. Finger prick blood samples are taken during the study. This carries a very small risk of infection. Appropriately trained members of the team take these samples and adhere to professional standards for blood collection to reduce this risk. The body composition analyser poses potential electrical hazard issues. The device is checked for full working condition before use and undergoes PAT testing in accordance with University annual inspections. All participant information is stored and protected. Any paperwork relating to research activities and participant information is stored in a locked filing cabinet at the University of Bedfordshire. Information stored on computers is protected by passwords. Before testing participants are assigned to a participant ID number allocated to them by the research team to maintain their anonymity.

Where is the study run from?
The University of Bedfordshire (UK)

When is the study starting and how long is it expected to run for?
June 2017 to December 2017

Who is funding the study?
The University of Bedfordshire (UK)

Who is the main contact?
Dr Daniel Bailey
daniel.bailey@beds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Daniel Bailey

ORCID ID
http://orcid.org/0000-0003-3772-630X

Contact details
Polhill Avenue
Bedford
United Kingdom
MK41 9EA
+44 (0)1234 793 237
daniel.bailey@beds.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2

Study information

Scientific Title
The feasibility of mobile phone application, MyHealthAvatar, for reducing sitting time and improving mood and glucose control in Type 2 diabetes

Study objectives
It is hypothesised that those in the intervention arm who will use the MyHealthAvatar mobile phone application will reduce their prolonged sedentary behaviour and improve their mood and glucose control compared to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge South NHS Research Ethics Committee, 18/04/2017, ref: 17/EE/0070

Study design
Experimental feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions

Randomisation will be completed using an online research randomiser tool (www.randomizer.org). Five blocks of four numbers will be generated to randomly assign each of the 20 participants to one of the two intervention conditions. Individuals will be randomly allocated to either the control group or intervention group and take part in the study for 8 weeks. Both groups of participants will attend the University of Bedfordshire Sport and Exercise Science Laboratories in Bedford before and after the 8 week study period for a testing session. On both occasions they will complete an Oral Glucose Tolerance Test (OGTT) and have height, weight, body fat %, waist circumference and blood pressure measured, along with the completion of a questionnaire booklet to assess psychological variables. They will also be provided with an ActivPAL activity monitor to wear for one week pre intervention and during the last week of the intervention.

Following the data collection session, the control group will be asked to continue with their normal behaviour for the 8 week time period, whilst the intervention group will download and utilise the mobile phone application, MyHealthAvatar, to use for 8 weeks and will receive weekly motivational text messages.

MyHealthAvatar is a mobile phone application system that serves as a suite for self-monitoring of health and lifestyle data. The user can enter and track health and lifestyle information related to non-communicable disease that encourages self-monitoring and self-management. There are a number of features that allow the user to add personal lifestyle and health data:
1. Internal data depositories for an individual's data including: blood glucose levels, weight, BMI, medication events
2. A suite for monitoring sitting behaviour and activity levels: number of steps, amount of time being active, distance travelled, amount of time spent sitting, number of breaks from sitting time
3. Goal setting: patients can set personal short or long term goals relating to sedentary time, interruptions in sedentary time, physical activity (step counts), and body weight. These goals are monitored within the app and the patient has a visual representation of the progress they are making toward each goal in the form of tables and charts
4. Reminders; the ability to set reminders to encourage individuals to meet daily goals for sitting behaviour and physical activity levels. This feature allows the patient to select the frequency that the reminders are provided throughout each day e.g. a reminder every 30 minutes to get up and move around
5. Links to external NHS news and information websites related to the relevant patient disease to serve as an educational tool for the patient. This includes information, for example, on optimal BMI levels, glucose levels and blood pressure

Participants will then receive ongoing text message reminders to promote the use of the app and to remind them to use it on a daily basis to log their data and review their goals. This will be done through weekly text messages that will be sent direct to the phone from the research team and will be based upon motivational interviewing.

Intervention Type
Behavioural

Primary outcome measure
1. Sedentary behaviour, measured using ActivPAL activity monitor at baseline and during the final week of the 8 week intervention
2. Oral glucose tolerance, measured using Oral Glucose Tolerance Test (OGTT) at baseline and post-intervention (8 weeks)

Secondary outcome measures
1. Physical activity, measured using ActivPAL activity monitor at baseline and during the final week of the 8 week intervention
2. Body fat, measured using bioelectrical impedance analysis and waist circumference at baseline and post-intervention (8 weeks)
3. Blood pressure, measured using using an automated oscillatory device at baseline and post-intervention (8 weeks)
4. Sedentary behaviour self-efficacy, measured using an adapted version of the Schwarzer and Renner (2007) Physical Exercise Self-Efficacy Scale at baseline and post-intervention (8 weeks)
5. Current mood, measured using the short Positive and Negative Affect Scale (PANAS) at baseline and post-intervention (8 weeks)
6. Psychological wellbeing, assessed using the National Wellbeing Measurement and the Warwick Edinburgh Mental Well-Being Scale (WEMWBS) at baseline and post-intervention (8 weeks)

Overall study start date
06/06/2017

Completion date
01/03/2018

Eligibility

Key inclusion criteria
1. Male or female
2. Aged 18-65 years
3. Diagnosed with Type 2 diabetes in the last 4 years
4. In the first stage (single non-insulin blood glucose lowering therapy) or first intensification (dual treatment of metformin plus one other drug) of drug treatment or using a diet and exercise management strategy
5. Speak and read English
6. Body mass index (BMI) < 40 kg/m2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Type 1 diabetes
2. Diseases or disorders related to diabetes (e.g. heart disease, damage to the retina at the back of the eye, kidney problems, and infections, ulcers or reduced ability to feel pain in feet)
3. Type 2 diabetes diagnosed more than 4 years ago
4. Pregnant
5. Severe obesity

Date of first enrolment
26/05/2017

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bedfordshire
Polhill Avenue
Bedford
United Kingdom
MK41 9EA

Sponsor information

Organisation
University of Bedfordshire

Sponsor details
Polhill Avenue
Bedford
England
United Kingdom
MK41 9EA

Sponsor type
University/education

ROR
https://ror.org/0400avk24

Funder(s)

Funder type
University/education

Funder Name
University of Bedfordshire

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of the study will be published in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Daniel Bailey (Daniel.bailey@beds.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/06/2020	29/06/2020	Yes	No
HRA research summary			28/06/2023	No	No