Impact of nutrition education and mindful breathing on binge eating, dietary intake, and body weight

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Main Information

Primary registry identifying number
LBCTR2025065729

Protocol number
LAU.SAS.RR1.12/Jun/2025

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
16/06/2025

Primary sponsor
Lebanese American Univeristy

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
08/08/2025

Date of registration in national regulatory agency
16/06/2025

Public title
Impact of nutrition education and mindful breathing on binge eating, dietary intake, and body weight

Acronym

Scientific title
The impact of an 8-Week Nutrition Education and Mindful Breathing Intervention on Binge Eating Behaviors, Dietary Intake, and Body Weight

Acronym

Brief summary of the study: English

Overweight and obesity are escalating public health challenges worldwide, with binge eating contributing significantly to these conditions. This study investigates the impact of an 8-week intervention combining nutrition education and mindful breathing exercises on binge eating, dietary intake, and body weight in adults with binge eating and overweight or obesity. Participants will be randomly assigned to either a control group receiving nutrition education only or an intervention group receiving both nutrition education and daily mindful breathing exercises. Assessments at baseline, week 4, and week 8 will measure binge eating, dietary intake, and body weight in addition to mindfulness and stress. The goal is to determine whether mindful breathing enhances the effectiveness of nutrition education by reducing binge eating and improving dietary intake and weight management. This study aims to inform of a simple, non-invasive, and sustainable strategy to potentiate nutrition education in addressing binge eating behaviors and obesity-related outcomes.

Brief summary of the study: Arabic

تُفاقم زيادة الوزن والسمنة من تحديات الصحة العامة في جميع أنحاء العالم، حيث يُسهم الإفراط في تناول الطعام بشكل كبير في هذه الحالات. أسابيع يجمع بين التثقيف الغذائي وتمارين التنفس الواعي على الأكل بنهم، وتناول الطعام، ووزن الجسم8تبحث هذه الدراسة في تأثير تدخل مدته لدى البالغين الذين يعانون من الأكل بنهم وزيادة الوزن أو السمنة. سيتم توزيع المشاركين عشوائيًا إما على مجموعة ضابطة تتلقى التثقيف الغذائي فقط أو مجموعة تدخل تتلقى كلاً من التثقيف الغذائي وتمارين التنفس الواعي اليومية. ستقيس التقييمات في البداية والأسبوع الرابع والأسبوع الثامن مؤشر الأكل بنهم، وتناول الطعام، ووزن الجسم بالإضافة إلى اليقظة والتوتر. الهدف هو تحديد ما إذا كان التنفس الواعي يعزز فعالية التثقيف الغذائي من خلال الحد من الأكل بنهم وتحسين تناول الطعام وإدارة الوزن. تهدف هذه الدراسة إلى تقديم استراتيجية بسيطة وغير جراحية ومستدامة لتعزيز التثقيف الغذائي في معالجة سلوكيات الأكل بنهم والنتائج المرتبطة بالسمنة.

Health conditions/problem studied: Specify

Binge eating: a maladaptive coping mechanism that leads to excessive consumption of energy-dense foods.

Interventions: Specify

The intervention group will receive weekly group session on nutrition education and mindful breathing training for 4 weeks in addition to a daily breathing exercise audio on WhatsApp. This will be followed by 4 weeks of daily breathing exercises.
The control group will receive nutrition education sessions weekly for 4 weeks. This will be followed by a 4-week follow-up without intervention.
The study will be 8 weeks long.

Key inclusion and exclusion criteria: Inclusion criteria

Adults aged 18 to 65 years, BMI ≥ 25 kg/m² (overweight or obese), BES score > 18 (indicating moderate to severe binge eating), Ability to provide informed consent and commit to an 8-week intervention.

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

65

Key inclusion and exclusion criteria: Exclusion criteria

Pregnant or lactating women, Current participation in other weight loss or psychological interventions, Medical conditions such as hypertension, heart disease, or stomach ulcers that could interfere with breathing exercises, Use of medications that influence appetite or weight (e.g., corticosteroids, weight loss medications) or pharmacotherapy for the treatment of Binge Eating Disorder. LAU students taking courses with the PI or co-PI will be excluded. The list of potential participants will be screened to ensure the students are properly excluded.

Type of study

Interventional

Type of intervention

Dietary interventions

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Placebo

Study phase

N/A

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class
Not applicable

Therapeutic indication
Not applicable

Therapeutic benefit
Not applicable

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
Not applicable

Target sample size
60

Actual enrollment target size

Date of first enrollment: Type
Anticipated

Date of first enrollment: Date
14/07/2025

Date of study closure: Type
Anticipated

Date of study closure: Date
29/09/2025

Recruitment status
Recruiting

Recruitment status: Specify

Date of completion

IPD sharing statement plan

IPD sharing statement description

No	None

Additional data URL

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	Rana Rizk	Byblos, Lebanon	Lebanon	01786456 ext. 3741	rana.rizk01@lau.edu.lb	Lebanese American University
Scientific	Rana Rizk	Byblos, Lebanon	Lebanon	01786456 ext. 3741	rana.rizk01@lau.edu.lb	Lebanese American University

Centers/Hospitals Involved in the Study

No Centers/Hospitals

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Lebanese American University- University Medical Center Rizk Hospital	12/06/2025	Dr. Joseph Stephan	irb@lau.edu.lb	01786456 ext. 2546

Countries of Recruitment

No Countries

Health Conditions or Problems Studied

No Problems Studied

Interventions

No Interventions

Primary Outcomes

Name	Time Points	Measure
Binge eating	Baseline, week 4, and week 8.	Assessed using the binge eating scale (BES). The Arabic BES demonstrates excellent validity among Lebanese adults for screening for binge eating behaviors. The BES is a self-report scale consisting of 16 items that assess behavioral, emotional, and cognitive symptoms of binge eating. Each item contains three or four statements, which reflect a range of severity from no problems (scored as 0) to severe problems (scored as 3). Based on the BES scores, uncontrolled eating behaviors can be classified into three different severity categories: individuals scoring 0–17 are considered non-binge eaters; those scoring 18–26 are categorized as moderate binge eaters; and individuals with scores ranging from 27 to 46 are classified as severe binge eaters.
Dietary intake	Baseline, week 4, and week 8	Assessed using 24-hour dietary recall conducted twice: on one weekday and one weekend day. Data will be collected via Whatsapp Video call. To enhance accuracy, the multiple pass method will be utilized by a well-trained interviewer, who is a licensed dietitian. Visual portion-size guides and digital recording will be employed to assist participants in accurately estimating portion sizes. Daily energy intake will be expressed as Kcal/kg of body weight, and nutrient intake will be reported as % of total energy, specifically % calories from simple sugars. Collected dietary data will be analyzed using NUTRITIONIST PRO™ diet analysis software.
Weight loss	Baseline, week 4, and week 8	Measured as the difference in weight by a licensed dietitian, using a calibrated scale.

Key Secondary Outcomes

Name	Time Points	Measure
Mindfulness levels	Baseline, week 4, and week 8	Assessed using the Arabic version of the short-form Freiburg Mindfulness Inventory (FMI). The Arabic version of the FMI was validated in Lebanese adults and assesses the level of mindfulness in individuals, particularly their ability to maintain awareness in daily life and accept experiences without judgment. This tool consists of 14 items assessing facets like awareness, attention, and acceptance that are rated on a 4-point frequency based responses, rarely, sometimes, often and almost always, with higher scores indicating greater mindfulness. This tool shows high internal consistency with a Cronbach's alpha of 0.92.
Stress	Baseline, week 4, and week 8.	Measured using the Beirut Distress Scale (BDS-10). The BDS-10 is the short, Arabic validated version in Lebanese adults. It includes 10 items related to feelings of anxiety, depression, and stress, with each item rated on a 5-point scale. Answer options are never, slightly, moderately, a lot/ frequently. The BDS shows high internal consistency with a Cronbach's alpha = 0.954.

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