ISRCTN71889430 https://doi.org/10.1186/ISRCTN71889430

Promoting a healthy lifestyle in adults with diabetes

Submission date 28/11/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/12/2020	**Overall study status** Completed	
Last Edited 18/01/2024	**Condition category** Other	

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?
Dr Thamra Al Ghafri, thamra74@yahoo.com
Dr Saud Al Harthi, smsbar07@gmail.com

Contact information

Type(s)
Public

Contact name
Dr Thamra Alghafri

ORCID ID
https://orcid.org/0000-0002-4818-9565

Contact details
PO Box 2723
Muscat
Oman
112
+968 (0)99279944
thamra74@yahoo.com

Type(s)
Public

Contact name
Dr Saud Al Harthi

Contact details
PO Box 2723
Muscat
Oman
112
+968 (0)99234543
smsbar07@gmail.com

Additional identifiers

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

Primary study design
Interventional

Study design
Cluster randomized control study

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 ≥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

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 ≤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?
Protocol article		10/08/2021	18/01/2024	Yes	No
Participant information sheet			02/12/2020	No	Yes