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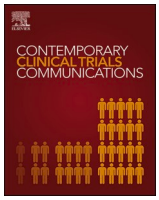

Multidisciplinary intervention and cognitive remediation therapy for adults with obesity: A study protocol for a randomized controlled clinical trial

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ABSTRACT

Background: Cognitive Remediation Therapy (CRT) is a psychological treatment which aims to improve the neurocognitive processes that interfere with the daily functioning of individuals and has proven to be useful in the treatment of obesity. This therapy has been implemented in some countries as a co-adjuvant treatment for people with obesity, but it has not been tested in Mexico, where obesity is one of the main public health problems, so it is essential to implement more studies of this type to obtain effective treatments to control weight.
Objective: To describe the research procedure of a multidisciplinary intervention protocol for adults with obesity in a randomized controlled clinical trial.
Method: Participants will be adults from 19 to 60 years of age with obesity, who will be randomly assigned to experimental and control groups. The control group will receive intervention only after the experimental group has completed the intervention program. Measurements of body composition, nutritional state, psychophysiological and physical activities of the participants will be obtained before and after the intervention, with a three-month follow-up after the intervention has concluded.
Conclusion: Results of this study will provide useful evidence for the implementation and follow-up of a multidisciplinary intervention with CRT to promote a better efficacy in the treatment and control of obesity.

1. Introduction

Obesity is a disease which has been declared as a pandemic by the World Health Organization [1] (WHO). In Mexico, the National Survey for Health and Nutrition 2018, demonstrates that the percentage of adults 20 years of age or older that who are considered over-weight or obese is above 75% [2]

Obesity is a metabolic disease that is chronic, complex, multifactorial, and a precursor of several non-transmissible chronic diseases such as type 2 diabetes mellitus, cardio-vascular disease, and cancer [3]. Obesity is also a principal risk factor which increases the probabilities of hospitalization and assisted mechanical ventilation in cases of SARS-CoV-2 [4].

1.1. Cognitive remediation therapy

Cognitive Remediation Therapy (CRT) emphasizes the improvement of cognitive functions, including working memory, digit span, processing speed, and executive functions through a structured system of specific instructions and neurocognitive exercises [5].

Some studies have found that people with obesity can have cognitive deficits, mostly in those related with the executive functions which is found to be associated with obesity regardless of age [6]. Other findings show that being overweight and obese is associated with a reduced capacity in inhibition and cognitive flexibility, as well as a deficiency in problem solving and decision-making abilities [7]. Research implementing CRT, initially focused on eating disorders [8], where a CRT program has been adapted to treat anorexia nervosa [9] with the purpose of promoting the reflection of the different thought designs, the development of meta-cognition and thought-changing strategies used in daily life. In addition, emotional ability training and cognitive remediation programs have been developed [10] with the purpose of improving social-emotional and neurocognitive abilities. These programs have been adapted for people with obesity and focus on cognitive abilities such as cognitive flexibility, central coherency and problem solving

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Abbreviations

CRT	Cognitive Remediation Therapy
BMI	Body Mass Index
BFP	Body Fat Percentage
WC	Waist Circumference
EF	Executive Functions
NBEF	Neuropsychological Battery for Executive Functions and Frontal Lobes
WAIS	Wechsler Adult Intelligence Scale
RCT	Randomized Clinical Trial

[11]. The effectiveness of these cognitive remediation programs in the treatment of obesity has been demonstrated in other countries. Raman, Hay, Tchanturia and Smith conducted a randomized controlled clinical trial, in which 80 adults with obesity participated. Their findings demonstrate that cognitive flexibility improved at the end of the treatment and that this improvement was maintained during a three-month period. Moreover, 68% of the participants had a 5% or more weight loss at the follow-up and showed a reduction in binge eating behaviors [12]. Allom and colleagues showed that when implementing CRT, participants showed an improvement in the performance of EF and a reduction of unhealthy habits. They demonstrated that their CRT program was effective in improving cognitive flexibility, inciting the change of habits, and increasing weight loss behaviors [13]. In Spain, Segura and colleagues used an adaptation of the Tchanturia program and obtained positive results including improvement in the cognitive and emotional abilities, improvement in food intake behaviors, and decrease in the weight of the participants [14]. The sum of these primary studies demonstrates the efficacy of CRT in patients with obesity, however, there are no studies for this type of therapy in Mexico. The main objective of the current study is to describe the research procedure for a randomized controlled clinical trial in a multidisciplinary intervention protocol using CRT to improve body composition, eating behavior, psycho-physiological aspects, neurocognitive processes, and physical activity in adults with obesity.

1.2. Specific aims

The specific aims for this project are: (1) Define the evaluation methodology to determine the effectiveness of the intervention in terms of the changes in the body mass index (BMI), body fat percentage (BFP), waist circumference (WC), and craving symptoms. Perception of body image, eating behaviors, cognitive performance, physical activity, and changes in skin conductance, heart electrical activity and skin temperature will also be evaluated. (2) To describe the procedures of the study, the multidisciplinary intervention, and the CRT in a sample of adults with obesity. (3) To describe the methods that will be used to perform the intervention.

2. Methods

2.1. Research design and study objectives

A randomized controlled clinical trial (RCT) will be conducted with both experimental and control groups, following a switching replication paradigm. Participants will be assigned to groups randomly. The study will be single-blinded. Measurements will be before treatment, following treatment, and at a three-month follow-up.

Our hypothesis suggests that the cognitive remediation therapy intervention with nutritional education and physical activity will significantly influence the reduction of the body mass index (BMI). Likewise, it is also expected to find a reduction of both the body mass percentage (BMP) and the waist circumference (WC). Furthermore, improvement is expected to be found in the psycho-physiological tests, cognitive performance, nutritional status, and physical activity.

Participation in this study will be voluntary. Participants will not receive any monetary incentives.

2.2. Procedures

2.2.1. Selection and recruitment of participants

Participants will be recruited via flyers placed and distributed in strategic areas of the city and through social media. Participants will indicate interest by filling out an online form, where they will be notified of the general aspects of the project and schedule an initial interview.

During that initial interview, individuals will be screened to verify that they meet the inclusion criteria. Then they will be asked to sign an informed consent form. They will receive a diagnostic report of their nutritional status and body composition. Selected participants will receive an initial evaluation that will include information about body composition, eating behavior, physical activity, biochemical indicators, psycho-physiological and neuropsychological tests, all as described in the instruments section.

2.2.2. Intervention

The intervention will be carried out through 12 weekly sessions of 90 min each. The intervention will be given in group sessions. The CRT sessions will be led by a therapist and a co-therapist. During CRT, different psycho-therapeutic techniques will be used, including psychoeducation, neurocognitive rehabilitation, problem solving, self-control and handling of emotions. Nutritional education sessions will be conducted by a specialist in nutrition. Also, a specialist in sports training will conduct the sessions focused on physical activity training, benefits, and general techniques to stay active in daily life (See Table 1).

2.2.2. Intervention location

This study will be carried out in Ciudad Juárez, Mexico, located in the northern border of the country. All study procedures will be carried out at the Universidad Autonoma de Ciudad Juárez, specifically at the facilities of the Institute of Biomedical Sciences and the Institute of Social Sciences and Administration.

2.3. Inclusion criteria and exclusion criteria

2.3.1. Inclusion criteria

1. Age from 19 to 60 years.
2. To have a BMI >30 (km/m2) indicating obesity according to the World Health Organization.
3. To Show a BFP that represents obesity in accordance with the Nieman body fat percentage classification which establishes ≥25% for women and ≥32% for men.
4. To present an elevated WC, in accordance with the Latin American Association for Diabetes in Latin American populations >88 cm for women and >94 cm for men.
5. To have signed the informed consent form

2.4. Exclusion criteria

1. That the participant is or has been involved in any program related to weight control or physical exercise during the past twelve months.
2. That the participant is under medical treatment or psychological treatment.
3. That the participant shows eating disorders, thyroid diseases or diagnosed neurological diseases.
4. Pregnant women.

Table 1
Sessions and objectives of the intervention program.

Number of Sessions	Sessions	Objective
1–4	Nutritional Education	Training in the use of the so-called "Healthy eating plate" in Mexico Training in food and beverage warning labeling. Developing decision-making skills to promote a healthy lifestyle.
1	Physical Activity	Physical activity education
1–2	The therapeutic relationship	Establish a therapeutic relationship Generate knowledge and empathy among participants Encourage group cohesion Promote motivation
1–2	Thought styles	Reflection on style of thought Identify thought strategies about daily life Explore new thought strategies and alternative ways of doing things
1–2	Thoughts centered on details and global thought	Stimulate attention to details Stimulate global thoughts Practice shifting focus Increase mental control over focus of attention Increase the fluidity of moving between ideas and tasks
1–2	Problem solving, planning and organization	Stimulation of abilities to solve the typical problems affecting an individual with obesity Training to improve in the abilities of planning, organization
1–2	The emotions	Learn about emotions and relationship with the styles of thought Discover the needs that emotions communicate Recognizing how the emotions relate to physical sensations Learn how to listen to body sensations to understand the emotions Increase emotional awareness of how to manage difficult emotions
1–2	Body image	Learning what body image is and what influences body image to be maintained Acceptance of body image
1	Closing	Learning what a relapse is and how to cope with it Closing activity among participants

2.5. Criteria for leaving the project

Participants may leave the project at any time if they decide to do so, without the obligation to provide an explanation or justification to the project director.

3. Randomization

Participants will be randomly assigned to the experimental and control groups. Randomization will be performed using a table of random numbers designed through an online program, to ensure that the digits from 0 to 9 have the same probability of occurrence.

3.1. Determination of eligibility and diagnostic evaluation

To determine the eligibility of the participants, the body mass index will be considered, by taking anthropometric measurements for the diagnostic evaluation, such as weight, waist circumference and size of the participant. These measurements will be performed by trained personnel in nutrition following the specifications established by the manual of the National Institute for Public Health [15].

3.2. Measurements

The first measurements of the body composition, blood biochemistry, eating behavior habits, craving, body image, executive functions, and the data of the physiological measurements will be obtained prior to the intervention. The second measurements will be taken after the implementation of the intervention.

3.3. Anthropometric

3.3.1. Body mass index and body fat percentage

The BMI and the BFP will be recorded and determined through the Seca mBCA 525 body analysis monitor. The Mbca includes an electronic stadimeter, weighing platform with a 300 kg capacity, tactile monitor, automatic detection electrode system and electronic system for data recording through the Seca analytics mBCA 115 software.

3.3.2. Waist Circumference

Waist circumference will be measured while the participant is standing upright in a straight position. Measurements will be taken at the narrowest part of the trunk with the middle part between the costal flange and iliac crest serving as a reference point using a flexible measuring tape.

Waist Circumference categories will be determined using the cut-off points according to the diagnostic criteria established by the Latin American Diabetes Association for Latin American populations, which for women is set at $>$ 88 cm and for men at $>$ 94 cm [16].

3.4. Biochemistry

To determine glucose and lipid levels, a CardioCkek PA capillary meter that provides rapid blood chemistry values and measurements will be used. The values established by the Latin American Diabetes Association for Latin American populations will be used as a basis, which establishes as a normal level for both glucose and lipids. [16].

3.5. Nutritional

3.5.1. Eating behavior questionnaire

Eating behavior will be assessed using a standardized questionnaire [17]. It consists of 31 multiple-choice questions, focusing on food selection, preparation, consumption schedule, food preference, beliefs, and barriers to change. The content validity of this questionnaire was determined by 15 experts. For the construct validity and internal consistency, a Rash analysis was used which resulted in a Cronbach's alpha of .98.

3.5.2. 24-H dietary recall

A 24-h recall instrument will be used. It involves participants recording a typical day's food consumption. The questionnaire will be also ask about ingredients, type, amount, time and place of consumption. This procedure helps to determine the amount of calories consumed and type of macronutrients. The questionnaire will be carried out by personnel specialized in nutrition in an individual interview [18].

3.6. Physiological measurements

Skin conductance, heart rate, electrical activity, and skin temperature will be measured while participants are exposed to visual images of appetizing foods. Skin conductance measurements will be made using an electrodermal activity amplifier (BIOPAC EDA100C). An electrocardiogram amplifier (BIOPAC ECG100C) will be used to measure the electrical activity of the heart rate, and skin temperature measurements will be made with a body temperature amplifier (BIOPAC SKT100C).

3.7. Psychological

3.7.1. Craving

The Food Craving Questionnaire-Trait [19] will be used to measure the intensity with which the desire to eat is present. This scale is composed of 39 items representing nine scales: (1) Having Intentions and Plans to Consume Food, (2) Anticipation of Positive Reinforcement that may Result from Eating, (3) Anticipation of Relief from Negative States and Feelings as a Result of Eating, (4) Lack of Control over Eating, (5) Thoughts or Preoccupation with Food, (6) Craving as a Physiological State, (7) Emotions that may be Experienced Before or During Food Cravings or Eating, (8) Cues that may Trigger Food Cravings, (9) Guilt from Cravings and/or for Giving in to Them. The Food Craving Questionnaire-Trait was validated in Mexico by exploratory and confirmatory factor analyses obtaining a Cronbach's alpha of .973 and a rho of 0.975 for each of the domains.

3.7.2. Body image

A body shape questionnaire will be used, which consists of 34 items that explore self-perception of body image and allows for the assessment of both body image dissatisfaction and body image concern [20] The scale has a Cronbach's Alpha of .98 [21].

3.8. Physical activity

The Global Physical Activity Questionnaire developed by WHO [22] will be used to measure physical activity through various components such as intensity, duration and frequency using 16 questions. The domains covered by this questionnaire are activity at work, travel to and from places and recreational activities.

3.9. Executive functions

Measurements related with cognitive performance will be realized using some of the subtests of the Wechsler Adult Intelligence Scale IV (WAIS IV) [22] and the Neuropsychological Battery for Executive Functions and Frontal Lobes 2 (NBEF2) [23]. Both tests have been validated and standardized for Mexican population.

3.9.1. Working memory

To measure this area, the main working memory subtests of the WAIS IV will be used: digit retention and arithmetic. These subtests assess simultaneous and sequential processing, attention, and concentration [23]. From the NBEF2, the self-directed pointing subtest will also be used, which assesses the ability to use visuospatial working memory to point in a self-directed manner to a set of figures and not to repeat or omit any of them. The maximum score to be achieved in this test is 25 [24]. These three subscales will be used for the pre-test assessment.

For the post-test assessment, in order to avoid the effects of practice in the first evaluation, different scales will be used. One of them is the supplementary subtest of the WAIS IV: sequencing of letters and numbers [23]. In addition, the NBEF2 Alphabetic Word Ordering subscale, which measures the ability to mentally manipulate, and order verbal information contained in working memory, will be used. The score is calculated based on the following: number of trials in which the list is correctly reproduced, perseveration of words that the person repeats more than once, intrusions, words mentioned but not in the list, sorting errors, words whose initial vowel or consonant does not correspond, and whether the subject does not remember any word on the first trial [24].

3.9.2. Processing speed

Processing speed is measured through the ability to respond quickly and correctly to tasks that require observation and discrimination. For this purpose, the main subscales of the WAIS IV [23] in this area will be used for the pretest evaluation: symbol search and key. To avoid the effects of practice in the first evaluation, the complementary WAIS IV [23] cancellation subtest will be used.

3.9.3. Flexibility

To measure this area, the letter/card classification subscale of the NBEF2 [24] will be used, which assesses the capability to generate a classification hypothesis, especially to flexibly change the classification criteria. The score is calculated by recording correct responses and three types of errors: normal error, perseverations, delayed perseverations, and maintenance errors.

3.9.4. Inhibition

This measurement will be performed using the Stroop effect subscale in its two forms A and B of the NBEF2 [24], which assesses the inhibitory control ability. In both parts, two types of errors and execution time are recorded. The types of errors that can be made are Stroop and Non-Stroop error.

3.9.5. Verbal fluency

It will be assessed through the verbal fluency subscale of the NBEF2 [24], which measures the ability to produce as many verbs as possible fluently and in a short time. The score is calculated based on the number of correct verbs and intrusions, mentioning the same verb two or more times.

3.9.6. Risk

This test evaluates the ability to operate under uncertainty and learn risk-benefit relationships and to make selections to the subject's advantage. The goal of the test is to obtain the highest possible score [24].

3.10. Ethical considerations

This study has been approved by the bioethics committee of the Autonomous University of Ciudad Juárez (UACJ). Participants will be required to sign an informed consent form prior to the intervention. The informed consent includes notification of the procedures to be performed, as well as the possible risks involved. The confidentiality of the data will be guaranteed and the mechanisms of transmission of the results will be explained to the participants.

Participants will be notified by a data protection confidentiality agreement in accordance with articles 12, 36, 47, 61–69, 73 and 134 of the Psychologist Ethical Code of the Mexican Society of Psychology [25]. This RCT is registered with ClinicalTrials.gov (trial ID NCT05295745) and can be retrieved at https://clinicaltrials.gov/ct2/show/NCT05295745.

4. Methods plan for data management and statistical analysis

Measurements will be taken before and after the intervention, with follow-up at the three-months. All information will be entered into databases. Statistical analysis will be performed using the Statistical Package for Social Sciences (SPSS) version 20.0.

In order to determine the effectiveness of the CRT, complete measurements will be taken three months after the end of the intervention and changes will be analyzed using statistical analyses that include Student's *t* tests for repeated measurements to contrast the values and the effect sizes will be measured by Cohen's *d* analyses. Changes will be analyzed for anthropometric, biochemical, nutritional, physiological, psychological, and executive functions tests (see Fig. 1).

4.1. Sample size calculation

Due to the limited resources, a convenience sample of 50 adults with obesity is suggested for this RCT, 25 for the experimental group and 25 for the control group [26]. This is based on the minimum sample size for

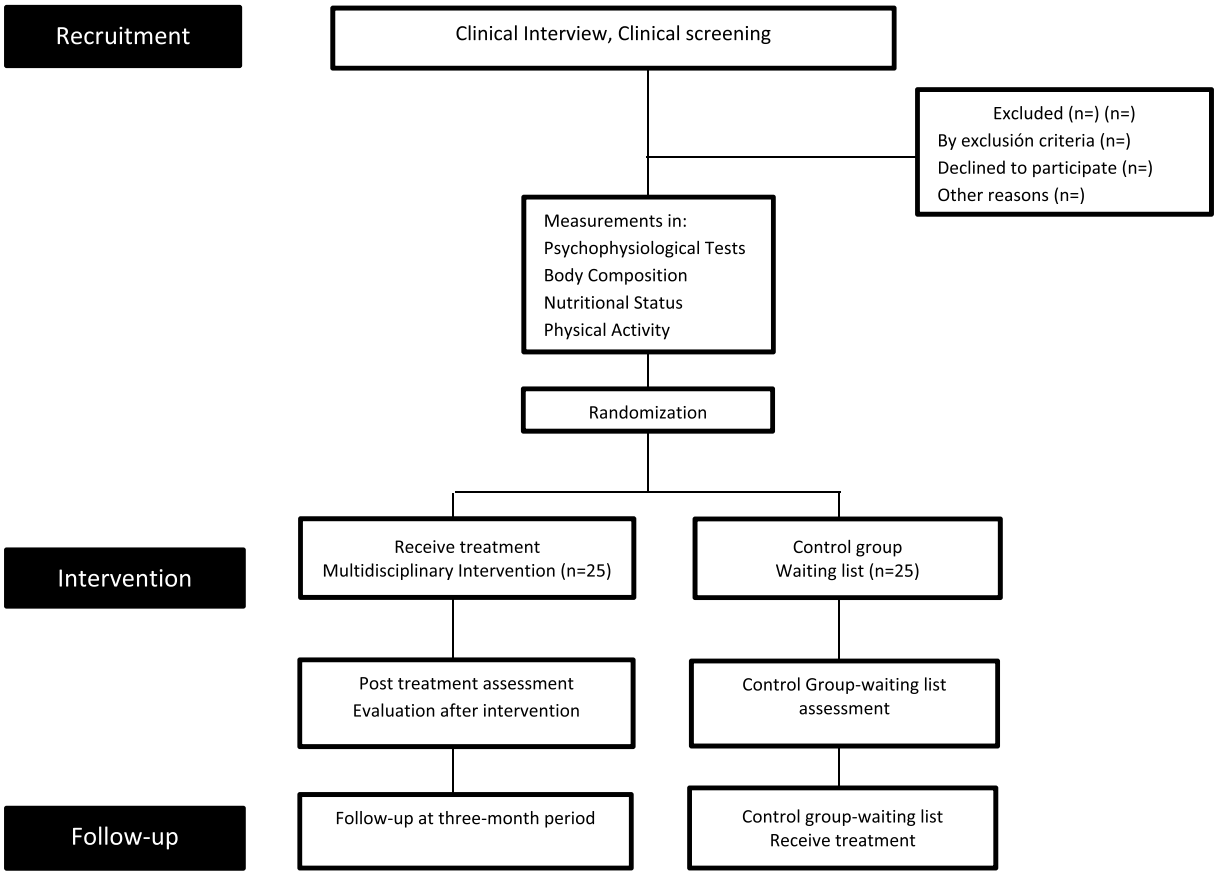

Fig. 1. Study design.

experimental and quasi-experimental designs which states that a minimum of 15 cases are required for each group or 21 cases for a unilateral hypothesis [27].

5. Discussion

CRT has been demonstrated to be effective in various disorders such as anorexia nervosa, addictions, and obesity. However, when reviewing literature, no studies of this type have been found in Mexico, so it is important to consider the procedures of this cognitive remediation therapy program aimed at obesity. This protocol describes the procedures performed in a randomized controlled clinical trial to test the effectiveness of the adaptation that was developed based on the cognitive remediation intervention programs of the Tchanturia *CRT* program [9] and the Tchanturia *CREST* program [8]. In addition, nutrition education and physical activity sessions are included in this intervention program, led by professional psychotherapists, as well as professionals in the field of nutrition and experts in sports training. The sessions are designed to be implemented in group format.

In Mexico there is a high prevalence of obesity in the general population; based on this information health authorities have promoted the dissemination of information regarding the risks of suffering an acute myocardial heart attack, arterial hypertension, or diabetes mellitus in those whose BMI exceeds normality. Prevention and treatment strategies that have been implemented have so far focused mainly on the nutritional aspect, this being understood as the provision of information to promote and achieve a well-balanced diet. These limited treatment strategies have resulted in ineffective actions. To improve nutrition, it is necessary to learn more about changing lifestyles and associated eating behavior, and to include well-articulated interdisciplinary approaches that integrate the psychological, neuropsychological, social, cultural, and biological aspects.

The results of this study will be published in peer-reviewed journals and at academic conferences. The full protocol and all data will be made publicly available. It is also intended to present the results to health professionals, preferably first in Mexico and then internationally. If the results of this intervention program are significant, they could be presented to representatives of the Mexican health care systems and therefore may be considered for larger scale clinical trials within the Mexican population.

One of the main strengths of this research protocol is that it will be conducted as a randomized controlled clinical trial, which will allow for a better control of all study variables, as well as obtaining stronger evidence of the results. Another strength is that it has a multidisciplinary approach, with Cognitive Remediation Therapy, involving different aspects in the development of obesity and which has not been implemented in Mexico.

Limitations

To the best of our knowledge, no studies of this type have been carried out in Mexico that have shown results, so it is not possible to contrast them.

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Authors contribution

Contribution of Graciela Avitia psychometric tests application and

writing of article, Ana García psychology area coordinator and writing of article and Yolanda Loya nutrition area coordinator and writing of article.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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