

Addressing sleep in a weight loss intervention: does it lead to more changes in diet, physical activity and weight loss in overweight Lebanese students?

Submission date 20/07/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 21/07/2026	Overall study status Ongoing	☒ Statistical analysis plan ☐ Results
Last Edited 01/09/2026	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

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Study information

Scientific Title

The effect of addressing sleep in a weight loss program on diet, exercise and weight loss in Lebanese university students: a pilot randomized controlled trial

Study objectives

1. Test if improving sleep behaviors produces positive spillover effects on weight-related behaviors, such as dietary and physical activity adherence and success.
2. Examine whether the process of striving for and achieving improvements in sleep strengthens individuals' self-identification with healthy behaviors, notably diet and exercise, and this beyond the direct effects of diet and exercise guidance.

Ethics approval required

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Ethics approval(s)

Approved 24/03/2026, Lebanese International University - Institutional review board (Beirut, Lebanon, Beirut, 146404 Mazraa, Lebanon; +961 776 76 01; hassan.khachfe@liu.edu.lb), ref: LIUIRB-260218-MA-450

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Effects of sleep improvement on weight loss outcomes and adherence to diet and exercise.

Study type(s)

Health condition(s) or problem(s) studied

Overweight and obesity

Interventions

This study will use a two-arm, parallel-group design to investigate whether improving sleep duration and quality, in parallel with a weight-loss program, leads to spillover effects on adherence and weight-loss outcomes. Participants will be randomly allocated in a 1:1 ratio to either (1) usual care (diet + exercise) or (2) sleep spillover group (usual care plus a sleep education and health identity stimulation). We aim to recruit approximately 12 participants per arm. Randomization will be done using a sealed-envelope method. An independent researcher who has no other role in intervention or assessment will prepare group assignments in advance according to a random sequence generated. Each assignment will be placed in an opaque, sealed, and sequentially numbered envelope. Upon enrollment, the study coordinator will open the next envelope in sequence to reveal group allocation. Participants will be followed for 6 months, with monthly visits conducted by a licensed nutritionist.

Group 1: Usual Care (diet + exercise)

Participants in this group will receive an individualized weight loss diet and exercise program without any sleep-related education or identity stimulation components.

Each participant will receive:

1. An individualized dietary program aiming at losing 1-2 pounds per week (removing 500-1000 Calories per day), accompanied by educational materials to support adherence.
2. Individualized physical activity recommendations aiming to reach at least 150 min/week.
3. Guidance on cognitive-behavioral strategies to support healthy habits, including the consumption of regular meals without skipping any of the 3 main meals, eating at consistent time, avoiding excessive snacking especially evening snacking, avoiding sweet snacks and avoiding eating late at night).

Group 2: Sleep spillover group + Usual Care for weight loss

Participants in this group will receive a weight loss program similar to Group 1 including dietary, physical activity, and behavior modification guidance. This ensures both groups are comparable in standard care. In addition, a sleep improvement intervention, focused on increasing total sleep duration and enhancing sleep quality through behavioral and educational strategies will be administered. The sleep education will be administered by the dietitian at the initial visit along with an individualized weight loss program. Sleep education will integrate brief activities designed to stimulate healthy lifestyle identity. It will be made clear to participants that working at a better sleep quality or sleeping longer, is an important step in becoming a healthier person, and will make it easier to behave healthier in other areas as well. Each small step they take (e.g. more regular sleeping times, giving themselves more sleeping opportunity at night) will be reinforced, and used to confirm their self-identity as a person working at a healthy lifestyle. Participants will also receive positive reinforcement for small improvements in other health-related behaviors, such as choosing a healthy snack (e.g., fruit), engaging in light physical activity during the day (e.g., taking the stairs instead of the elevator or going for a short walk), or establishing regular meal times. Reinforcing these behaviors will be used to strengthen a healthy self-identity and subsequently encourage spillover to other behaviors, including sleep-related behaviors. At each contact session, positive feedback will be given to participants highlighting any successful effort (small improvements in behavior with respect to sleep, diet or physical activity), and those healthy steps will be connected to a better health, showing the participant that (s)he is the kind of individual who takes care of his health, which facilitates a potential spillover of behavior change from one health behavior to another.

Intervention Type

Behavioural

Primary outcome(s)

1. Adherence to exercise measured using International Physical Activity Questionnaire (IPAQ)-Short Arabic version at monthly for 6 months
2. Adherence to dietary recommendations measured using 24-hour recall at monthly for 6 months
3. Exercise identity measured using the Four-item exercise identity scale (4-EI) at baseline, 3 months and 6 months
4. Eating identity measured using four-item healthy-eater identity scale (4-HEI) at baseline, 3 months and 6 months
5. Health identity measured using health identity scale at baseline, 3 months and 6 months
6. Weight (kg) measured using calibrated scale at monthly for 6 months
7. Feasibility measured using sleep hygiene index at baseline, 3 months and 6 months

Key secondary outcome(s)

1. Body composition changes (fat mass and muscle mass) measured using bioelectrical impedance machine (BOCA X1) at monthly for 6 months
2. Waist circumference (cm) measured using flexible non-stretchable tape at monthly for 6 months

Completion date

01/03/2027

Eligibility

Key inclusion criteria

1. Participants should be overweight or obese ($BMI \geq 25 \text{ kg/m}^2$)
2. Participants should have a short sleep duration (< 7 hours per night) and/or a poor sleep quality (PSQI score > 5) (The validated Arabic version of the PSQI will be used to assess eligibility)
3. Participants should be healthy, not suffering from any metabolic or other chronic diseases

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Students diagnosed or being treated for insomnia, obstructive sleep apnea (OSA), other sleep disorders or any other medical condition that may affect negatively the weight loss like endocrine problems (hypothyroidism...)
2. Students having any medical contraindication to weight loss
3. Students taking any medication known to affect body weight
4. Students taking any medication known to affect sleep
5. Students who are already engaged in another weight loss program or who were recently losing weight (> 5% in the past 3 months)
6. Pregnant/planning to become pregnant in the next 6 months, or breastfeeding
7. Students who smoke waterpipe as this has been found in a previous study to affect weight loss

Date of first enrolment

10/10/2026

Date of final enrolment

10/11/2026

Locations**Countries of recruitment**

Lebanon

Sponsor information**Organisation**

Lebanese International University

ROR

<https://ror.org/034agrd14>

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

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Mira Alfikany (m.alfikany@maastrichtuniversity.nl)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			22/07/2026	No	No