

# Promoting a healthy lifestyle in adults with diabetes

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<b>Registration date</b> 01/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/01/2024	<b>Condition category</b> 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

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

### **Study type(s)**

Quality of life

### **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(s)**

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

**Key secondary outcome(s))**

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

**Completion date**

06/06/2022

**Eligibility****Key inclusion criteria**

1. Adults aged  $\geq 18$  - 65 years of age
2. Diagnosed with diabetes and overweight/obese
3. Attending (registered) health facilities for at least 6 months
4. HbA1c  $> 7\%$  ( $\geq 48$  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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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  $\leq 7\%$

**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

## **Funder(s)**

**Funder type**

Government

**Funder Name**

The Research Council and Ministry of Health Oman

## **Results and Publications**

**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?
<a href="#">Protocol article</a>		10/08/2021	18/01/2024	Yes	No
<a href="#">Participant information sheet</a>			02/12/2020	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes