The impact of poor sleep health on weight loss

04/04/2025 15:08:17

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. أخيرا, سيتم البحث في مدى التزام المشاركين بحضور كافة جلسات المتابعة, الالتزام بالنصائح الغذائية وبالنصائح 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 asses 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≥ 25 kg/m2).
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