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Virtual health trainer to promote physical activity

Submission date
10/07/2014

Recruitment status
No longer recruiting

Registration date
20/08/2014

Overall study status
Completed

Last Edited
08/10/2018

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
People with type 2 diabetes have to take very good care of their health . Among other things, physical activity is very important as it helps to reduce and maintain glucose level in the blood. It is vital that people with type 2 diabetes do regular exercise (physical activity) in order to maintain a healthy blood glucose levels . Here, we investigate how good a virtual health trainer, which is accessible through a website, is at promoting physical activity in people with type 2 diabetes living in remote and/or rural areas of the UK.

Who can participate?
Adults with diabetes, managing their disease with pills or lifestyle changes and residents of Inverness, Fort William, Skye and Caithness areas of the UK.

What does the study involve?
Participants are randomly allocated to receive the interactive virtual health trainer (intervention group 1), information only virtual health trainer (intervention group 2) or usual care (standard care exercise information). Chemical changes within their body and their level of physical activity are measured on three occasions over a 7-day period at the start of the study, then after 3 and 6 months. This is compared with their self-reporting of physical activity and with the previous measures taken at the start of the study or 3 months. The usual care group receive leaflets based on the website material regarding information on the benefits of physical activity on type 2 diabetes, current recommendations for physical activity and information on exercise and diabetes-related complications. The virtual health trainer group are also given this information but it is accessed through the website. The interactive virtual health group have access to this information but are able to log onto the website. This gives them access to interactive features such as a tool to monitor their physical activity, a physical activity consultation which helps them to set up goals and targets and the option to choose challenges which they can accomplish over a few physical activity sessions. This group also have access to a map that can help them find places in their area to become more active. The website acts as a support tool to promote physical activity in remote areas. Each participant is given a physical activity monitor (accelerometer) and is asked to wear this for 7 days during all waking hours to measure their

level of activity at these time points. A small number of people of the group who already perform home blood glucose testing are also asked to wear a continuous glucose monitoring system for 3 days at the same time they wear the accelerometer.

What are the possible benefits and risks of participating?
Participants receive access to a support tool which helps increase and monitor physical activity. By increasing physical activity they may find improvements in their blood glucose and insulin sensitivity as well as other associated health benefits. No significant risks are expected as a result of taking part in this study. However, patients may experience a little discomfort during the blood collection procedure and they are warned that they may feel a little pain when the needle is inserted. Also increasing physical activity can result in some muscle soreness but structured advice is given on how to best avoid this.

Where is the study run from?
The study is run from Inverness, Fort William, Skye and Caithness areas in the UK.

When is the study starting and how long is it expected to run for?
November 2013 to September 2014

Who is funding the study?
Lifescan Ltd, Inverness (UK)

Who is the main contact?
Miss Jenni Connelly
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Contact information

Type(s)
Scientific

Contact name
Miss Jenni Connelly

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Trial of a virtual health trainer to promote physical activity in the management of type 2 diabetes in rural and remote areas

Study objectives
To identify whether a web-based virtual trainer can increase physical activity in people with type 2 diabetes

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland NRES Committee, 03/07/2014, ref.13/NS/0069

Study design
Single-centre interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

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
Type 2 diabetes

Interventions
This is an intervention study where diabetes physical activity advice will be given to three different groups. The control group will receive written advice in leaflet form, intervention group 1 will receive the same advice but in the form of a website and the third group will have access to this advice as well as interactive components on the site.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Physical activity, measured using actigraph acclerometers over a 7-day period at baseline, 3 and 6 months

Secondary outcome measures
The following measures will be collected at three time points: baseline, 3 and 6 months:
1. Physiological measures:
1.1. Blood pressure
1.2. Height
1.3. Weight and calculation of BMI
1.4. Waist/hip measurements
2. Venepuncture - sampling blood to measure:
2.1. HbA1c
2.2. Cholesterol
3. Physical activity, objectively measured using actigraph accelerometers and subjectively measured using the International Physical Activity Questionnaire (IPAQ)
4. Continuous blood glucose, measured using Medtronic iPro2 in a subsample of the group at the same three timepoints but for 6 days

Overall study start date
04/11/2013

Completion date
14/09/2014

Eligibility

Key inclusion criteria
1. People with type 2 diabetes
2. Over 18 years old
3. Must manage their diabetes through lifestyle or oral medication
4. Able to give informed consent
5. Must be able to speak English
6. Resident in Inverness, Fort William, Skye and Caithness areas
7. Must have access to a computer with internet access

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
36

Key exclusion criteria
1. Under 18 years old
2. Unable to give informed consent
3. Living outside the sample geographical areas
4. Must not manage their diabetes through insulin
5. Those with any physical disability or diabetes related complication that precludes increasing physical activity or impairs communication
6. People with visual or hearing impairments
7. People that have no access to the internet

Date of first enrolment
04/11/2013

Date of final enrolment
14/09/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Centre for Health Science
Inverness
United Kingdom
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Sponsor information

Organisation
University of The Highlands and Islands (UK)

Sponsor details
c/o Jenni Connelly
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Sponsor type
Research organisation

ROR
https://ror.org/02s08xt61

Funder(s)

Funder type
Industry

Funder Name
Lifescan Ltd, Inverness (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?
Results article	results	19/10/2017		Yes	No
HRA research summary			28/06/2023	No	No