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Association between stages of change regarding weight reduction in patients with cardiovascular risk factors: A randomized controlled trial

Asociación entre las etapas de cambio con la reducción de peso en pacientes con factores de riesgo cardiovascular: Ensayo clínico controlado

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ABSTRACT

Background: There is very low-quality evidence that the transtheoretical stages of change model combined with physical activity or diet, or both, can result in significant improvements in dietary and physical activity habits. **Objective:** To evaluate the association between stages of change on weight reduction, after a nutritional intervention, in patients with cardiovascular risk. **Methods:** In a randomized controlled clinical trial, patients >18 years old with body mass index ≥ 25 kg/m² and at least two cardiovascular risk factors were distributed to an intervention or control group. The intervention group received, according to stage of change, a multidisciplinary intervention formed by a nutritionist, a psychologist, a chef and a physiotherapist to improve healthy eating, while the control group was given a nutritional prescription. Stage of change from the transtheoretical model, anthropometric variables, physical activity, and 24-hour recall of food intake were measured at baseline and 12 months postintervention. The main outcomes were change in weight, waist and hip circumferences. **Results:** We included 188 subjects (intervention group= 93, control group= 95), where 75% were female, 68.6% had obesity, and mean age 50.3 ± 13 . After 12-months, subjects in the intervention group that were ready to change showed a greater decrease in weight and energy intake, with differences between ready to change vs not ready to change subjects and an interaction between intervention group and ready to change. **Conclusions:** An intervention with a multidisciplinary team can be as effective as the current standard of care in promoting weight loss when taking into account baseline stage of change. **Keyword:** Multidisciplinary intervention; Nutritional intervention; Stage of change; Transtheoretical model; Weight loss.

RESUMEN

Introducción: existe poca evidencia sobre el efecto de la etapa de cambio del modelo transteórico en conjunto con actividad física, dieta, o ambas, en los hábitos dietéticos y de actividad física. **Objetivo:** evaluar el efecto de una intervención nutricional y la etapa de cambio inicial sobre la reducción de peso después de una intervención nutricional en pacientes con riesgo cardiovascular. **Métodos:** Ensayo clínico controlado aleatorizado. Pacientes >18 años con índice de masa corporal ≥ 25 kg/m² y al menos 2 factores de riesgo cardiovascular fueron asignados a: grupo intervención o grupo control. El grupo de intervención recibió de acuerdo a la etapa de cambio una intervención multidisciplinaria formada por: nutricionista, psicólogo, chef y fisioterapeuta, mientras que el grupo control solo recibió prescripción nutricional habitual. Se evaluaron al inicio del estudio y 12 meses después de la intervención: etapa de cambio del modelo transteórico, variables antropométricas, actividad física y recordatorio de 24 horas. **Resultados:** se incluyeron 188 sujetos (grupo intervención 93, grupo control 95), 75% eran mujeres, 68,6% tenían obesidad, con promedio de 50.3 ± 13 . Después de 12 meses, los sujetos en el grupo de intervención que estaban listos para el cambio, mostraron una mayor disminución en el peso y en el consumo calórico, con diferencias estadísticamente significativas en la interacción grupo y etapa de cambio. **Conclusiones:** Una intervención con un equipo multidisciplinario puede ser tan eficaz como el tratamiento habitual para promover la pérdida de peso cuando se tiene en cuenta la etapa de cambio basal.

Palabras clave: Etapa de cambio; Intervención multidisciplinaria; Intervención nutricional; Modelo transteórico; Pérdida de peso.

INTRODUCTION

Obesity has become a cause of major concern due to its association with other cardiovascular risk factors¹. Additionally, eating patterns with a high consumption of saturated fat, sodium, and refined carbohydrates and a low consumption of fruits and vegetables are strongly associated with increased cardiovascular risk².

However, adherence to nutritional recommendations is poor because providing information about healthy eating patterns and increasing physical activity is not enough³. A key barrier to behavioral change is a lack of motivation⁴. Therefore, new nutrition counselling strategies have been incorporated in behavioral-change theories such as the transtheoretical model stages of change (TTM)^{4,5}, as most people are not ready to change their behavior and, therefore, will not be able to follow traditional action-oriented diet programs⁵. Stage of change is a key construct of the TTM. It describes a five-stage temporal process where people make behavioral changes and cognitive behavioral processes, which are necessary to successfully transition across the stages. The five stages of change are as follows: precontemplation (not intending to change behavior in the foreseeable future, usually measured as the next 6 months); contemplation (intending to change behavior within the next 6 months); preparation (intending to change behavior in the immediate future); action (overt behavior change have been made within the past 6 months, but changes are not well established); and maintenance (attempting to avoid relapse but less actively engaged in change processes)^{5,6}. Motivational interviewing techniques aims to strengthen personal motivation for a specific goal by eliciting and exploring the subject's own reasons for change within an atmosphere of acceptance⁴.

Previous studies have reported that the transtheoretical stages of change model combined with physical activity or diet, or both, can result in significant improvement and are more effective for weight reduction compared to traditional approaches^{7,8,9,10}. However, a Cochrane systematic review reported that there is very low-quality evidence and is produced in high-income countries^{11,12}.

The aim of the present study was to evaluate the effect of stage of change on weight reduction, as the primary outcome, and waist and hip circumferences as secondary outcomes, after a nutritional intervention in patients with cardiovascular risk factors. We hypothesized that subjects in the intervention group that were ready to change would have a greater decrease in weight.

METHODS

Study design and participants

The present study was a single-center, single-blind randomized clinical trial. Subjects were recruited at the outpatient Clinical Nutrition Service of the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubiran (INCMNSZ), Mexico from November 2017 to November 2019.

Patients were randomly assigned to a control or intervention group. An external researcher used the website www.randomization.com to generate the random allocation sequence with a 1:1 allocation ratio. Investigators performed the enrollment process. Investigators that performed the outcome assessment and statistical analysis were blinded to assignment.

Sample size was calculated using the formula for comparing two independent means considering the differences in weight change (1.8 ± 1.7 kg) from the Karintrakul study¹³, with 80% power and 95% of accuracy. Including an additional 20% for possible losses to follow-up, sample size was estimated as 22 patients per group.

The follow-up period was 12 months and all variables were assessed at enrollment and after completion by one independent researcher masked to treatment allocation. All participants signed an informed consent form. The present study was approved by the Institutional Human Ethics and Research Committees (Reference 1692) and was registered on <http://www.clinicaltrials.gov> unique identifier: NCT03296722.

A database of 865 subjects was reviewed to identify patients with confirmed cardiovascular risk factors and eligibility criteria (n= 210). Patients were included if: were

men and women >18 years old that had an e-mail, telephone or personal cell phone with at least 2 of the following cardiovascular risk factors: body mass index (BMI) ≥ 25 kg/m², waist circumference >80 cm in women and >90 cm in men, DMT2 with pharmacological treatment, hypertension, hypertriglyceridemia, or hypercholesterolemia. Participants were excluded if they had a diagnosis of major depression, cancer, human immunodeficiency virus, uncontrolled thyroid dysfunction, DMT2 treated with insulin, and/or acute and chronic diseases such as chronic kidney disease, chronic liver disease or heart failure, had already performed a structured exercise program, were on another diet regime, consumed food supplements in the previous 6 months, or there was a contraindication to perform physical activity.

Allocation and sample size calculation are presented in supplementary material.

Interventions

All patients, independent of the intervention group, received standard pharmacological treatment for the comorbidities they presented according to the opinion of the Internal Medicine Service. Patients did not have restrictions on changing their medication regime during the study.

Nutritional and protein requirements for both groups were calculated as 20-25 kcal/kg ideal body weight/day and 1.2-1.5 g/kg, respectively.

Patients randomized in the intervention group attended a face-to-face nutritional education program in a group format, according to patient's baseline stage of change to healthy eating¹⁴ (see supplementary material). Motivational interviewing techniques were used in all sessions to deliver education messages.

The program consisted of sixty-minute sessions once-per-month, over 12 months. Some session topics were: 1) Healthy eating habits given by a dietitian. 2) Recommendations for preparing healthy food given by a chef. 3) Recommendations to solve eating and exercising problems and ways to stay motivated led by a psychologist. 4) Benefits of exercising, as well as an initial guide to home exercise that describes the components of training (heating, strength and flexibility) to achieve an increase in time, frequency, and duration of exercise conducted by a physical therapist. All counselors received formal instruction in motivational interviewing and provided by psychologist specialist.

A DASH-style dietary pattern¹⁵ was prescribed to the intervention group according to international guides of the ACC and AHA for the reduction of cardiovascular risk¹⁶. The DASH dietary pattern is high in vegetables, fruits, low-fat dairy products, whole grains, poultry, fish, and nuts; and low in sweets, sugar-sweetened beverages, and red meats and is low in saturated fat, total fat, and cholesterol. It is rich in potassium, magnesium, and calcium, as well as protein and fiber¹⁵. All patients received oral instructions and a nutritional handbook with seven menus that were individually tailored to them by a dietitian and reviewed by a chef.

The control group continued with the usual care of the

outpatient Clinical Nutrition Service. Usual care consisted of twenty-minute individual face-to-face counseling sessions once per month with verbal instructions, from the dietitian only, and a handbook containing exchange lists for meal planning with a prescription for a hypocaloric diet. These sessions did not consider patient stage of change.

Measures and instruments

Weight was measured using a digital scale (SECA model 813, Seca Ltd. Birmingham, UK), height with stadiometer (SECA model 220, Hamburg, Germany) graduated in cm and waist and hip circumferences with an inextensible tape (Lufkin model W606PM, Baltimore, MD, USA), according to the reference manual of Lohman et al.¹⁷. BMI was calculated by dividing total body weight (kilograms) by height squared (square meters).

To identify stage of change, in regards to healthy eating, a self-administered questionnaire was answered by participants to indicate which of five statements best represented them^{5,14}: "I do not eat a healthy diet, and I do not plan to change in the next 6 months" (precontemplation); "I am thinking about changing my diet, and I will begin in the next 6 months" (contemplation); "I am planning to change my diet in the next 30 days" (preparation); "I am eating a healthy diet and I made these changes in the past 6 months" (action) "I am eating a healthy diet, and I made these changes more than 6 months ago" (maintenance). The questionnaire was applied after the first visit session where it was explained what eating a healthy diet meant.

The rapid assessment physical activity (RAPA) score¹⁸ was used to evaluate physical activity. RAPA is a validated and culturally adapted self-administered questionnaire¹⁹ to assess habitual physical activity based on a scale of 1-7 measuring the amount, intensity and duration of physical activity that a subject does. A score ≤ 3 corresponds to a sedentary/underactive subject, whereas a score ≥ 4 corresponds to a moderate to vigorously active subject.

Using 24-hour dietary recall, a trained research dietitian collected information on foods and beverages consumed on the previous day (type, quantity, mode of preparation, sugars). These data were analyzed with Food Processor version 10.14.2 (The Food Processor®, Nutrition Analysis Software from ESHA Research). To evaluate adherence to the diet, DASH score previously developed and validated by Mellen et al.²⁰ was calculated. DASH nutrient goals for 9 target nutrients (total fat, saturated fat, protein, fiber, cholesterol, calcium, magnesium, potassium and sodium) were indexed to total energy intake (with the exception of macronutrients). DASH score was generated by summing all the nutrient targets that were met (maximum score= 9). Individuals with an intake meeting a goal between the DASH goal and the nutrient content of the DASH control diet were given a score of 0.5 for that nutrient²⁰.

Individuals meeting approximately half of the DASH targets (DASH score ≥ 4.5) were considered adherent²⁰.

All comorbidities and medical treatments were collected from electronic medical records for each patient.

Statistical analysis

For primary and secondary outcomes (change in weight, waist and hip circumferences), the Student's t-test was used to determine the difference in the mean individual change from baseline to 12-month values in the study groups. A general linear model was used to determine whether there was an interaction between the study group and stage of change (ready to change: action and maintenance, and not ready to change: preparation, precontemplation and contemplation).

The primary analysis included all available data from all randomized participants. Missing data were handled using multiple imputation technique with the Markov chain Monte Carlo simulation, to produce five complete data sets. These data sets were analyzed separately using ANOVA and the results were combined across data sets using Rubin's rules and pooled for an intention-to treat analysis.

A p value <0.05 was considered statistically significant. Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 21.

RESULTS

Two-hundred and ten patients were assessed for eligibility; the most frequent exclusion criteria were pre-existing acute and chronic diseases. One hundred eighty-eight patients were randomized, 93 to the intervention group and 95 to the control group from which 14 (15.1%) and 12 (12.6%) were lost to follow-up, respectively as shown in figure 1.

Baseline characteristics of the intervention and control groups are presented in table 1. There were no significant differences between the groups for the variables of age and comorbidities.

Figure 2 shows baseline stages of change frequency by study group, where we can see that in both groups, patients in contemplation were more frequent.

Table 2 shows changes in anthropometric and dietary variables between baseline and 12-months by study group and stage of change. The subjects ready to change at baseline in both groups (control and intervention) had greater loss of weight, waist circumference and energy intake compared to those not ready for change. Patients ready to change in the intervention group showed a greater decrease in weight and energy intake.

Figure 1: Flow chart of the patients included in the study.

Table 1. Baseline characteristics by study group (n=188).

Variables	Intervention (n= 95)	Control (n= 93)
Age (years)	47.2±13.6	53.4±12.3
Sex men/women, n (%)	30 (31.6)/65 (68.4)	17 (18.3)/76 (81.7)
BMI	30.4±4.8	31.5±4.9
Weight (kg)	79.5±15.1	76.6±12.1
Waist circumference (cm)	98±13.2	99±10.5
Hip circumference (cm)	106.3±10.5	108.4±10.2
Hypertension, n (%)	44 (46.3)	46 (49.5)
Diabetes, n (%)	38 (40)	50 (54.3)
Obesity, n (%)	64 (67.4)	65 (70)
Dyslipidemia, n (%)	52 (54.7)	53 (57)
Hypothyroidism, n (%)	17 (17.9)	30 (32.3)
Energy (Kcal)	1889±539	1800±538
DASH score	3.4±1.5	3.6±1.4
RAPA score	3.4±2.1	3.3±2.1

Data are presented as mean ± standard deviation or n (%).

Figure 2: Frequency of baseline stages of change in the study groups.

Table 2. Changes of anthropometric and dietary variables between baseline and 12 months by study group and stage of change.

Variables	Ready to change		Not ready to change		p*
	Intervention (n= 14)	Control (n= 18)	Intervention (n= 81)	Control (n= 75)	
Weight (kg)	-5.1±2.7	-3.3±4.2	-0.26±2.2	-0.78±2.6	0.03
WC (cm)	-5.9±6.7	-4.2±5.4	-1.4±5.3	-1.6±5.3	0.39
HC (cm)	-2.5±4	-1.1±4.1	-0.89±3.9	-0.45±4.0	0.31
Energy (Kcal)	-305±524	-164±349	-186.4±392	-8±211	0.04

Data are presented as the mean ± standard deviation. WC=Waist circumference; HC=Hip circumference. *Differences for interaction group x ready and not ready to change.

With respect to the differences between study groups in anthropometric and dietary variables, a significant decrease was observed in energy intake in the intervention group compared with the control group (-204.5±418.5 vs. -38.3±249.9, $p = 0.02$).

There were no significant differences between groups in percentage of subjects with a DASH score ≥ 4.5 (intervention group 71.4% and control group 61.1%) or with a RAPA score ≥ 4 (intervention group 64.3% and control group 61.1%), $p = 0.06$.

DISCUSSION

In this randomized controlled trial, patients with cardiovascular risk factors who were classified as ready to change (action and maintenance) at the beginning of the study and were in the intervention group experienced the greatest weight and energy intake reduction after 12 months. Independent of study group (multidisciplinary intervention or habitual intervention), subjects that were ready to change had a statistically significant decrease in weight, waist circumference and energy intake compared with subjects that were classified as not ready to change. These results suggest that it is essential to incorporate baseline stage of change measurement, and tailored counseling to each subject according to the result, for the success of long-term interventions with the goal of encouraging healthy eating habits and exercise.

Similar results were found in a study among family members of hospitalized cardiovascular disease patients, where effectiveness of an intervention to lower saturated fat varied by baseline stage of change²¹. However, a change in anthropometric variables was not reported. Karintrakul, et al.¹³ used a nutritional education program paired with the TTM to achieve weight loss and found that the intervention group (individualized nutrition counseling matched with a stage of change) showed a higher weight loss compared with the control group (received an educational handbook

at baseline without counseling). Also, De Freitas, et al.²² in a randomized controlled trial, where the intervention group received the same orientation as the comparison group plus individual health counseling based on the TTM aimed at weight loss (participants were classified into two groups pre-action and action), found a difference between groups of -1.4 kg in body weight after 6 months. However, these two last studies only included women.

In contrast, Kristal et al.²³ did not find a consistent trend among stage of change at baseline and decreased percentage of energy from fat and in servings of fruits and vegetables.

Other studies have been successful in using multidisciplinary interventions and recurrent phone or electronic monitoring of healthy eating habits and behavioral therapy in both individual and group intervention^{7,8}. Trained health professionals can promote the process of change by building relationships with patients and encouraging their personal motivation and self-efficacy, which leads to changes in behavior.

This study showed that multidisciplinary and monthly structured interventions in a group format over a 12-month had significant results in patients ready to change, perhaps in patients not ready to change a longer intervention is needed. To improve support for adults with obesity and cardiovascular risk, it is necessary to establish the beginning of care, provide follow-up, and include patients in multidisciplinary activities according to the baseline stage of change and reduce the use of traditional intervention.

The limitations of the present study were as follows: single-center trial, limited sample size within stage of change strata and the intention to treat analysis. Although there were no statistically significant differences between groups in DASH and RAPA scores, the magnitude of the differences could be clinically relevant to promote a decrease in weight in addition to the reduction in energy intake. In addition, we did not evaluate baseline stage of change for physical exercise. Being ready to change for physical exercise and

healthy eating at the same time may be associated with higher weight loss. However, it has been reported that a person is more likely to be in a higher stage for different behaviors at the same time²⁴.

The results of the present study suggest the evaluation of stages of change at baseline to determine whether subjects are ready and able to make changes in their eating habits is necessary, regardless of the type of intervention. Those who are in preparation, action or maintenance stages are more likely to make changes in their eating habits because they actively promote their empowerment, become more responsible and are more likely to comply with therapeutic guidelines to achieve cardiovascular risk reduction. These results also suggest that the most effective interventions will focus on continued change among persons ready to change, as well as attempting to move people not ready to change with a strong emphasis on cognitive changes to increase motivation and awareness about health challenges, in addition to the information about healthy eating and increasing physical activity. To perform these interventions, it is necessary that health professionals receive formal instruction to develop clinical and self-regulation skills to promote adherence to treatment in a nutritional intervention.

Finally, future studies should include and analyze the interaction between readiness to change diet and physical activity with large sample sizes and long durations of intervention and follow-up, for sustainable weight loss. In conclusion, an intervention with a multidisciplinary team can be as effective as the current standard of care in promoting weight loss when considering baseline stage of change for healthy eating.

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