

Want to improve your relationship with food?

Submission date 26/11/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/12/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/12/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Chile is one of the countries that leads the prevalence of overweight and obesity worldwide. Currently, weight loss treatments are not free of controversy, because to date no treatments demonstrate long-term effectiveness in sustained weight loss, let alone weight loss that is maintained in the long term. Even bariatric surgery involving making changes to your digestive system to help you lose weight, which allows rapid weight loss, presents high rates of weight regain according to all longitudinal studies in the area. Therefore, it seems inappropriate to focus on strategies whose main objective is weight loss. From this perspective, interventions that improve a person's relationship with food may have a greater impact on their quality of life. This study aims to evaluate the effect of an intervention to improve the relationship with food on psychological variables in overweight adults.

Who can participate?

Adults aged 18 years old and over who present with some degree of excess weight (BMI greater than or equal to 25kg/m²)

What does the study involve?

In this research, two different types of intervention will be conducted in a workshop format. Participants will be randomly assigned to one of the two workshops, so they will only receive the workshop to which they are assigned. Regardless of the group assignment, participants will be asked to answer questionnaires that assess psychological factors before and after the intervention. All participants will also receive training to improve their relationship with food for two hours per week for eight weeks, led in pairs by a psychologist, a nutritionist and a psychiatrist with expertise in the subject. The intervention will be conducted live through the online platform Zoom.

What are the possible benefits and risks of participating?

By participating in this research you may not receive a direct benefit from it. But your participation in this research will help us to improve our understanding of issues associated with eating behavior, the role of psychological variables, and the scope of workshops with a strong emphasis on improving the relationship with eating. This will allow us to develop and improve prevention and treatment protocols for people with excess malnutrition. These results could also benefit applied sciences, which use empirical findings obtained from studies such as this one. There are no risks associated with this study. Although by responding, you disclose certain

private information, all information collected through the questionnaires, surveys and assessments applied will be used exclusively for scientific purposes, safeguarding the privacy and confidentiality of all your data, as only aggregated data are of interest and not individual data.

However, if you feel any inconvenience of any kind, whether emotional or psychological, after participating in this study, you will be offered the possibility of accessing psychological counseling.

Where is the study run from?
Universidad Adolfo Ibáñez (Chile)

When is the study starting and how long is it expected to run for?
September 2019 to March 2022

Who is funding the study?
National Agency for Research and Development (ANID) through its FONDECYT postdoctoral program (Chile)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

FONDECYT3200764

Study information

Scientific Title

Effects of mindful eating (MB-EAT) on eating behaviors associated with overeating in overweight individuals

Acronym

MBEAT_Psyched

Study objectives

1. The group receiving the training (MB-EAT) will present lower levels of external, emotional and restrictive eating at the end of the intervention compared to the control group.
2. The group receiving the training (MB-EAT) will present lower levels of binge eating disorder symptoms at the end of the intervention compared to the control group.
3. The training (MB-EAT) will generate significant changes in eating styles that favor overeating, through improvement in interoceptive awareness and reduction of anxiety and depression symptoms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/09/2020, Universidad Adolfo Ibáñez Research Ethics Committee (Avenida Diagonal Las Torres 2640, Peñalolén, Santiago de Chile; +562 2331-1812; paula.rojas.s@uai.cl, macarena.cardenas@uai.cl), ref: 84/2020

Study design

Randomized controlled case-control trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Eating behavior and overeating and self-reported feeding control difficulties

Interventions

We posted social media announcements on Facebook, Instagram, and LinkedIn profiles connected to the authors' professional and institutional networks. The posts sought individuals "with problems controlling their eating" or "interested in improving their relationship with food." Participants contacted us via email and we called them back to set up an eligibility screening via Zoom. To participate, respondents had to be at least 18 years old, have a BMI >24.9 , and report a lack of control over their eating. Women participants who were pregnant or had given birth within 6 months, or were breastfeeding, were excluded. Participants who engaged in purging behaviors to control their weight, or had had bariatric surgery in the previous 12 months were also excluded. Eligible participants received an email that included the informed consent form and a code-protected link with access to the outcome baseline measures. The baseline survey required participants to report their age, gender, weight (kg), and height (m), and complete all the treatment outcome variables.

Those who completed the baseline survey were randomly assigned to the MB-EAT or Psych-Ed interventions. Simple randomization: responses even in one group (MB-EAT) and odd in the other group (Psych-Ed). Both interventions were run concurrently on Tuesdays and Thursdays in weekly, 2-hour sessions over an 8-week period. There were three enrollment waves, with a similar number of participants assigned to the two interventions per wave ($n = 14$ to 18 per group). Both interventions were led by the same team of specialized licensed professionals, which consisted of a psychiatrist, a psychologist, and a nutritionist, all with extensive training and experience in MB-EAT and Psych-Ed.

The MB-EAT intervention was modelled after Kristeller et al. (2014). The purpose of the intervention was to increase mindful awareness of eating-related experiences and to reduce emotionally and contextually triggered eating. Activities were practiced in session and prescribed to be practiced at home for the duration of the intervention. The activities focused on increasing awareness of a) physical hunger and physical satiety cues, b) amount of food consumed, and c) the physical, cognitive, social–environmental, and emotional triggers of binge eating. Meditation exercises included a) general (breath/open awareness) mindfulness, b) guided eating meditations, and c) brief, in-the-moment meditation strategies to practice at mealtime and throughout the day.

The Psych-Ed control intervention rested on a cognitive-behavioral (mechanistic) explanation of the binge eating cycle, and taught cognitive-behavioral coping strategies to develop healthy habits and cope with distress and daily challenges. An important goal of the intervention was to familiarized participants with cognitive behavioral theory and gain a barebones understanding of how thoughts feelings and behaviors are connected, as well as how habits develop (particularly around eating and food). As with MB-EAT, participants learned and practice the activities they would then need to carry out as homework assignments for the duration of the intervention.

Intervention Type

Behavioural

Primary outcome measure

1. Body Mass Index measured using kg/m^2 at baseline, post-intervention (eight weeks) and six months

2. Binge eating-related symptoms measured using the Binge Eating Scale (BES) scoring at baseline, post-intervention (eight weeks) and six months
3. Restrained, emotional, and external eating measured using the Dutch Eating Behavior Questionnaire (DEBQ) scoring at baseline, post-intervention (eight weeks) and six months

Secondary outcome measures

1. Interoception measured using the Multidimensional Assessment of Interoceptive Awareness questionnaire at baseline, post-intervention (eight weeks) and six months
2. Anxiety and depression symptoms in patients measured using the Hospital Anxiety and Depression Scale at baseline, post-intervention (eight weeks) and six months

Overall study start date

24/09/2019

Completion date

15/03/2022

Eligibility

Key inclusion criteria

1. Men and women over 18 years of age
2. Some degree of excess weight (BMI greater than or equal to 25 kg/m²).

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Total enrolment: 98; MBEAT: 49; Psych-Ed: 49

Total final enrolment

98

Key exclusion criteria

Reported anorexia or bulimia nervosa symptoms or other severe health problems

Date of first enrolment

03/01/2021

Date of final enrolment

30/06/2021

Locations

Countries of recruitment

Chile

Study participating centre

Universidad Adolfo Ibáñez

Eating Behavior Research Center

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Funder(s)

Funder type

Government

Funder Name

Agencia Nacional de Investigación y Desarrollo

Alternative Name(s)

Agencia Nacional de Investigación y Desarrollo de Chile, National Agency for Research and Development, Government of Chile, Chilean National Agency for Research and Development, ANID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Chile

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

03/01/2023

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			02/12/2022	No	Yes
Results article		17/05/2023	29/12/2023	Yes	No