

Study Protocol

**Promoting Positive Mental Health for Sustainable Eating Behaviors:
the PROMISE study in patients with obesity**

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INTRODUCTION

Premises and Rationale

In the last decades, there has been a significant increase in overweight and obesity cases, with rates of 39% and 13% in the global adult population, respectively (WHO, 2020). This huge increase is largely attributed to unhealthy and unsustainable dietary behaviors, such as the excessive consumption of ultra-processed foods high in saturated fats, sodium, and sugar (Popkin & Ng, 2022). The Food and Agriculture Organization of the United Nations (FAO) has defined sustainable food consumption as an approach with a reduced environmental impact, that meets nutritional guidelines, that is economically fair and affordable, and culturally acceptable (FAO, 2010). As evident from this definition, food sustainability is a multidimensional concept involving several aspects.

For individuals with obesity, the implementation of sustainable eating behaviors implies radical changes in their lifestyle and dietary habits, which could not only improve the physical and psychological health of the individual but also reduce the impact of this condition on the environment and the healthcare system. The impact of overweight and obesity is further compounded by their frequent association with chronic diseases such as diabetes, cardiovascular disorders, and hypertension (Chu et al., 2018; Afshin et al., 2017), as well as psychological problems, including anxiety, depression (Alimoradi et al., 2020), and eating and nutritional disorders (Da Luz et al., 2018; Agüera et al., 2020).

Despite the existence of standardized pharmacological and psychological treatments for weight loss and unhealthy lifestyles modification, one of the major challenges observed in this clinical population is the achievement and the maintenance of treatment goals (Sharma, 2007; Kantartzis et al., 2011; Bischoff et al., 2017).

In an attempt to improve treatment response in this clinical population, numerous studies have highlighted the role that specific psychological factors might play in hindering the achievement of these goals (Teixeira et al., 2004; Hudson et al., 2007; Manzoni et al., 2010; Castelnuevo et al., 2015). Among these, the presence of psychological distress in individuals with obesity has been identified as a significant barrier to the adoption of healthy lifestyles and a cause of emotional eating (Fisher et al., 2020), defined as the tendency to eat in response to both positive and negative emotions (Turton et al., 2017). Simultaneously, hedonic hunger, the sense of immediate pleasure deriving from the assumption of certain foods, represents an additional barrier to the implementation of healthy lifestyles. It is indeed associated with the difficulties faced by individuals with obesity in regulating food intake, especially in social situations or when exposed to highly enticing foods (Fisher et al., 2020). In situations like these, it has been highlighted that individuals tend to use dysfunctional cognitive mechanisms to justify

behavioral choices that are in contrast with long-term goals (e.g., giving in more easily to the temptation of eating certain foods despite the goal of losing weight) (Mantzios & Egan, 2017). While the consumption of food in individuals with obesity can indeed generate an immediate sense of well-being derived from the satisfaction of a pleasure (Diener, 2009), on the flip side, this can lead to a compromise in psychological well-being levels associated with weight gain and difficulties in adopting healthy lifestyles (Vallis, 2016; Sarwer et al., 2019; Zhu et al., 2022).

In line with these findings, previous studies have emphasized the effectiveness, in terms of weight loss, of psychological interventions focused on distress reduction, quality of life improvement, and psychological well-being promotion in patients with obesity (Lillis & Kendra, 2014; Webber et al., 2016; Zhu et al., 2022). Specifically, Well-Being Therapy (WBT), a therapeutic strategy aimed at promoting optimal levels of psychological well-being through the monitoring of well-being moments, the identification of automatic thoughts leading to their premature interruption, cognitive restructuring, and exposure tasks (Fava, 2016a), could be useful for promoting healthy eating behaviors (Fava, 2016b). A recent preliminary study tested the efficacy of WBT in sequential combination with an intervention on healthy lifestyles in patients with obesity (Zhu et al., 2022). Although WBT, compared to a control group receiving only the lifestyle intervention, was effective in reducing psychological distress and improving psychological well-being levels, weight loss was observed in both groups, with no significant differences between them (Zhu et al., 2022).

The present study aims to further investigate the effectiveness of a psychological intervention based on the principles of Well-Being Therapy (WBT), in comparison to a Basic Nutritional Intervention (BNI), in terms of weight loss, promotion of healthy and sustainable eating behaviors, and optimal psychological functioning. The latter, in particular, can be obtained by targeting some key psychological factors, including psychological distress, dysfunctional eating styles, psychological well-being, and the use of cognitive justification mechanisms, which may act as obstacles to weight loss and the adoption of healthy lifestyles. Given the existing evidence on the relationship between unhealthy eating behaviors and the development of overweight and obesity, it might also be useful to preliminarily examine the effectiveness of this psychological intervention in promoting healthy and sustainable eating behaviors.

OBJECTIVES

The primary objective of this pilot study is to assess the effects and the effectiveness, both post-treatment and at 1- and 3-month follow-ups, of a group intervention inspired by the principles of Well-Being Therapy (WBT), combined with a nutritional education, compared to treatment as usual (TAU), namely a Basic Nutritional Intervention (BNI) in a group setting, in terms of weight loss (primary outcome).

The secondary objective is to evaluate the effects and effectiveness of this intervention, both post-treatment and at 1- and 3-month follow-ups, compared to BNI, in promoting healthy and sustainable eating behaviors (in terms food choices, cooking, food storing, consumption and disposal) and an optimal psychological functioning. This includes the promotion of balanced psychological well-being levels and functional eating styles, and the reduction of both psychological distress and dysfunctional cognitive justification mechanisms use (secondary outcomes).

HYPOTHESES

Regarding the first objective, it is hypothesized that the psychological intervention inspired by the principles of WBT, compared to BNI, will lead to a greater reduction in body weight, both post-intervention and at 1- and 3-month follow-ups.

Concerning the second objective, it is hypothesized that this intervention, compared to BNI, will be more effective in promoting healthy and sustainable eating behaviors (in terms food choices, cooking, food storing, consumption and disposal) and an optimal psychological functioning. This includes the promotion of balanced levels of psychological well-being and of functional eating styles, and a reduction of psychological distress and dysfunctional cognitive justification mechanisms use.

METHODS

Study Design

This study, conducted in six phases, is a randomized, controlled, monocentric longitudinal pilot study.

Phase 1. In the initial phase, participants will be recruited from patients with obesity treated in the Clinical Nutrition and Metabolism Unit of Sant'Orsola Hospital in Bologna and who are selected for the participation in a Basic Nutritional Intervention (BNI) course. After an initial screening assessment conducted by a researcher under the supervision of the Unit's referring physician, eligible patients interested in participating in the study will be asked to provide their informed consent for study participation and data processing. Consent collection will be carried out by one of the researchers belonging to the clinical research team.

Phase 2. Participants who have provided their informed consent will be assigned to either the experimental group (E) or the control group (C) using a 1:1 allocation ratio. To ensure a fair distribution within the groups, a block randomization method will be employed. The allocation sequence will be generated using a computer.

Phase 3. Participants from both groups will fill-in a self-report online questionnaire through the Qualtrics platform. This questionnaire will collect socio-demographic (e.g., age, education, occupation, etc.), anthropometric (weight, height), clinical (e.g., weight history, current weight, medical conditions,

etc.), and lifestyle data (e.g., physical activity, alcohol consumption, smoking, etc.). Additionally, participants will complete a set of self-administered questionnaires to assess the psychological variables of interest.

Weight measurement will also be confirmed by the Unit's referring physician during routine patient visits. Participants in the experimental group will participate in 6 weekly group sessions of two hours each. One part will be held by a trained dietitian and will focus on nutritional education, particularly emphasizing the adoption of healthy and sustainable eating behaviors. Nutritional education will cover topics related to the causes and risk factors of obesity, nutritional principles of foods, preparation of balanced meals, food labels reading, and the importance of physical activity. The remaining part will be dedicated to a group psychological intervention inspired by the principles of Well-Being Therapy (WBT; Fava, 2016a) and will be held by a trained psychologist. This intervention aims to promote weight loss, healthier and more sustainable eating behaviors, and an optimal psychological functioning. During these sessions, participants will be introduced to the six dimensions of psychological well-being: 1) self-acceptance, 2) personal growth, 3) purpose in life, 4) positive relations with others, 5) environmental mastery, and 6) autonomy (Ryff, 1996). Gradually, cognitive-behavioral strategies will be provided to enhance psychological well-being and seek a balance between the presented dimensions through self-monitoring of well-being episodes, restructuring thoughts that interrupt well-being, and exposure tasks to optimal experiences. Additionally, participants will be given cognitive-behavioral tools to recognize justifying cognitive mechanisms and replace them with more functional cognitions related to eating. These objectives will also be achieved through the use of a food diary to highlight emotions and thoughts experienced during food intake. The control group, on the other hand, will receive treatment as usual (TAU) by participating in 6 two-hour group sessions of Basic Nutritional Intervention (BNI) held by a trained dietitian. This course focuses on promoting healthier lifestyles through nutritional education, diet monitoring using a dedicated food diary, and recommendations for proper physical activity.

Phase 4. A post-intervention assessment will be conducted for anthropometric variables (weight, height), lifestyle variables (e.g., physical activity, alcohol consumption, smoking, etc.), and psychological variables of interest in both the experimental and control groups.

Phases 5 and 6. These phases will involve assessments of anthropometric variables (weight, height), lifestyle variables (e.g., physical activity, alcohol consumption, smoking, etc.), and psychological variables of interest in both the experimental and control groups at 1- and 3-month follow-ups.

OUTCOMES

All outcomes will be assessed at baseline (T0), post-intervention (T1), and at 1 (T2) and 3 months (T3) follow-ups.

Primary Outcome:

- Weight loss, measured in kilograms and expressed in percentage of weight loss in both the experimental and control groups, assessed in terms of change over time and in reference to the intervention condition. A reduction of at least 3% compared to the baseline assessment is expected at T1, with a maintenance of this weight loss at T2 and T3 and with a higher incidence of weight loss in the experimental group compared to the control group. The choice of this criterion has been based on retrospective audits conducted in the same Hospital Unit.

Secondary Outcomes:

- Increase in healthy and sustainable dietary behaviors measured through the Sustainable and Healthy Dietary Behaviors Scale (SHDB; Kawasaki et al., 2022).
- Balancing of psychological well-being levels measured through the Psychological Well-Being Scales-42 (PWBs; Ryff & Keys, 1995; Ruini et al., 2003).
- Promotion of functional eating styles assessed through the Dutch Eating Behavior Questionnaire (DEBQ; Van Strien et al., 1986; Dakanalis et al., 2013).
- Reduction of psychological distress levels measured through the Depression and Anxiety Stress Scale-21 (DASS-21; Lovibond & Lovibond, 1995; Bottesi et al., 2015).
- Reduction in the use of dysfunctional cognitive justifying mechanisms related to food intake evaluated through an adapted assessment index from Plazonic & Herrada (2020).

Participants

Inclusion Criteria. Patients will be eligible for inclusion in the study if they: a) are affiliated with the Clinical Nutrition and Metabolism Unit of Policlinico S. Orsola-Malpighi; b) have a BMI ≥ 30 ; c) are aged ≥ 18 years; d) voluntarily agree to participate in the study; e) have access to a computer and can use it independently.

Exclusion Criteria. Exclusion criteria for this study include: a) lack of the informed consent to participation in the study; b) limited knowledge of the Italian language; c) presence of cognitive deficits; d) meeting the diagnostic criteria for one or more of the following psychiatric diagnoses: binge-eating disorder (BED), drug and/or alcohol abuse, psychotic disorders, neuro-cognitive disorders, suicidal behaviors; e) participation in another weight loss study or program; f) taking weight loss medications; g) engaging in individual or group psychotherapeutic interventions; h) having undergone weight loss surgery in the 16 months preceding the study's commencement and during the entire study period (approximately five months); i) in women, being pregnant or planning pregnancy in the 16 months preceding the study and during the entire study period (approximately five months).

METHODS OF ASSESSMENT

Phase 1 – Screening

An initial screening assessment based on inclusion and exclusion criteria will be conducted by a physician and the multidisciplinary staff of the Unit.

Phase 2 – Baseline Assessment

All subjects included in the study will be asked to complete the following self-administered questionnaires online:

- Ad-hoc form for socio-demographic, anthropometric, clinical, and lifestyle data collection: includes socio-demographic information (e.g., age, education, occupation), anthropometric data (weight, height), clinical history (e.g., weight history, current medical information), and lifestyle factors (e.g., physical activity, alcohol use, smoking). Weight measurement will also be confirmed by the Unit's referring doctor.
- Sustainable and Healthy Dietary Behaviors (SHDB; Kawasaki et al., 2022) to assess the implementation of healthy and sustainable dietary behaviors through 30 items with a six-point Likert scale response. Items are divided into five sub-scales: food choices, storing, cooking, food consumption and food disposal. As this questionnaire has not yet been translated and validated in Italian, it has been translated by the researchers involved in this study.
- Psychological Well-Being Scales – 42 items (PWB; Ryff, 1989) to evaluate psychological well-being through 42 items with a six-point Likert scale response, divided into six dimensions: autonomy, environmental mastery, personal growth, positive relations with others, purpose in life, and self-acceptance. The Italian version by Ruini and colleagues (2003) will be used for this study.
- Dutch Eating Behavior Questionnaire (DEBQ; Van Strien et al., 1986) to assess dysfunctional eating styles through 33 items with a five-point Likert scale response, divided into three sub-scales: dietary restraint, external eating, and emotional eating. For this research, only 21 items selected based on their saturation level will be used. The Italian version by Dakanalis and colleagues (2013) will be used for this study.
- Depression and Anxiety Stress Scale-21 (DASS-21; Lovibond & Lovibond, 1995) to assess levels of psychological distress through 21 items with a 4-point Likert scale response, divided into three sub-scales: anxiety, depression, and stress. The Italian version by Bottesi and colleagues (2015) will be used for this study.

- Dysfunctional cognitive justification mechanisms use (adapted from Taylor & Sheeran, 2014; Plazonic & Herrada, 2020). To evaluate dysfunctional cognitive justification mechanisms, an ad-hoc assessment index will be administered. This index presents three hypothetical scenarios (related to emotional distress, social context, and habitual behavior) that could pose dilemmas for participants regarding adherence to a healthy diet. For each scenario, participants will be asked to indicate their level of identification with it on a 10-point Likert scale and to specify the types of cognitive justification mechanisms most frequently used. Participants will choose from six possible responses to justify their food choices: availability (e.g., it's right in front of me), compensatory behavior (e.g., I'll compensate for what I ate with physical activity), exception to the rule (e.g., I never do it, so I can do it now), deservingness (e.g., today has been a very difficult day, I deserve to eat something good), curiosity (e.g., I saw the advertisement for this product, and it seemed very enticing), irresistibility (e.g., I can't resist the temptation to eat this food). The index has been translated in Italian by the researchers involved in this study.

Phases 4, 5, and 6 – Post-intervention and Follow-up Assessments

At the end of the intervention and at the 1 and 3-month follow-ups, all participants will fill-in the following questionnaires online:

- Ad-hoc form for anthropometric data evaluation for assessing Body Mass Index (BMI) and changes in lifestyle (e.g., physical activity, alcohol consumption, smoking).
- Sustainable and Healthy Dietary Behaviors (SHDB; Kawasaki et al., 2022).
- Psychological Well Being Scales – 42 item (PWB; Ryff, 1989; Ruini et al., 2003).
- Dutch Eating Behavior Questionnaire (DEBQ; Van Strien et al., 1986; Dakanalis et al., 2013).
- Depression and Anxiety Stress Scale-21 (DASS-21; Lovibond & Lovibond, 1995; Bottesi et al., 2015).
- Assessment of Justificatory Cognitive Mechanisms (adapted from Taylor & Sheeran, 2014; Plazonic & Herrada, 2020).

Body weight assessment will also be verified by the medical staff during follow-up visits.

CONTEXT

The study will be conducted partly at Policlinico Sant'Orsola-Malpighi, in the Clinical Nutrition and Metabolism Unit of S. Orsola Hospital, and partly online via the Microsoft Teams platform.

STATISTICAL CONSIDERATIONS

Sample Size Calculation

The sample size was assessed using G*Power 3.1 statistical software. Based on a previous study conducted in the same recruitment center with the same clinical population (Zhu et al., 2022), the sample size was estimated considering an effect size of 0.25, a type I error < 0.05 , and a type II error (power) of 0.95, for 2 groups and 4 measurements (baseline; post-intervention; 1-month follow-up; 3-month follow-up). It is estimated that a sample size of 36 subjects is sufficient. Considering a 30% dropout risk in this clinical population (Brantley et al., 2014), it is estimated to recruit approximately 50 subjects, 25 for the experimental condition and 25 for the control condition.

Statistical Analysis

Statistical Package for Social Science 29.0 (SPSS) will be used for data analysis. Descriptive statistical analyses (frequencies, means, medians, modes, and standard deviations) will be conducted to analyze the sociodemographic, anthropometric, clinical characteristics, and lifestyle of the sample, as well as the mean scores on administered questionnaires. To assess differences between the experimental and control groups at post-intervention and the 1- and 3-month follow-ups in terms of weight loss, healthy and sustainable dietary behaviors, and optimal psychological functioning (psychological well-being, eating styles, psychological distress, and use of justification mechanisms), repeated measures analysis of variance (ANOVA) will be performed, using time (T0, T1, T2, T3) as a within-subject factor and group (E or C) as a between-subjects factor. Missing data will be handled through Intention to Treat (ITT) Analysis. Differences will be considered significant at $p \leq 0.05$.

ETHICAL PROCEDURES

The procedures regarding the conduction, execution, and data collection of this research adhere to the ethical principles outlined in the Declaration of Helsinki and its revisions. The study will be conducted in accordance with regulatory requirements and legal obligations (DM 17/12/2004).

During the screening phase, eligible subjects will receive all relevant information on the study, both in written and oral form. Additionally, before proceeding with data collection, informed consent and consent for the processing of personal data will be obtained for each participant, in an anonymous and aggregated form, in accordance with Law 675/1996 and Law 196/03 on the protection of individuals and the processing of personal data.

A copy of the informational and consent forms for participation in the research and data processing will be presented by the referring physician to the potential participant deemed eligible for the study. If interested, the participant will sign the consent forms, which will be collected and stored in a designated

space at the Department while informational forms will be left to the participant.

The data collected will be digitized anonymously using statistical software for data processing (SPSS).

Furthermore, a decoding list of the code assigned to each individual participant will be securely stored in encrypted form exclusively at the Department of Psychology of the University of Bologna.

In both paper and digital forms, all data will be appropriately preserved in accordance with the ethical code for research in psychology and as stipulated by privacy laws (Legislative Decree no. 196/2003) at the Department of Psychology of the University of Bologna for at least 4 years from the conclusion of the study.

All researchers involved in the study will be responsible for its conduction in accordance with the current International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use/Good Clinical Practice (ICH/GCP) guidelines. These guidelines represent the international standard of quality for the design, conduction, and reporting of studies involving human subjects. Adhering to these standards ensures the protection of participants' rights, safety, and well-being, and guarantees the credibility of the data obtained from the study.

The study will proceed only after obtaining approval from the Independent Ethics Committee of Area Vasta Emilia Centro (CE-AVEC). The request for evaluation will be submitted to the local secretariat CE-AVEC for the Bologna University Hospital, Policlinico S. Orsola-Malpighi, and the University of Bologna. Any relevant modifications made to the protocol during the study will be communicated to CE-AVEC for further review.

RESPONSIBILITIES AND PUBLICATION POLICY

All data generated in this study are the property of the Department of Psychology of the University of Bologna. All materials, information (oral or written), and unpublished documentation regarding this protocol provided to coordinators and investigators are considered confidential and cannot be disclosed to third parties.

Data from this study will be used exclusively for scientific dissemination, either in written or oral form.

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