ISRCTN20754766 https://doi.org/10.1186/ISRCTN20754766

An intervention examining the effect of an intensive lifestyle intervention consisting of a low energy diet and physical activity on weight loss in subjects with early type 2 diabetes.

Submission date
22/02/2017

Recruitment status
No longer recruiting

Registration date
07/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a condition where a person has too high or uncontrollable blood sugar levels. Diabetes is one of the greatest challenges faced by healthcare services worldwide. It is associated with serious complications such as heart attacks, stroke, and peripheral artery disease as well as kidney disease, eye disease, and nerve dysfunction. Data from weight loss with bariatric surgery suggest that with the appropriate intervention, it should be possible to reverse diabetes and that the earlier the intervention occurs, the greater the chances of placing diabetes into remission. There is now a need to translate this knowledge into the medical care of younger patients with early diabetes who are overweight/obese. The aim of this study is to see if younger adult patients with overweight/obesity and type 2 diabetes who are participants in a programme incorporating a low energy diet and physical activity (lifestyle) will lower their weight, cardiovascular risk and improve their glycaemic control as compared to the usual care.

Who can participate?
Adults aged 18 to 50 years who have type 2 diabetes.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group consume low energy meal replacements followed by gradual food reintroduction and increase in physical activity levels for 12 months. Those in the second group receive the standard medical care which includes routine advice about diet and physical activity for 12 months. Participants are followed up to measure their body weight and symptoms prior to the study and at three, six, nine and 12 months.

What are the possible benefits and risks of participating?
Participants may benefit from controlling their blood sugar levels and from losing weight. Notable risks to participants include low blood sugar and feeling discomfort when providing blood samples. Participants may also feel burdened by the time commitment.

Where is the study run from?
The study is being run by Weill Cornell Medicine (Qatar) and takes place in the Hamad Medical Corporation hospitals in Doha (Qatar), Primary Health Care Corporation health centres in Doha (Qatar) and at the Qatar Diabetes Association(Qatar).

When is the study starting and how long is it expected to run for?
May 2015 to December 2020

Who is funding the study?
Qatar National Research Fund (Qatar)

Who is the main contact?
Prof. Shahrad Taheri
szt2004@qatar-med.cornell.edu

Contact information

Type(s)
Public

Contact name
Prof Shahrad Taheri

ORCID ID
http://orcid.org/0000-0001-8314-1500

Contact details
Department of Medicine
Weill Cornell Medicine
PO box 24144
Doha
Qatar
PO24144
+974 4492 8470
szt2004@qatar-med.cornell.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03225339

Secondary identifying numbers
NPRP 8-912-3-192

Study information

Scientific Title
Diabetes Intervention Accentuating Diet and Enhancing Metabolism (DIADEM-I): a randomised controlled trial assessing the impact of low energy diet and activity on body weight and glycaemia in diabetes

Acronym
DIADEM-I

Study objectives
Patients in the low energy and physical activity (lifestyle) intervention arm will have greater weight reduction leading to significant improvements in glycaemic control and cardiovascular risk compared to the usual clinical care arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Weill Cornell Medicine, Qatar IRB, 29/10/2015, ref: 15-00071
2. Hamad Medical Corporation, Qatar IRB, 04/11/2015, ref: 15395/15
3. Primary Healthcare Corporation, Qatar IRB, 14/03/2017, ref: PHCC/IEC/17/02/002

Study design
Prospective parallel group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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 Mellitus

Interventions
Participants are randomly allocated to one of two groups.

Group 1 Lifestyle Intervention [low energy diet and physical activity]: Participants in this group use low energy meal replacement products in combination with physical activity, followed by gradual introduction of food, and increasing physical activity. Behavioural support for the lifestyle intervention is also provided.

Group 2 Usual Medical Care: Participants in this group receive the standard treatment based on current clinical practice aiming to reduce diabetes symptoms and complications, and general recommendations on diet and physical activity.

Participants are enrolled in the treatment for 12 months. Participants are followed up at baseline, three, six, nine, and 12 months.

Intervention Type
Mixed

Primary outcome measure
Body weight is measured using Tanita scales at baseline, 3 months, 6 months, 9 months, and 12 months.

Secondary outcome measures
1. Diabetes control is measured biochemically using HbA1c and fasting glucose at baseline, 3 months, 6 months, 9 months, and 12 months
2. Medication use is recorded using patient medical records at baseline, 3 months, 6 months, 9 months, and 12 months
3. Body composition is measured using bioimpedance (Tanita) at baseline, 3 months, 6 months, 9 months, and 12 months
4. Physical activity levels are measured using International Physical Activity Questionnaire (IPAQ), GT3X+ accelerometers, and SIT-Q-7d questionnaire for sedentariness at baseline, 3 months, 6 months, 9 months, and 12 months
5. Cardiovascular health and markers are measured blood pressure, heart rate, ankle-brachial pressure index, Vicorder and dynamic visual analyser testing, dyslipidaemia (triglycerides, total cholesterol, LDL-cholesterol, HDL-cholesterol), hsCRP (high sensitivity C-reactive protein) at baseline, 3 months, 6 months, 9 months, and 12 months
6. Quality of life is measured using Euro-QoL-5D and a weight-specific quality of life questionnaire (IWQOL-LITE) at baseline, 3 months, 6 months, 9 months, and 12 months

Overall study start date
12/05/2015

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Type 2 diabetes mellitus
2. Diabetes of ≤ 3-year duration
3. BMI ≥27.0 kg/m²
4. Men and women
5. Age 18-50 years
6. Originating from the Middle East and North Africa region and resident in Qatar
7. Able to commit to the study duration
8. Able to give informed consent and willing to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
138

Total final enrolment
158

Key exclusion criteria
1. Type 1 diabetes mellitus based on clinical history
2. Cardiovascular event in the previous 6 months
3. Chronic kidney disease stage 3b or greater (eGFR <30 mL/min/1.73 m^2)
4. Currently pregnant, lactating, or planning pregnancy within the study period
5. Any condition precipitating fluid overload such as heart failure (NYHA class > I) and liver cirrhosis
6. Significant previously diagnosed psychiatric disorder (e.g. schizophrenia, post-traumatic stress disorder, obsessive-compulsive disorder)
7. Uncontrolled depression
8. Uncontrolled epilepsy
9. Known lactose intolerance
10. Severe arthritis preventing walking
11. Active gout
12. Active gallstone disease or known asymptomatic gallstones

Date of first enrolment
01/03/2017

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
Qatar

Study participating centre
Hamad Medical Corporation (HMC)
Al Rayyan Road

PO 3050
Doha
Qatar
PO3050

Study participating centre
Qatar Diabetes Association (QDA)
Rawdat Al Khail
Al Muntaza
PO 752
Doha
Qatar
PO752

Study participating centre
Primary Health Care Corporation
Rawdat Al-Khail Street B Ring Road
Doha
Qatar
PO 26555

Sponsor information

Organisation
Weill Cornell Medicine in Qatar

Sponsor details
Qatar Foundation
Education City
Doha
Qatar
PO 24144

Sponsor type
University/education

Website
https://qatar-weill.cornell.edu/

ROR
https://ror.org/05v5hg569

Funder(s)

Funder type
Research organisation

Funder Name
Qatar National Research Fund

Alternative Name(s)
, QNRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Qatar

Results and Publications

Publication and dissemination plan
Publication is planned in high-impact peer reviewed journals and through an effective dissemination plan, the study will aim to inform current diabetes care provision in Qatar and other countries.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/05/2018		Yes	No
Results article	results	01/06/2020	25/05/2020	Yes	No
Results article	Recruitment and baseline characteristics	07/12/2020	11/07/2023	Yes	No