



# The impact of poor sleep health on weight loss

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## Main Information

### Primary registry identifying number

LBCTR2024045561

### Protocol number

WLS2024

### MOH registration number

13596

### Study registered at the country of origin

Yes

### Study registered at the country of origin: Specify

### Type of registration

Retrospective

### Type of registration: Justify

I lost some time to get an IRB from an authorized institution. I also faced problems in registering the trial on the system.

### Date of registration in national regulatory agency

24/04/2024

### Primary sponsor

Mira Alfikany

### Primary sponsor: Country of origin

Lebanon

### Date of registration in primary registry

31/05/2024

### Date of registration in national regulatory agency

24/04/2024

### Public title

The impact of poor sleep health on weight loss

### Acronym

NA

### Scientific title

The impact of poor sleep health on weight loss intervention outcomes among a group of Lebanese university students

### Acronym

NA

### Brief summary of the study: English

In this study, we will recruit university students to receive a free weight loss program along with physical activity recommendations and all the necessary education about healthful eating patterns needed to change their unhealthy behaviors and promote weight loss. We will follow them up for 6 months to examine the association between their baseline sleep characteristics (duration and quality) and the outcomes of the weight loss intervention (total weight loss, body composition changes). We also intend to explore some additional aspects related to the adherence of participants to the key components of the dietary intervention, including the attendance of all follow up sessions, the adherence to physical activity recommendations and the adherence to energy intake.

### Brief summary of the study: Arabic

في هذه الدراسة، سوف يحصل مجموعة من الطلاب الجامعيين على نظام ومتابعة غذائية مجانية تشمل نصائح غذائية، نصائح لممارسة الرياضة ولتحسين السلوكيات الغذائية. سوف يتم متابعة الطلاب لمدة ستة أشهر. من بعدها، سوف يتم دراسة تأثير صحة النوم عند المشتركين على نتائج نظامهم الغذائي لجهة خسارة الوزن، خسارة الدهون والكتلة العضلية. أخيراً، سيتم البحث في مدى التزام المشاركين بحضور كافة جلسات المتابعة والالتزام بالنصائح الغذائية والنصائح الرياضية.

### Health conditions/problem studied: Specify

Overweight/obesity

Association between sleep duration/quality and outcomes of a weight loss program in overweight and obese participants.

Keywords: overweight, obesity, sleep duration, sleep quality, weight loss

### Interventions: Specify





Intervention name: weight loss

For each participant, we will measure the weight, height, waist circumference and body composition. Based on the results, an individualized diet plan will be formulated.

The dietary program consists of:

1. A weight loss program aiming at losing 1-2 pounds per week (removing 500-1000 Calories per day); it will be provided along with all the educational material needed to adhere to the diet.
2. Individualized physical activity recommendations aiming to reach at least 180 min/week of moderate to vigorous physical activity.
3. Finally, cognitive and behavioral factors that might be implicated in weight gain will be addressed (consuming regular meals without skipping any of the 3 main meals, eating at consistent times, avoiding excessive snacking especially evening snacking and avoiding sweet snacks, avoiding late night eating).

To collect necessary data, participants will be asked to fill some questionnaires:

1. Pittsburgh Sleep Quality Index (PSQI) will be administered to each participant to assess sleep quality and disturbances over the preceding 1-month interval. We will use the validated Arabic version of the PSQI. Assessment will be blinded from other staff nutritionists who will analyze adherence to PA and energy prescription. This questionnaire will also be administered at 3 months and 6 months.
2. International Physical Activity Questionnaire (IPAQ)- Short Arabic version will be used to assess baseline physical activity patterns. It will be completed at baseline and each month to check for the adherence of the participants to the physical activity questionnaire.
3. During each month, participants will be asked to fill a 3-day food record including a weekend day to check for their adherence to the caloric recommendations. Participants will be considered compliant if their total caloric intake is equal or less than the prescribed calories. Food records will be analyzed by the staff dietitians who will be blinded to the PSQI score of each participant.

At the end of the 6 months, we will check for a possible association between baseline sleep duration and quality (as assessed by the Pittsburgh Sleep Quality Index) and the outcomes of the weight loss program.

#### Key inclusion and exclusion criteria: Inclusion criteria

1. Lebanese students
2. Students should be enrolled for the full academic year (Fall and Spring 2023-2024) and not in their last semester.
3. Participants should be overweight or obese (BMI  $\geq$  25 kg/m<sup>2</sup>).
4. Participants should be healthy, not suffering from any metabolic or other chronic diseases.

#### Key inclusion and exclusion criteria: Gender

Both

#### Key inclusion and exclusion criteria: Specify gender

#### Key inclusion and exclusion criteria: Age minimum

18

#### Key inclusion and exclusion criteria: Age maximum

100

#### Key inclusion and exclusion criteria: Exclusion criteria

1. Students suffering from insomnia, obstructive sleep apnea (OSA) 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 who are already engaged in another weight loss program or who were recently losing weight.
5. Pregnant/planning to become pregnant in the next 6 months or breastfeeding mothers.

#### Type of study

Interventional

#### Type of intervention

Dietary interventions

#### Type of intervention: Specify type

N/A

#### Trial scope

Other

#### Trial scope: Specify scope

#### Study design: Allocation

Non-randomized controlled trial

#### Study design: Masking

Open (masking not used)

#### Study design: Control

N/A

#### Study phase

N/A

#### Study design: Purpose

Health services research

#### Study design: Specify purpose

N/A

#### Study design: Assignment

Other

#### Study design: Specify assignment

quasi experimental study

#### IMP has market authorization

#### IMP has market authorization: Specify



**Name of IMP**

**Year of authorization**

**Month of authorization**

**Type of IMP**

**Pharmaceutical class**

NA

**Therapeutic indication**

Weight loss is indicated for people who are overweight or obese.

**Therapeutic benefit**

Benefits of losing weight include among others improvement in health status and well-being and reduction of chronic diseases.

**Study model**

N/A

**Study model: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Explain time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration**

**Target follow-up duration: Unit**

**Number of groups/cohorts**

**Biospecimen retention**

None retained

**Biospecimen description**

NA

**Target sample size**

101

**Actual enrollment target size**

125

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

01/02/2024

**Date of study closure: Type**

Actual

**Date of study closure: Date**

30/09/2024

**Recruitment status**

**Recruitment status: Specify**



Complete

**Date of completion**

04/03/2024

**IPD sharing statement plan**

No

**IPD sharing statement description**

NA

**Additional data URL**

NA

**Admin comments**

**Trial status**

Approved

## Secondary Identifying Numbers

No Numbers

## Sources of Monetary or Material Support

No Sources

## Secondary Sponsors

No Sponsors



## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Mira Alfikany	Lebanese International University	Lebanon	28640930	mira.fikani@liu.edu.lb	Lebanese International University and Maastricht University
Scientific	Mira Alfikany	Lebanese International University	Lebanon	28640930	mira.fikani@liu.edu.lb	Lebanese International University and Maastricht University

## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Lebanese International University	Mira Alfikany	Dietitian and university instructor	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Rayak Hospital	19/01/2024	Ms. Victoria Taleb	quality@rayakhospital.com	08901300
Other Lebanese International University	12/12/2023	Prof. Hassan Khachfe	hassan.khachfe@liu.edu.lb	07767601

## Countries of Recruitment

Name
Lebanon

## Health Conditions or Problems Studied

Condition	Code	Keyword
obesity, unspecified	2-Propanol (T51.2)	obesity



## Interventions

Intervention	Description	Keyword
Weight loss program	Caloric restriction of 500-1000 Calories per day in order to lose 1-2 lb/week + physical activity recommendations (target: 180 min/week) and healthy nutrition tips	diet, exercise

## Primary Outcomes

Name	Time Points	Measure
Total weight loss	after 6 months of starting the intervention	we will look for any significant difference in the total amount of weight lost at the end of the 6 months between short sleepers and regular sleepers
Difference in weight loss between short sleepers and regular sleepers	after 6 months of starting the intervention	we will look for any significant difference in the success rate of the weight loss program between short sleepers and regular sleepers.
fat mass loss	every month for 6 months after starting the intervention	Bioelectrical impedance machine (BOCA X1): we will check for any significant difference between short sleepers and long sleepers concerning their percentage of fat mass loss at the end of the 6 months.

## Key Secondary Outcomes

Name	Time Points	Measure
Body composition (abdominal fat/waist circumference, lean body mass loss)	every month for 6 months after starting the intervention	Bioelectrical impedance machine (BOCA X1)
Percentage of participants who achieved 5% and 10% weight loss	after 6 months of starting the intervention	calculation
Adherence/compliance to the key intervention components	- every month for 6 months after the start of the intervention	3-days food records, international Physical Activity Questionnaire



## Trial Results

**Summary results**

**Study results globally**

**Date of posting of results summaries**

**Date of first journal publication of results**

**Results URL link**

**Baseline characteristics**

**Participant flow**

**Adverse events**

**Outcome measures**

**URL to protocol files**