

# 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.

<b>Submission date</b> 22/02/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/07/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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. Shahrads Taheri

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## Contact information

**Type(s)**

Public

**Contact name**

Prof Shahrads Taheri

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## Additional identifiers

**ClinicalTrials.gov (NCT)**

NCT03225339

**Protocol serial number**

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

## **Study type(s)**

Treatment

## **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(s)**

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

**Key secondary outcome(s)**

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

**Completion date**

31/12/2020

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

1. Type 2 diabetes mellitus
2. Diabetes of  $\leq 3$ -year duration
3. BMI  $\geq 27.0$  kg/m<sup>2</sup>
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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

50 years

**Sex**

All

**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<sup>2</sup>)
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

**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

## 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?
<a href="#">Results article</a>	results	01/06/2020	25/05/2020	Yes	No
<a href="#">Results article</a>	Recruitment and baseline characteristics	07/12/2020	11/07/2023	Yes	No
<a href="#">Protocol article</a>	protocol	21/05/2018		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes