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Original Research Article

Randomized clinical trial of a motivational interdisciplinary intervention based on the transtheoretical model of change for lifestyle modification in overweight/obese adolescents: MERC study protocol

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ABSTRACT

Background: Obesity worldwide has more than doubled between 1980 and 2014, and this number has grown substantially in adolescents. An increase in this number can be prevented with the modification of lifestyle, healthy food choices and regular physical activity. The aim of this study is to evaluate the effect of a motivational interdisciplinary intervention based on the transtheoretical model of change for lifestyle modification in overweight/obese adolescents.
Methods: A randomized, single-blind clinical trial with a control group, which aims to recruit 120 overweight/obese adolescents aged between 15-18 years (BMI ≥ 85th percentile). The sample will be selected through announcements in print media, social networks, television and radio. Groups will meet weekly over three months. The control group will receive a traditional health education intervention using pedagogy of transmission. The experimental group will receive a group-based motivational interdisciplinary intervention using a motivational interdisciplinary protocol based on the transtheoretical model of change.
Conclusions: The results of this randomized clinical trial will determine if the motivational interdisciplinary intervention based on the transtheoretical model of change has an impact on lifestyle modification of the overweight/obese adolescents. If successful, the MERC program has the potential for application in different treatment scenarios, including that of the public health system.

Trial Registration: The protocol for this study is registered with the Clinical Trial Registry (NTC02455973) and the Brazilian Registry of Clinical Trials (RBR-234nb5).

Keywords: Interdisciplinary intervention, Motivational approach, Transtheoretical model of change, Obesity, Adolescents

INTRODUCTION

This study aims to present an interdisciplinary intervention in a group of overweight/obese adolescents. The lifestyle and cardiovascular risk modification (MERC) program seeks the modification and maintenance of lifestyle through the inclusion of regular physical activity and healthy eating, using a motivational interdisciplinary protocol based on the transtheoretical model of change. An overview of the scientific literature that guided the development of this research follows.

Overweight/obesity

Obesity worldwide has more than doubled between 1980 and 2014. In 2014, over 1.9 billion adults, aged 18 years

or more, were classified as overweight, with more than 600 million of these being considered obese. In 2013, 42 million children under 5 years of age were classified as overweight or obese.[1] Overweight and obesity in adolescents has increased substantially. A systematic analysis in 2013 that sought to estimate the global, national and regional prevalence of overweight and obesity found that 23.8% of adolescent boys and 22.6% of adolescent girls in developed nations were overweight or obese. These figures compared to 16.9% of boys and 16.2% of girls in 1980. In developing countries, the figures for overweight or obesity increased from 8.1% to 12.9% in adolescent boys and from 8.4% to 13.4% in adolescent girls, which indicates an increase when compared to 1980.[2]

Overweight and obesity are characterized as the abnormal or excessive accumulation of fat that can harm health. The main cause of obesity and overweight is an energy imbalance between calories consumed and calories expended. Body mass index (BMI) is used to classify overweight and obesity.[1] Adolescent BMI-for-age is the best indicator of nutritional status and this should be analyzed according to the percentile tables published by the World Health Organization[3].A high BMI is a risk factor for non-communicable diseases, such as cardiovascular disease, diabetes, musculoskeletal disorders and some forms of cancer.[1]

A study involving adolescents, aged 14 to 19 years, from a city in Brazil (São Paulo) reported that those considered overweight (BMI ≥ 85th percentile) presented a higher frequency of cardiovascular risk factors in comparison to the eutrophic group.[3] The risk factors associated with being overweight were HDLc ≤ 35 mg/dl, triglycerides ≥ 150 mg/dl, altered basal insulin >15 μU/ml, and abnormal arterial blood pressure. Of the overweight adolescents, 22.09% had more than three risk factors, as compared to 6.12% of the eutrophic group.[4]

Overweight and obesity, as well as the related non-communicable diseases, can be prevented. The World Health Organization (2015) recommends the choice of healthy foods and regular physical activity. At an individual level, people can reduce their consumption of total fats and sugars, increase consumption of fruits and vegetables, as well as legumes, whole grains and nuts, and engage in regular physical activity (60 minutes a day for children and 150 minutes per week for adults).

Transtheoretical model of change

It is important to assess the stage of change of the individual, i.e., how motivated they are to modify their behavior. The transtheoretical model (TTM) of change shows how people make successful changes in their lives.[5] DiClemente and Prochaska demonstrate that people who are changing behaviors move through a series of stages, from precontemplation to maintenance.[6] The stages of change represent a temporal dimension that allows us to understand the modifications in attitudes, intentions and behaviors. The five stages of change are precontemplation, contemplation, preparation, action and maintenance. A person develops greater perception of their behavioral problem increased motivation to change it.[7]

The processes of change in the TTM are the "engines" that help the movement through the stages. There are ten processes of change, with five being cognitive and five behavioral. The cognitive processes are more related to the early stages of change as they concern internal thought processes and how the person sees the behavior to be modified. The behavioral processes relate more to the final stages, in which there is more action in relation to the behavior to be modified.[7]

In a randomized clinical trial involving 51 obese adolescents, the experimental group received an TTM-based intervention via eight meetings in a 1-year period at a specialist hospital, while the control group, who also attended the hospital, received no intervention. The results revealed a significant impact on BMI ($p = 0.004$) and reduced waist circumference measurements ($p = 0.004$) for the TTM group participants, as compared to the control group.[8] In another randomized clinical trial with obese adolescents who participated in gymnastics, a treatment including the TTM stages of change was performed during weekly meetings, associated with a motivational approach and principles of social cognitive theory.[9] A significant difference in the main outcomes for the 76 participants was seen in a comparison between the groups after six months of follow-up (BMI $p < 0.001$; body fat $p < 0.001$; abdominal circumference $p = 0.025$).[9]

Motivational interviewing

Motivational interviewing (MI) is an approach that works on facilitating the motivation to change. MI, according to Miller and Rollnick, is a direct assistance style to illicit the patient's motivations for change, reducing resistance and stimulating them to change.[10] MI guides patients to convince themselves of the need to change, as when a person articulates the reasons for change their internal motivation is enhanced. In the early stages of adaptation, MI facilitates the stimulation of motivation. In the later stages, although more directed towards action, the motivational approach helps by being carried out in a careful and empathetic manner.[5]

A systematic review of research involving randomized clinical trials that used motivational interviewing, found the interventions had satisfactory results in relation to BMI, total blood cholesterol and systolic blood pressure, and improvement in the state of cardiovascular health.[11-13]

Study rationale

This study is the first randomized clinical trial in Brazil in which an interdisciplinary intervention is performed with

overweight/obese adolescents. Therefore, it is our understanding that this study will present an innovative intervention proposal in the health care of adolescents affected by the conditions presented.

The main aim of the study was to observe different types of prescription audit parameters & evaluate the compliance & non-compliance data of audit according to the checklist as per National Accreditations Board of Hospitals Health (NABH).

Aims and hypotheses

The primary objective of this study is to evaluate the effect of an intervention using a motivational interdisciplinary protocol on overweight/obese adolescents, based on the transtheoretical model of change for lifestyle modification. The secondary objective is to verify the effect of this intervention on physical, dietary, metabolic and behavioral aspects.

Comparison with the control group after three months of intervention is expected to show:

- Reduction in Body Mass Index (BMI)
- Reduction in waist circumference
- Improvement in diet quality
- Increased cardiopulmonary capacity
- Reduction in systolic blood pressure
- Reduction in plasma triglycerides, increased plasma HDL-cholesterol, and reduction in total cholesterol and LDL-cholesterol
- Reduction in glycaemic profile
- Increased readiness to change through performing physical exercise and diet modification
- Decision to lose weight
- Improvement in perception of parental dietary practices
- Increased family support for the child's motivation to change
- Improved self-efficacy for dietary habits and physical exercise
- Change in body image perception
- Change in binge eating rates
- Improvement in quality of life

METHODS

Study design

Randomized, single-blind clinical trial with a control group. The study flowchart is represented in Figure 1. The study has been registered on the Clinical Trial Registry (NCT02455973) and on the Brazilian Registry of Clinical Trials (RBR-234nb5), and is approved by the Research Ethics Committee of the Pontifical Catholic University of Rio Grande do Sul (PUCRS) (nº10/834.1).

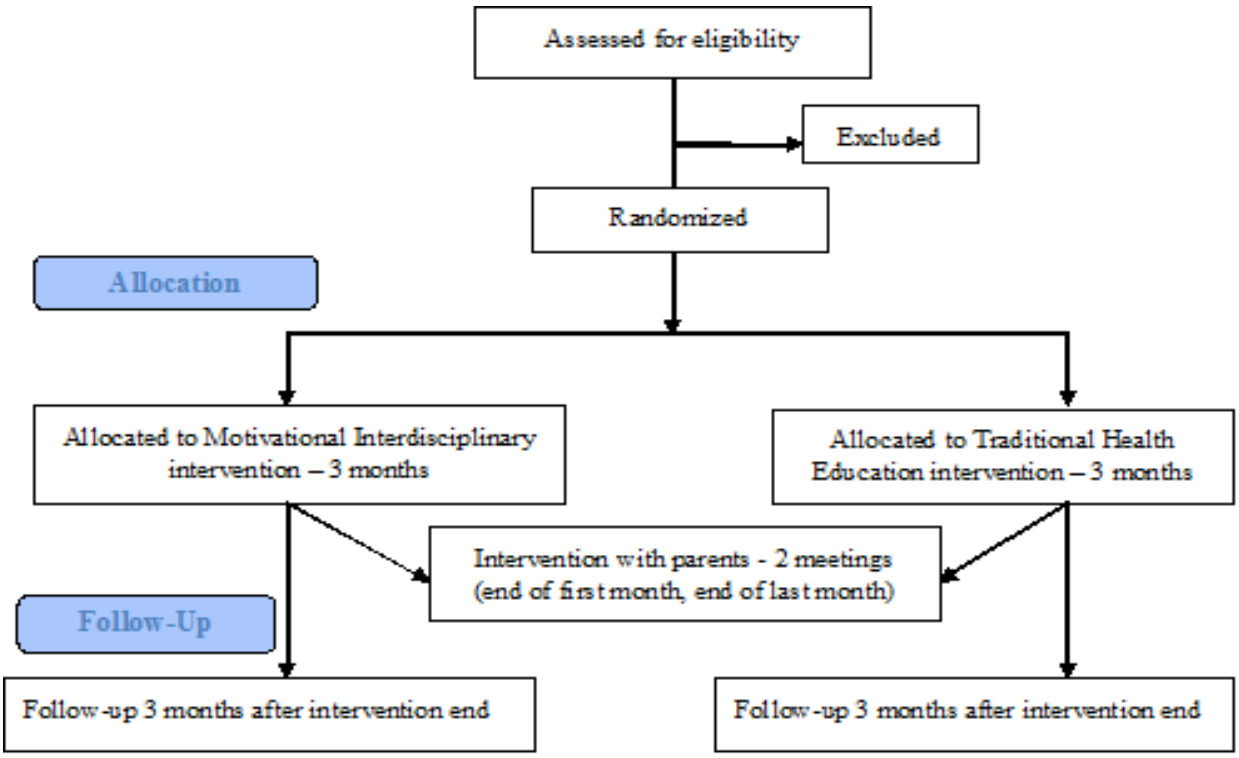

Figure 1: Flow chart of study design.

Participants

Recruitment

The convenience sample will be selected through announcements in print media, social networks, television and radio. The intervention will take place at the Pontifical Catholic University of Rio Grande do Sul, Brazil. Participants will always receive a public transport return-ticket for travel to and from the university.

Eligibility criteria

First contact with the participants will be via a telephone call, in which their age and willingness to participate in the intervention will be verified. The inclusion and exclusion criteria for assessment of the adolescent can be seen in Table 1.

Table 1: Inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
Aged 15-18 years, Overweight/obese, BMI $\geq 85^{th}$ percentile Available to participate in the intervention once a week	Present absolute contraindication for physical activity due to musculoskeletal, neurological, vascular (intermittent claudication), pulmonary or cardiac problems; Presence of diagnosis of a severe psychiatric disorder and/or the presence of significant cognitive impairment; Pregnancy; Diagnosis of Diabetes Mellitus type I; Participation in other research protocols; Difficult contact and unavailability to participate once a week and to return for follow-up assessments, i.e., unavailability for participation in the program.

Following the initial telephone contact, an in-person second meeting will take place at the Nutrition Laboratory, PUCRS. The study objectives will be presented and the inclusion/exclusion criteria for participation evaluated by means of the following instruments:

Anthropometric profile

Assessment includes the measurement of body weight, height and waist circumference. Reference parameters according to gender and adolescent age, as set out by the World Health Organization (2006), will be adopted for classification of nutritional status.[14] A cut off point of the 90^{th} percentile of waist circumference in relation to gender and age will be established for classification of the waist circumference as a predictor of abdominal obesity.[15]

Blood pressure (BP)

Auscultation will be the method used for measuring blood pressure. The recorded pressure measurements will be evaluated according to arterial blood pressure tables for a given age, height and gender, following guidelines set by the Brazilian Society of Cardiology (2010).[16]

Youth self-report (YSR)

Self-report instrument for screening mental health problems in adolescents.[17] The YSR provides an adolescent behavioral profile based on 118 items, which grouped together allow the identification of eight syndromes (subscales): anxiety/depression; withdrawn/depressed; somatic complaints; social contact problems; thought problems; attention problems; rule breaking and aggressive behavior.

Child behavior checklist (CBCL)

The CBCL for ages 6-18 years is a questionnaire composed of 138 items, intended for parents/mothers or caregivers to provide answers regarding the social and behavioral aspects of their children. Twenty of the items relate to assessment of a child's social competence and 118 aims to evaluate their behavioral problems.[17]

Randomization

Participants will be randomized using the Research Randomizer (version 4.0) software in one of two intervention modes.[18] The software generates the randomization sequence, which is performed in a single block of 156 numbers, divided into two groups. One team member is responsible for the blind allocation of the group to which a participant will belong, according to the randomization software. The responsible person follows randomization, allocating adolescents to the "Intervention Group (IG)" or "Traditional Health Education Intervention Group (Control Group - CG)", as per the study criteria.

After being randomized, each individual is provided with information relating to the procedures involved in the research through the Informed Consent Form (ICF), specific to each group. Parents or legal guardians will receive the consent form and the adolescent the assent form. The next number for allocation in the group is then used and the process continued until all participants have been allocated.

Sample size calculation

Sample size calculation was based on BMI variation as this is the main outcome variable. A similar study to that which is proposed found a mean post-intervention reduction of 1.1 (kg/m2), implying a measure of effect of approximately 0.60 (initial BMI: 37.2±6.0 vs. final BMI: 36.1±6.1).[19] Taking into consideration that the effect size for the case group is higher by a margin of 40-60% (with a 0.4 difference in magnitude of the measure of effect for the case group in comparison to the control), and assuming a significance level of 5% (α=0.05) and sample power of 80% (i-β), it will be necessary to have 60 volunteers per group, totaling 120 participants. The software Stata, version 10.1 (Stata v.10.1 for Windows, Stata Corporation College Station, Texas, USA) was used to perform this calculation.

Study interventions

Interventions will take place at the Pontifical Catholic University of Rio Grande do Sul, at the School of Nursing, Nutrition and Physiotherapy (FAENFI). There will be 12 weekly sessions for each of the following groups:

Traditional health education intervention group (CG)

The main focus of CG will be on the development of skills through educational initiatives in health, using pedagogy of transmission. The meetings will be weekly, each lasting 1 h 15 min, following a lecture schedule addressing cardiovascular risk factors and their prevention, as shown in Table 2. Psychology, nutrition, nursing and physiotherapy professionals will coordinate the group. Two meetings with the parents are planned, at the beginning and end of treatment, in order to help clarify any possible doubts.

Table 2: Control group sessions.

Session	Session Theme
1	Exam results
2	Malignant TRIO
3	Guidance on physical exercise
4	Obesity-related diseases and food labeling
5	Food plate model and producing dishes
6	Self-care
7	The importance of meals
8	Intuitive Eating - physiological hunger x emotional hunger
9	Dividing up meals
10	Exercise pyramid
11	How to avoid tempting situations
12	Review and conclusion

Motivational interdisciplinary group intervention (GI)

The main goal of GI is to develop the skills through educational initiatives in health that enable the development of autonomy and empowerment, seeking changes in eating behavior and exercise. Specific techniques will be addressed to drive the use of the process of change, promoting movement through the stages of change. Group meetings will be held in the presence of a member from the nursing, physiotherapy, nutrition and psychology team. Meetings will occur weekly with a duration of 1 h 45 min. Health themes related to lifestyle modification (self-care, healthy eating and physical activity) will be discussed within first 1 h 15 min, using a motivational interdisciplinary intervention based on the transtheoretical model of change, as presented in Table 3.

All topics will focus on the main cardiovascular risk factors that are considered modifiable. The treatment protocol at each session, based on the transtheoretical model of change, aims to work on the stages of change and processes of specific change. Technological resources will be used, such as tablets, apps and video games with motion sensor.

The inclusion of a guided light physical activity is scheduled for the last 30 minutes of the session. This activity aims to motivate the adolescent to include other physical activity sessions throughout the week, by giving the example of different types of physical exercise and activity. Two meetings are destined to the parents or legal guardians of the adolescents. Those will happen at the beginning of the first month and the end of the last month, aimed at motivating them to support their children's behavior change.

Quality control

Team training

The group facilitators receive standardized training in relation to the session content and the motivational approach. A manual for the sessions contains detailed information regarding each meeting, including the theoretical foundation upon which each session is based, targets, materials needed, and a summary and step-by-step plan for each occasion. The group facilitators will participate in a weekly meeting with the project manager in order to guarantee the fulfillment of the session protocol.

Evaluation of group sessions

Sessions will be recorded and evaluated through the Motivational Interviewing Treatment Integrity (MITI 4.1) instrument, which focuses on the verbal behavior of the practitioner of the motivational approach, and not on the patient answers.[20]

Measures

Three evaluations will be carried out: Zero Time (T0) (moment of inclusion in the study); after three months (T1) (intervention end); and during follow-up (T2) (three months after intervention end), for both the intervention and control groups. The instruments and evaluations are detailed in Table 4. A questionnaire will be applied to all participants at the end of each session to measure how much the session fulfilled the proposed objectives.

Table 3: Intervention group sessions.

Session	Stage of Change	Process of Change	Session Theme
1	Precontemplation, Contemplation, Preparation	Increased awareness	Knowing my exam results and initiating change
2		Self-re-evaluation Emotional relief	Physical inactivity and poor diet What do we want? Expressions of concern and lifestyle values
3		Environmental re-evaluation	Knowing what happens to my body Roles that I have/would like to have if I had a different lifestyle
4		Decisional balance	Where am I in the exercise pyramid, what I am eating and what will be my decision?
5		Self-efficacy	Why not make healthy changes against temptation
6		Self-deliberation	So you want to lose weight, tell me more about what you can do about it?
7	Action Maintenance	Conditioning, Control of stimuli, Counter-conditioning, Reinforcement management	Temptation table: Identifying triggers, managing desires and impulses, rewarding successes
8		Control of stimuli, Counter-conditioning, Reinforcement management	Mindfulness helping me to identify and manage thoughts
9		Counter-conditioning, Reinforcement management	Saying "No" and dealing with criticism: Yes, I Can!
10		Control of stimuli, Counter-conditioning, Reward management, Helping relationship, Social deliberation	Brainstorming on Post-its - it will help me find new ways to enjoy life
11		Self-deliberation	I had a lapse: now what?! Help me!
12		Self-efficacy, Reinforcement management	Review and conclusion

Planned data analysis

Data statistical analysis will be performed using the software Statistical Package for the Social Sciences (SPSS) 20.0, adopting a significance level of 5%. Analysis of the categorical variables between the groups will be conducted using *Pearson's* chi-square or *Fisher's* exact tests. The *McNemar* test will be used to evaluate between the categorical data for the intervention start and intervention end (intragroup).

Study of data distribution for continuous variables will be performed through the Kolmogorov-Smirnov test. Student's t test or the Mann Whitney test will be used to compare between groups if the data distribution is not symmetric. The comparison between baseline (initial evaluation) and end data will be carried out using Student's t test for paired data or the Wilcoxon test (nonparametric equivalent).

Verification of the intervention effect on the groups and time (evaluated in two stages) will be ascertained through use of the two-way repeated measures ANOVA, relating to the intragroup factor and the intervention as a factor between groups. The Bonferroni test will be used for post-hoc analysis ($p < 0.05$).

Table 4: Instruments and assesments.

Instruments/assesments	Zero Time T0	After 3 months T1	Follow up T2	Assessment with parents
Sociodemographic data questionnaire	X			
BMI z-score evaluation	X	X	X	
Blood biochemical markers (lipid profile)	X	X	X	
Blood biochemical markers (glycemic profile)	X	X	X	
Arterial blood pressure	X	X	X	
Vitamin D	X	X	X	
Cardiopulmonary capacity evaluation (VO2 max)	X	X	X	
Physical activity questionnaire	X	X	X	
Level of physical activity assessment by means of an objective measure	X	X		
***Global school-based student health survey* (GSHS)**	X			
Readiness-to-change ruler	X	X	X	
Figure rating scale	X	X	X	
Regular dietary habits self-efficacy scale	X	X	X	
Regular physical exercise self-efficacy scale	X	X	X	
***Pediatric Quality of Life Inventory* (PedsQL 4.0)**	X	X	X	X
Decisional balance sheet for weight loss	X	X	X	
Binge Eating Scale (BES)	X	X	X	
Child Behavior Checklist (CBCL)				X
Parent or legal guardian questionnaire				X
Adolescent perception scale regarding parental dietary habits	X	X	X	
24-hour dietary recall survey	X	X		
2-day dietary record	X	X		

The degree of linearity between continuous variables will be assessed using either Pearson's (symmetric distribution) or Spearman's (asymmetric distribution) test of linear correlation.

Time plan for the MERC

The MERC project with adolescents began in October 2014, randomization of the first adolescent volunteers took place in March 2015, and completion of the project is scheduled for December 2017.

DISCUSSION

This is the first randomized clinical trial with an interdisciplinary intervention for overweight or obese adolescents. This intervention seeks to maintain the change to a healthy lifestyle. The results of this randomized clinical trial will determine if the motivational interdisciplinary intervention, based on the transtheoretical model of change, has an impact on lifestyle modification in overweight/obese adolescents.

This research will also provide important information regarding the practical aspects of an interdisciplinary group intervention, which can be implemented in any interdisciplinary team. If successful, the MERC program has the potential for application in different treatment scenarios, including that of the public health system.

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