

# A study testing two diets to help people with type 2 diabetes lose weight and improve health in Northern Lebanon

<b>Submission date</b> 09/01/2026	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/01/2026	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 10/04/2026	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Type 2 diabetes is becoming more common worldwide, mainly due to excess body weight and unhealthy lifestyle habits. Losing weight can sometimes lead to remission of diabetes, which means blood sugar levels return to a non-diabetic range without the need for medication. However, achieving and maintaining weight loss is challenging and requires long-term behavioral changes.

The aim of this study is to plan and implement a structured dietary intervention, guided by the Intervention Mapping approach, to support weight loss and promote diabetes remission among adults with type 2 diabetes in Lebanon. The study compares two dietary approaches and includes behavioral support to improve long-term adherence.

### Who can participate?

Adults aged 18–65 years with type 2 diabetes mellitus who are overweight or obese and are treated with oral anti-diabetic medications

### What does the study involve?

Participants are randomly assigned to one of two dietary interventions: a Mediterranean diet or a low-carbohydrate diet. The study is conducted in two phases.

In the first phase, the two diets are compared, and participants receive structured dietary guidance and behavioral support. Barriers to weight loss and diabetes management are also identified, and communication between participants and healthcare providers is strengthened. In the second phase, a mobile health application is introduced to support behavior change and help participants maintain healthy lifestyle habits over time. Participants are followed regularly, and outcomes such as weight loss and diabetes remission are assessed at baseline, every three months, and at the end of the intervention.

### What are the possible benefits and risks of participating?

Participants may benefit from improved weight management, better blood sugar control, and increased knowledge and skills to manage their diabetes. They may also benefit from personalized dietary guidance and behavioral support.

Possible risks are minimal and mainly related to dietary changes, such as temporary discomfort or difficulty adjusting to new eating patterns. Participants are monitored throughout the study to ensure safety.

Where is the study run from?

Lebanese International University (Lebanon)

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

February 2026 to February 2027

Who is funding the study?

1. Lebanese International University (Lebanon)
2. Maastricht University (Netherlands)

Who is the main contact?

Janot Ayoub, janot.ayoub@maastrichtuniversity.nl or janot.ayoub@liu.edu.lb

## Contact information

### Type(s)

Principal investigator, Public, Scientific

### Contact name

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## Additional identifiers

## Study information

### Scientific Title

Applying intervention mapping to develop an intervention for promoting weight loss and diabetes remission in individuals with type 2 diabetes mellitus living in Northern Lebanon: a randomized control trial

### Study objectives

1. Compare the effects of the Mediterranean diet and the low-carbohydrate diet on weight loss and metabolic parameters.
2. Promote sustainable, favourable behaviour change.
3. Achieve diabetes remission through weight loss.
4. Design a mobile app to help achieve weight maintenance.

### Ethics approval required

Ethics approval required

### **Ethics approval(s)**

approved 02/10/2023, LIU Institutional Review Board (IRB) (Lebanese International University, Beirut, 1107, Lebanon; +961 (0)7-76 76 01; hassan.khachfe@liu.edu.lb), ref: LIUIRB-230817-JA-295

### **Primary study design**

Interventional

### **Allocation**

Randomized controlled trial

### **Masking**

Open (masking not used)

### **Control**

Active

### **Assignment**

Parallel

### **Purpose**

Treatment

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

### **Health condition(s) or problem(s) studied**

Type 2 diabetes mellitus

### **Interventions**

This is a two-phase (weight-loss diet through low-carb and med diets, and weight-maintenance phase using a customized mobile app) parallel-group randomized controlled trial conducted among adults with type 2 diabetes mellitus in Northern Lebanon. Eligible participants (n = 100; aged 18–65 years, BMI  $\geq 25$  kg/m<sup>2</sup>, disease duration  $\leq 6$  years, treated exclusively with oral anti-diabetic medications) will be randomly allocated to one of two intervention arms.

Arm 1: Moderately low-carbohydrate diet (LC):

Participants allocated to this arm will follow a moderately low-carbohydrate dietary pattern, with carbohydrates providing approximately 26–45% of total daily energy intake. The intervention aims to improve glycemic control and promote diabetes remission through controlled carbohydrate intake while maintaining nutritional adequacy.

Arm 2: Mediterranean diet (MD):

Participants allocated to this arm will follow a Mediterranean dietary pattern, characterized by higher intake of fruits, vegetables, whole grains, and legumes, and moderate intake of fish and poultry, with olive oil as the primary source of fat. This diet serves as the comparator intervention and reflects an evidence-based dietary approach for diabetes management.

Randomization method:

Participants will be randomized in a 1:1 ratio using a computer-generated minimization

procedure (QMinim software) to ensure balance between groups for key baseline covariates, including age, sex, duration of diabetes, and baseline BMI. The randomization sequence will be generated by a research assistant who is independent of participant recruitment and intervention delivery.

In the first phase, the two diets are compared, and participants receive structured dietary guidance and behavioral support. Barriers to weight loss and diabetes management are also identified, and communication between participants and healthcare providers is strengthened.

In the second phase, a mobile health application is introduced to support behavior change and help participants maintain healthy lifestyle habits over time. Participants are followed regularly, and outcomes such as weight loss and diabetes remission are assessed at baseline, every three months, and at the end of the intervention.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

1. Weight loss measured using bioelectrical impedance analysis conducted at the dietetic clinic at baseline, every 3 months, and at the end of the intervention
2. Diabetes remission measured using HbA1c values and fasting blood glucose at baseline, every 3 months, and at the end of the intervention

### **Key secondary outcome(s)**

Measured at baseline and every 3 months:

1. Lipid profile (HDL, LDL, triglycerides, total cholesterol) and C-reactive protein (CRP) as an inflammatory marker, measured using blood tests
2. Diabetes knowledge assessed using diabetes knowledge questionnaire
3. Physical activity assessed using the International Physical Activity Questionnaire (IPAQ)
4. Sleep quality assessed using the Pittsburgh Sleep Quality Index (PSQI)
5. Psychological stress assessed using the Perceived Stress Scale (PSS)
6. Medication adherence assessed using the Morisky–Green–Levine (MGL) scale
7. Dietary intake and adherence assessed using 24-hour dietary recalls at each dietetic visit and the Mediterranean Diet Adherence Scale at baseline, after 3 months, and at the end of the intervention

### **Completion date**

04/02/2027

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged 18–65 years with T2DM
2. BMI  $\geq 25$  kg/m<sup>2</sup>
3. Exclusively on oral anti-diabetic medications
4. Disease duration of 6 years or less

### **Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Renal failure
2. Cancer
3. Mental problems
4. Insulin use
5. Diabetes for more than 6 years

**Date of first enrolment**

02/02/2026

**Date of final enrolment**

02/03/2026

**Locations****Countries of recruitment**

Lebanon

**Sponsor information****Organisation**

Maastricht University

**ROR**

<https://ror.org/02jz4aj89>

**Funder(s)****Funder type**

**Funder Name**

Universiteit Maastricht

**Alternative Name(s)**

Maastricht University, UM

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Netherlands

**Funder Name**

Lebanese International University

**Alternative Name(s)**

, Bekaa University, LIU

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Lebanon

## Results and Publications

**Individual participant data (IPD) sharing plan**

De-identified participant data, questionnaires, and related materials will be available upon reasonable request from the corresponding author Janot Ayoub (janot.ayoub@maastrichtuniversity.nl)

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		08/04/2026	10/04/2026	Yes	No