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“MOVEdiabetes” a trial to promote physical activity for adults with type 2 diabetes in primary health care in Oman

Submission date
05/04/2016

Recruitment status
No longer recruiting

Registration date
10/04/2016

Overall study status
Completed

Last Edited
19/02/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes is a major public health problem. The benefits of physical activity in the prevention and management of diabetes is well known. However, many people with diabetes do a lot of exercise. Hence, it is critical to develop and test ways to encourage people with diabetes to adopt a more physical and healthy lifestyle, that are both feasible and acceptable. Previous studies promoting physical activity for this patient group have mostly been run from western countries. This study will take place in Oman, an Arabic speaking country and where both diabetes and physical inactivity are very common. The aim is to look at the impact of a multi-component physical activity intervention (that is, a physical activity program with a number of different components) called “MOVEdiabetes” aimed at changing physical activity levels in adults with type 2 diabetes that do not exercise a lot (i.e. are physically inactive).

Who can participate?

Adults aged 18-60 with type 2 diabetes and physical inactive, that have attended one of the eight participating health centres for 6 months or more.

What does the study involve?

The health centres recruited into the study are randomly assigned to one of two groups. The patients participating in the study that attend a health centre in group 1 are placed in the intervention group. They are all given a physical activity monitor to wear for a week before they attend their first study visit held at their heath study. The monitors use temperature and activity sensors to monitor how active they are. At the first study visit, routine body measurements are taken (height, weight, blood pressure and waist circumference) and routine blood tests are carried out (cholesterol, lipids (fat), glucose (sugar) and HbA1c). They are then asked about how active they are and how healthy they consider themselves to be. They return the physical activity monitor and are given a pedometer to wear instead, a device that counts the number of steps taken each day. Each participant is asked to take note of the number of steps they take each day in a using the pedometer in a table for the next week and they have a 20 minute physical activity consultation. They are also asked to join a WhatsApp chat on their mobile phone so that they receive messages that motivate them to become more physically active. On the second visit (one

month later), the pedometer readings are reviewed and the participants have a second physical activity consultation. On the third visit (a month after the second visit), the pedometer readings are reviewed as well as the WhatsApp messages. The participants also have a third physical activity consultation. For visit 4 (which takes place 12 months after the start of the study), participants are again asked to wear the physical activity monitor for a week before and then about their experience of taking part in the study. The patients attending a health centre in group 2 are also given a physical activity monitor to wear a week before their first and last study visit. They undergo the same routine body measurements and blood tests as those in group 1. They don't, however, undergo the physical activity consultation or asked to record their physical activity using a pedometer.

What are the possible benefits and risks of participating?
There are no known risks to taking part in the study.

Where is the study run from?
A total of eight Health Centres in Seeb, Oman

When is the study starting and how long is it expected to run for?
April 2016 to May 2017

Who is funding the study?
1. Ministry of Health, Oman
2. The Research Council, Oman

Who is the main contact?
1. Dr Thama Alghafri (scientific)
2. Dr Saud Alharthi (scientific)

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
“MOVEdiabetes” a cluster randomised controlled trial to promote physical activity for adults with type 2 diabetes in primary health care in Oman

Study objectives
A multi-component physical activity intervention “MOVEdiabetes” increases physical activity levels in inactive adults with type 2 diabetes

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Omani Research and Ethical Review and Approve Committee in the Ministry of Health, 05/01/2016
2. University of Dundee (UK), 19/01/2016, ref: 16006

Study design
A 12 month two-arm cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Available as downloadable content in Additional Files section below

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

Interventions
1. The Intervention Group (IG) will receive the “MOVEdiabetes” personalised three PA consultations (baseline, 2nd month and 3rd months), pedometer (YAMAX Digi-walker SW-200) to supervise the weekly step counts and monthly and weekly telephone WhatsApp messages. The treatment period will last for 12 months from the date of baseline measurements.
1.1. Personalised PA consultations:
The MOVEdiabetes personalised, multiple contact, intervention programme is based on the US diabetes prevention programme (American Diabetes Association, 2010, Diabetes Prevention Program Research Group, 2009) and on several behavior change techniques based on the Abraham and Michie taxonomy (Abraham and Michie, 2008) which includes (a) goal-setting for PA; (b) self-monitoring to achieve these goals; (c) frequent contact to provide accountability and sustain focus; (d) use of problem-solving and other “toolbox” strategies to address goals and potential barriers to achieving them; and (e) emphasis on managing individual high-risk situations. Based on these techniques, various intervention components were chosen to offer flexibility; to adjust to individual differences and preferences and to strengthen change. The approach will take particular care to emphasise the importance of regular (weekly) step count recordings through the pedometers.
1.2. Pedometer (monitoring tool):
Participants will be given a pedometer (YAMAX Digi-walker SW-200) at visit 1. Instructions how to use the pedometer, how to record their daily steps and to set a daily step goal will be discussed by the Project Officers (POs). They will be asked to fill in a daily step count and submit it to the POs in their health centre. Participants will also be asked to report their weekly step counts to the PO through individual WhatsApp application throughout study period (12months). The participants are asked to decide on individual goals after the first week of wearing the pedometer. If a pedometer stops working or gets lost the participants are encouraged to pick up a new pedometer at the health centre or a new pedometer will be sent.
1.3. WhatsApp:
Participants will be asked to open and share a telephone WhatsApp application with the PO in their health centre. The participants are asked to report their pedometer step counts and ask the POs any questions related to the intervention. The POs will remind the participants to report their step counts every week if not reported. Additionally, monthly standardized physical activity motivational messages will be delivered through this telephone application.
Participants are invited to join WhatsApp groups to share the motivational messages with other MOVEdiabetes participants.

2. The Usual Care (comparison) group will be receiving the same routine care of patients with diabetes.

Intervention Type
Behavioural

Primary outcome measure
Change in physical activity levels measured by changes in MET-min/week reported by participants using the Global physical activity questionnaire (GPAQ) and validated objectively by activPAL accelerometers at baseline, 3 months and 12 months

Secondary outcome measures
1. Changes in metabolic and cardiovascular biomarkers (BMI, waist circumference, BP, HbA1c and lipids) recorded from the health information system in the health centre at baseline, 3 months and 12 months
2. General health, self-efficacy and social support, evaulated by questionnaire at baseline and 3 months
3. Perceived acceptability of the programme and intervention cost description assessed at 12 months

Overall study start date
17/04/2016

Completion date
01/05/2017

Eligibility

Key inclusion criteria
1. Adults aged 18 to 60 years
2. Diagnosed with type 2 diabetes
3. Attending HC for at least six months previously for follow up
4. Assessed by research officer as having inactive behaviour using a structured screening questionnaire designed for this project.
5. No contraindication to physical activity
6. Able to speak and read Arabic
7. Willing and able to consent to the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
112

Total final enrolment
232

Key exclusion criteria

1. Patients with Type 1 diabetes
2. Patients with a history of myocardial infarction in the previous 6 months
3. Patients with a serum creatinine >140 mmol/L (from previous readings –Alshifa system).
4. Patients with diabetic foot ulcers or at high risk of ulcer (severe peripheral neuropathy)
5. Insulin usage
6. Repeated hypoglycaemia or sever hypoglycaemia in previous 12 months
7. No internet access for WhatsApp

Date of first enrolment
17/04/2016

Date of final enrolment
03/08/2016

Locations

Countries of recruitment
Oman

Study participating centre
Seeb Health Center
Seeb
Oman
-

Study participating centre
Al Khodh Medical Center
Seeb
Oman
-

Study participating centre
Al Hail Health Center
Seeb
Oman
-

Study participating centre
Almabeelah Health Centre
Seeb
Oman
-

Study participating centre
Al Khuwair Health Center
Seeb
Oman
-

Study participating centre
North Al Mawaleh Health Center
Seeb
Oman
-

Study participating centre
South Amabeela Health Centre
Seeb
Oman
-

Study participating centre
Ashadi Health Centre
Seeb
Oman
-

Sponsor information

Organisation
Ministry of Health, Oman

Sponsor details
PO Box 393
Muscat
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100

Sponsor type
Government

Website

http://www.moh.gov.om

Organisation
The Research Council, Oman

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PO Box 1422
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130

Sponsor type
Research council

Website
https://home.trc.gov.om

Funder(s)

Funder type
Government

Funder Name
Ministry of Health, Oman

Funder Name
The Research Council, Oman

Results and Publications

Publication and dissemination plan

Intention to publish date
01/05/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			15/04/2016	No	Yes
Participant information sheet			15/04/2016	No	Yes
Protocol article	protocol	06/01/2017		Yes	No
Results article	results	08/06/2020	19/02/2021	Yes	No