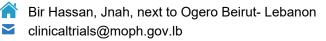
REPUBLIC OF LEBANON MINISTRY OF PUBLIC HEALTH Lebanon Clinical Trials Registry

The impact of poor sleep health on weight loss

13/08/2025 23:40:02

LBCTR202404561 WLS224 MOH registration number 13596 Study registered at the country of origin Study registered at the country of origin: Specify Yes Type of registration: Justify Retrospective Type of registration: Justify Date of registration in national regulatory aggins? Primary sponsor Primary sponsor Primary sponsor: Country of origin Natifikany Lebanon Date of registration in national regulatory aggins? 24/04/2024 Public title Acronym The impact of poor sleep health on weight loss NA Scientific title Acronym The study, we will recruit university students to receive a free weight loss program along with physical activity recommendations and all the necessary education and proteine specifies and proteine specine and protei	lain Information	
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في هذه الدراسة, سوف يحصل مجموعة من الطلاب الجامعيين على نظام ومتابعة غذائية مجانية تشمل نصائح عذائية, 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 العصلية. أخير إرسيتم البحث في مدى التزام المشاركين بحضور كافة جلسات المتابعة الالتزام بالنصائح الغذائية وبالنصائح الموزن, خسارة الدهون والكتلة العصلية. أخير إرسيتم البحث في مدى التزام المشاركين بحضور كافة جلسات المتابعة الالتزام بالنصائح الغذائية وبالنصائح الوزن, خسارة الدهون والكتلة العصلية. أخير إرسيتم البحث في مدى التزام المشاركين بحضور كافة جلسات 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.	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	
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Association between sleep duration/quality and outcomes of a weight loss program in overweight and obese participants.	Health conditions/problem studied: Specify	
	o i	program in overweight and obese participants.



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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 1month 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: Age minimum

18

Key inclusion and exclusion criteria: Age maximum 100

Key inclusion and exclusion criteria: Specify gender

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	Study design: Masking
Non-randomized controlled trial	Open (masking not used)
Study design: Control N/A	Study phase N/A
Study design: Purpose	Study design: Specify purpose
Health services research	N/A
Study design: Assignment Other	Study design: Specify assignment quasi experimental study
IMP has market authorization	IMP has market authorization: Specify

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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 reduction of chronic diseases.	and well-being and	
Study model	Study model: Explain model	
N/A	N/A	
Study model: Specify model N/A		
Time perspective N/A	Time perspective: Explain time	perspective
Time perspective: Specify perspective N/A		
Target follow-up duration	Target follow-up duration: Unit	
Number of groups/cohorts		
Biospecimen retention	Biospecimen description	
None retained	NA	
Target sample size	Actual enrollment target size	
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



Contac	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.e du.lb	Lebanese Internation al University and Maastricht University
Scientific	Mira Alfikany	Lebanese International University	Lebanon	28640930	mira.fikani@liu.e du.lb	Lebanese Internation al University and Maastricht University

Centers/Hospitals Involved in the Study			
Center/Hospital name	al name Name of principles investigator Principles investigator speciality Ethical approva		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 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