

Promoting a healthy lifestyle in adults with diabetes

Submission date 28/11/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/01/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The study aims to evaluate the effectiveness of a bespoke phone application, pedometers and phone consultations in promoting healthy lifestyle in adults with diabetes attending primary care facilities in Muscat, Oman.

Who can participate?

Adults aged 18-65 years of age, diagnosed with diabetes and overweight/obese

What does the study involve?

Participants will be randomly allocated to receive the intervention or usual care. Participants in the intervention group will receive phone personalised physical activity and diet consultations on four occasions (4, 12, 24 and 36 weeks), pedometers, and an interactive phone application (developed by the higher college of technology in Oman). The intervention will include self-monitoring and feedback on step counts and diet which will be provided within physical activity and diet consultations and discussed through communications in the interactive application.

What are the possible benefits and risks of participating?

No risks or side effects are anticipated from this study. However, participants will be advised to report any if it happens due to excessive physical activities which are rare.

Where is the study run from?

Health facilities in Muscat region (Oman)

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

January 2020 to May 2022

Who is funding the study?

The Research Council (Ministry of higher education) and Ministry of Health in Oman.

Who is the main contact?

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Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Behaviour change intervention to promote a healthy diet and physical activity in overweight /obese adults with diabetes attending health care facilities in Muscat: a cluster randomized control trial

Study objectives

A multi-component intervention using pedometer, phone consultation and a phone application is effective in promoting positive physical activity and diet control in obese adults with type 2 diabetes in primary diabetes care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 02/03/2020, National research and ethical review approval, Ministry of Health Oman (PO Box 393, Muscat, 100, Oman; +968 22357254; dg.plan16@gmail.com), ref: MOH/CSR/20/11516

Study design

Cluster randomized control study

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

See additional file ISRCTN71889430_PIS (added 02/12/2020)

Health condition(s) or problem(s) studied

Prevention of multi-organ complications in obese adults with diabetes through healthy lifestyle (physical activity and diet)

Interventions

The study will be undertaken over a 1-year period in ten health facilities in Muscat. Participants in the intervention group will receive phone personalised physical activity and diet consultations on four occasions (4, 12, 24 and 36 weeks), pedometers, and an interactive phone application (developed by the higher college of technology in Oman). The intervention will include self-monitoring and feedback on step counts and diet which will be provided within physical activity and diet consultations and discussed through communications in the interactive application. The comparison group will receive usual care. These visits also allowed for data collection by clinic staff for research purposes in all health facilities at baseline, 3, 6 and 12 months.

Randomisation: Random generated tables through SPSS v21

Intervention Type

Behavioural

Primary outcome measure

Measured at baseline and 1 year:

1. Physical activity behaviour (including sitting time) using the Global Physical activity questionnaire (GPAQ)
2. Diet control measured using a bespoke validated questionnaire

Secondary outcome measures

1. Cardiovascular outcomes (BP and lipids) collected from the existing health information system at baseline and 12 months follow up
2. Anthropometric measures (weight, waist circumference and BMI) collected from the existing health information system at baseline and 12 months follow up
3. Metabolic outcomes (HbA1c) from the existing health information system at baseline and 12 months follow up

Overall study start date

09/09/2019

Completion date

06/06/2022

Eligibility

Key inclusion criteria

1. Adults aged ≥ 18 - 65 years of age
2. Diagnosed with diabetes and overweight/obese
3. Attending (registered) health facilities for at least 6 months
4. HbA1c $> 7\%$ (≥ 48 mmol/mol) according to Oman diabetes management guidelines
5. Assessed by project officer as having inactive behaviour
6. No contraindication to physical activity
7. Able to speak and read Arabic
8. Willing and able to provide written informed consent to the study
9. Can use phone applications

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Health facilities in Muscat region, Oman (n = 10), 750 participants

Key exclusion criteria

Patients with:

1. A history of myocardial infarction in the previous 6 months
2. A serum creatinine >140 mmol/l (from previous recorded readings in the electronic health information system)
3. Diabetic foot ulcers or at high risk of ulcer (severe peripheral neuropathy)
4. Repeated hypoglycaemia or severe hypoglycaemia in the previous 12 months
5. No internet access for the phone application
6. Physical activity > 150 minutes per week
7. Hba1c ≤7%

Date of first enrolment

06/06/2021

Date of final enrolment

01/08/2021

Locations

Countries of recruitment

Oman

Study participating centre

Health facilities in Muscat region

Muscat

Oman

112

Sponsor information

Organisation

The Research Council and Ministry of Health Oman

Sponsor details

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Sponsor type

Government

Funder(s)

Funder type

Government

Funder Name

The Research Council and Ministry of Health Oman

Results and Publications

Publication and dissemination plan

It is expected to have at least six publications from this project. Proposed topics could be:

1. Study protocol
2. Study results (main results)
3. Description of sedentary behaviour in adults with diabetes
4. Behaviour change influencers
5. Results on the exit surveys
6. Factors influencing change in PA and sedentary behaviour

Intention to publish date

01/01/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

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			02/12/2020	No	Yes
Protocol article		10/08/2021	18/01/2024	Yes	No