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The effects of self-directed walking and/or step training combined with a mobile phone based adaptive coaching system in type 2 diabetes mellitus

Submission date
24/01/2017

Recruitment status
No longer recruiting

Registration date
30/01/2017

Overall study status
Completed

Last Edited
11/10/2018

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
Type 2 diabetes mellitus (T2DM) is a long term condition where sufferers have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). In recent years, many studies have shown that regular physical activity and exercise can help to control the disease. However, encouraging patients to keep up with exercise programs in their own time can be difficult. Walking and step training are forms of exercise that can be carried out in any location. This allows individuals to incorporate short bouts of exercise, which have previously been shown to be beneficial in both diabetic and non-diabetic individuals, into their daily routines. This study is looking at a new exercise prescription in complication with a mobile phone application designed specifically for this study that helps to monitor the physical activity of participants, tailor their daily individual prescription based on their successful or not completion of previous exercise sessions and provide them with further encouragement. The aim of this study is to find out whether this program can help patients to keep exercising on their own to help control their diabetes.

Who can participate?
Inactive adults aged between 40 and 65 who have T2DM that is not treated with insulin.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group are given an outline for an exercise program that they are asked to incorporate into their routines over a period of 16 weeks. The program gradually increases the length and frequency of exercise sessions over the course of the 16 weeks. Those in the second group take part in the same exercise program as the first group in addition to being able to download a mobile phone app which automatically provides reminders and encouragement to complete the prescribed exercise sessions and outline the next exercise session to be completed and record the completion rates of exercise sessions. Participants are asked to input into the app how

strenuous they feel each exercise session is. Those in the third group continue with their normal lifestyles for the 16 weeks of the study. At the start of the study and again after 16 weeks, participants have their physical activity levels and weight assessed as well as providing blood samples to test fat levels and blood sugar levels.

What are the possible benefits and risks of participating?
There are no guaranteed benefits of participating however exercising can lead to general health benefits. Risks not provided at time of registration.

Where is the study run from?
University College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
October 2016 to December 2018

Who is funding the study?
Science Foundation Ireland (Ireland)

Who is the main contact?
Mr Hugh Byrne

Contact information

Type(s)
Scientific

Contact name
Mr Hugh Byrne

Contact details
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Additional identifiers

Protocol serial number
HBGDVUCDT2DMRCT

Study information

Scientific Title
The effects of a novel prescription of multiple short bout of self-directed walking and/or step training combined with a mobile phone based adaptive coaching system in type 2 diabetes mellitus

Study objectives
The novel exercise prescriptions will increase adherence to exercise and the adherence will be further increased when used in conjunction with the adaptive coaching system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UCD Human Research Ethics Committee - Sciences (HREC-LS), 06/10/2016

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Interventions as of 11/10/2018:
Some changes were made to the study, largely to do with challenges in recruitment. The methods for the study, in the preliminary version of the journal article, are below.
A summary of the main changes:

2 populations were included, type 2 diabetics and sedentary middle aged individuals.

There was no non-intervention control group but rather the groups had a run-in period and acted as controls for one another.

T2DM patients were recruited through 3 diabetes outpatient clinics in one public and one private hospital. Non T2DM individuals were recruited via emails sent to university staff and alumni and through word of mouth. Participants were not engaged in regular or formal physical activity and were between 30 and 65 (Non T2DM) or 40 and 65 (T2DM) years of age. Written consent was given by the university ethics committee and by the ethics committees of the 2 hospitals.

Individuals with any mental, neurological, cardiovascular, musculoskeletal or orthopaedic deficiency contra-indicating training and/or muscular testing or making it impossible or preventing knowing consent to the study were not included. Individuals with current infectious or inflammatory condition, evidence of chronic renal failure or liver disease, severe proliferative diabetic retinopathy, current or recent pregnancy were also excluded. T2DM participants were not treated with insulin and had a HbA1c of between 53-86mmol/mol and the non T2DM participants also had no other chronic illness or disorder.

In total there were 4 intervention groups and for both population groups there were 2 interventions to which to which participants were randomised. The 2 sets of interventions were identical for both so that there was one intervention group from each population conducting

the same intervention as a group from the other population. For both interventions, the exercise protocol was similar and was designed using recent literature with the aim of yielding a high compliance and improving health related outcome measures (Eriksen et al., 2007; Karstoft et al., 2012; Mair et al., 2014; Kearney et al. 2014, Doheny et al., 2013; Serwe et al., 2011; Puglisi et al., 2008). 2 of the intervention groups were provided with a logbook that outlined their exercise programme for the 16 weeks and they were asked to record each of the exercise sessions they completed in the logbook. The exercise programme they followed consisted of small bouts of walking and/or step training spread throughout the day. Participants chose either walking or step training for each individual session to provide them with greater autonomy and to minimise the impact of Irish weather as a barrier to exercise. Participants were asked to incorporate the exercise programme into their routines over 16 weeks. The protocol began with two 2-minute sessions per day at 12/20 on the Borg rating of perceived exertion (RPE) scale on 3 days per week for the first week. The duration, frequency and intensity all progressed gradually to three 12-minute sessions every day at 16/20 on the Borg scale in week 16.

The other 2 intervention groups were provided with a smartphone adaptive coaching application that was designed to be used in conjunction with the specific exercise programme used in this study. Details of the smartphone adaptive coaching application have been reported elsewhere previously (Byrne et al., 2018b). In short, the application automatically provided daily and weekly reminders and encouragement to complete prescribed exercise sessions, record recent sessions and outlined the exercise session to be completed over the coming week. The messages included persuasive methods including positive and negative reinforcement. Participants also recorded their adherence in the application alongside the logbook and the application adapted upcoming exercise prescriptions based on previous adherence of the participants. The application treated each week as a “level” and participants needed to complete 75% of sessions within an individual week to progress onto the next. If they failed to complete 75% of sessions, they remained on that level the following week. It also augmented the daily and weekly feedback messages provided the individual in line with this. The app aimed to use a combination of the “goal setting” and “self-efficacy” theories of behavioural change to find an exercise prescription that best encouraged participants to conduct the progressive exercise prescription. The 4 intervention groups were: non-diabetic and app (NonT2DMApp), non-diabetic and logbook (NonT2DMLog), diabetic and app (T2DMApp), diabetic and logbook (T2DMLog).

Following recruitment, all participants attended laboratory facilities for testing at baseline, which was 4 weeks prior to commencement of the intervention, and immediately before and after the 16-week intervention period. This run-in period was conducted to assess the consistency of the outcomes assessed in the groups during periods without any exercise intervention. The testing protocol was outlined to participants when they arrived at the laboratory on day 1. They then completed a consent form and physical activity readiness questionnaire (PAR-Q). Following this the primary (six-minute walk test (6MWT)) and secondary (Active Australia Survey, Short Form 36 (SF-36) quality of life questionnaire, body mass index (BMI) using height & weight and grip strength) outcomes were recorded. For T2DM participants, blood samples were taken and analysed in their diabetes clinics at the three testing timepoints. For both populations, randomisation took place following the initial 4-week run in period and was conducted based on the sequence in which the individuals began the intervention in their respective populations.

Previous interventions:
Participants will be randomly allocated to one of three groups,.

Exercise only group: Participants will be given an outline of the exercise programme that will gradually increase in length and frequency of exercise sessions and are asked to incorporate it

into their routines over 16 weeks. The exercise intervention is made up of a 16-week long programme consisting of short bouts of walking and or/step training spread throughout the day where the participants can decide when and where to conduct the individual short bouts of exercise and to choose if they conduct walking or step training at each session. The prescription given to the exercise alone group is progressive in nature and begins with 2 sessions of 2 minutes length on 3 days at 12/20 on Borg RPE scale in week one and gradually progresses in session length, duration, frequency and intensity to 3 sessions of 12 minutes length on 7 days at 16/20 on Borg scale in week 16.

Exercise with coaching app group: Participants will be given an outline of the exercise programme that will gradually increase in length and frequency of exercise sessions and are asked to incorporate it into their routines over 16 weeks. They will also download the mobile phone app which automatically provides reminders and encouragement to complete the prescribed exercise sessions and outline the next exercise session to be completed and record the completion rates of exercise sessions. Participants will be asked to input how strenuous they felt each exercise session was.

Control group: Participants will continue their normal routines for the duration of the study.

Participants are followed up at 16 weeks.

Intervention Type
Behavioural

Primary outcome(s)
1. Adherence to the exercise prescription is assessed using logbooks in the exercise alone group and using logbooks and self reported adherence in the mobile phone application in the exercise and coaching app group at 16 weeks (exercise groups only)
2. Physical activity levels are measured using the Active Australia Survey at baseline and 16 weeks

Key secondary outcome(s))
Secondary outcome measures as of 09/10/2018:
1. Weight is measured using a weighing scales at baseline and 16 weeks
2. BMI is calculated using height and weight measurements taken at baseline and 16 weeks
3. Neuromuscular function using electromyography (EMG) during isometric and isokinetic dynamometry at different speeds at baseline and 16 weeks
4. Functional fitness is measured using the 6 minute walk test at baseline and 16 weeks
5. Grip strength is measured using a hand grip dynamometer at baseline and 16 weeks
6. Lipid profile is measured using blood testing at baseline and 16 weeks
7. Glycated haemoglobin is measured using blood samples collected at baseline and 16 weeks

Exit interviews were conducted to allow for qualitative analysis of the interventions.

Previous secondary outcome measures:
1. Weight is measured using a weighing scales at baseline and 16 weeks
2. BMI is calculated using height and weight measurements taken at baseline and 16 weeks
3. Blood pressure is measured using a sphygmomanometer at baseline and 16 weeks
4. Neuromuscular function using electromyography (EMG) during isometric and isokinetic dynamometry at different speeds at baseline and 16 weeks
5. Functional fitness is measured using the 6 minute walk test at baseline and 16 weeks

6. Grip strength is measured using a hand grip dynamometer at baseline and 16 weeks
7. Lipid profile is measured using blood testing at baseline and 16 weeks
8. Glycated haemoglobin is measured using blood samples collected at baseline and 16 weeks

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of T2DM > 6 months
2. Sedentary – not currently participating in any physical activity (in line with results of the Active Australia Survey)
3. Treated with oral hypoglycaemic agents and diet alone and not with insulin
4. Aged 40-65 years
5. Male and Female
6. Hba1c 7-10%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any mental, neurological, cardiovascular, musculoskeletal or orthopaedic deficiency contra-indicating regular training and/or muscular testing or making it impossible or preventing knowing consent to the study
2. Infectious or inflammatory evolving affection
3. Evidence of chronic renal failure or liver disease
4. Severe proliferative diabetic retinopathy
5. Currently or recently pregnant

Date of first enrolment
01/12/2016

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Stillorgan Road
Belfield
Dublin
Ireland
Dublin 4

Sponsor information

Organisation
University College Dublin

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Government

Funder Name
Science Foundation Ireland

Alternative Name(s)
SFI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		09/10/2018	09/10/2018	No	No