ISRCTN99204002 https://doi.org/10.1186/ISRCTN99204002

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

Submission date 09/01/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/01/2026	**Overall study status** Ongoing	
Last Edited 12/01/2026	**Condition category** Nutritional, Metabolic, Endocrine	

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
Ms Janot Ayoub

Contact details
Zgharta
Zgharta
Lebanon
1304
+961 (0)3558792
janot.ayoub@maastrichtuniversity.nl

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 ≥25 kg/m², disease duration ≤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 ≥25 kg/m²
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