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Weight gain prevention during the December holiday season in adults: Pilot Randomized Controlled Trial

Prevención del aumento de peso durante las fiestas decembrinas en adultos: Ensayo Controlado Aleatorio Piloto

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ABSTRACT

The December holiday season is a critical period for weight gain in adults, accounting for 50 % of annual weight gain. Actually, there are few preventive interventions during this period. This work evaluated the effect of two online interventions for the prevention of weight gain in Mexican adults during the December holiday season in the COVID-19 pandemic. A three-arm pilot randomized controlled trial was implemented. The primary outcome was change in body weight at 8 weeks (at the end of the holiday season). At the end of the study, 78.1 % of the participants were retained. No differences between groups were found in body weight change (Watch your Weight During the Holidays (WWDH): -0.10 ± 1.81 (SD), 95 % CI [-1.40, 1.19]; Relative Fasting 5:2 (RF5:2): 0.92 ± 1.18, 95 % CI [0.12, 1.71] and control group: 0.15 ± 1.68, 95 % CI [-0.98, 1.28]). The results show that the trial was feasible, that a behavioral intervention using self-weighing and nutrition counseling (WWDH group) had potentially beneficial results, while the RF5:2 intervention was not promising during this period. In addition, this pilot allowed the design of a definitive study.

Keywords: Primary Prevention, Holidays, Weight Gain, Adults, Overweight.

RESUMEN

Las fiestas decembrinas son un periodo crítico para la ganancia de peso en adultos, donde se gana más del 50 % del incremento de peso anual. Actualmente, existen pocas intervenciones preventivas durante este periodo. Este trabajo evaluó el efecto de dos intervenciones en línea para la prevención del aumento de peso en adultos mexicanos durante las fiestas decembrinas en la pandemia por COVID-19. Se implementó un ensayo controlado aleatorio piloto de tres brazos. La variable principal fue el cambio en el peso corporal a las 8 semanas (al finalizar las fiestas decembrinas). Al final del estudio, se retuvo al 78.1 % de los participantes. No se encontraron diferencias en el cambio del peso corporal entre los grupos (Cuida tu Peso Durante las Fiestas Decembrinas (CPDFD): -0.10 ± 1.81 (DE), IC95 % de [-1.40 a 1.19]; Ayuno Relativo 5:2 (AR5:2): 0.92 ± 1.18, IC95 % [0.12 a 1.71] y grupo control: 0.15 ± 1.68, IC95 % [-0.98 a 1.28]). Los resultados muestran que el ensayo fue factible, que la intervención con auto pesaje y consejería nutricional (grupo CPDFD) aplicada tuvo resultados potencialmente beneficiosos, mientras que la intervención RF5:2 no fue prometedora durante este período. Asimismo, el trabajo permitió el diseño de un estudio definitivo.

Palabras clave: Prevención Primaria, Vacaciones y Feriados, Aumento de Peso, Adultos, Sobrepeso.

INTRODUCTION

The December holiday season is the festive period with the greatest impact on adult body weight (Zorbas *et al*., 2020; Díaz-Zavala *et al*., 2017). Observational studies have shown that more than 50 % of the annual weight is gained during this period (Yanovski *et al*., 2000; Sturm *et al*., 2016). Globally, few preventive interventions have been conducted during the December holidays and have been implemented in US and UK (Kaviani *et al*., 2019; Hirsh *et al*., 2019; Mason *et al*., 2018; Watras *et al*., 2006; Zorbas *et al*., 2020). Therefore, interventions are needed to prevent weight gain in this critical period, and outside these populations. This work sought to evaluate the effect of two online interventions on the prevention of body weight gain, compared to a control group in Mexican adults during the holiday season, in order to test the feasibility of the methodology and obtain data to calculate the sample size of a definitive study. The study coincided with the COVID-19 pandemic, which appears to have nega-

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tively affected diet, physical activity, and body weight of the population (Bennett *et al*., 2021).

MATERIALS AND METHODS

This exploratory pilot randomized controlled trial of parallel groups, with three arms, was approved by the Research Ethics Committee of the Department of Nursing at the University of Sonora (registration number: CEI-ENFERMERÍA-EPD-002-2020). This report follows the recommendations of the Consolidated Standards of Reporting Trials guide, in its extension for pilot studies (Eldridge *et al*., 2016) and was registered in ClinicalTrials.gov platform (NCT05060978) prior to conduct of the trial.

Participants

Participants were adults with normal weight, overweight or obesity, recruited online (through flyers, posters, direct invitation, and social networks) at the city of Hermosillo, Sonora, México. Eligibility criteria were evaluated and their consent was obtained. Participants were eligible for inclusion if they were adults with a BMI classified as normal weight, overweight or obesity (BMI ≥ 23 kg/m^2 and ≤ 40 kg/m^2), aged between 20 and 65 years, and residents of the city of Hermosillo, Sonora. They also had to commit to not undertake any other intervention outside the one assigned in the study during the 8 weeks of the intervention. We excluded people with a previous diagnosis of a medical condition that constituted a contraindication for the intervention or that could affect body weight.

Randomization

Participants were randomized by blocks, stratified by sex and age, with a 1:1:1 allocation ratio, to the three different intervention groups: 1) Watch your Weight During the Holidays Program (WWDH), 2) Relative fasting 5:2 (RF5:2), or 3) control group. Assignment to groups was performed by a member of the research group not involved in the recruitment of participants, nor intervention implementation.

Interventions

The WWDH group comprised self-efficacy and habit formation through encouragement of participants to record their weight at least one time during each week (self-weighing), follow 10 tips for weight management during the holidays, graphical information about physical activity calorie equivalents (PACE) of Mexican foods and drinks, and three video calls for nutrition counseling (one group and two individual video calls). The RF5:2 group received a dietary recommendation to follow a 5:2 intermittent fasting approach, along with two video calls for nutrition counseling related to intermittent fasting (one group and one individual video call). They were given low-energy menus of 550 kcal/day and 660 kcal/day for women and men, respectively, to follow during two fasting days. During the remaining five days, there was no energy restriction. The control group received an explanation of a healthy eating leaflet, based on a Mexican Standard for health promotion: NOM-043-SSA-2012. To encourage retention, study participants obtained a weighing scale as a reward for completing the ten-week measurements. Detailed information about each intervention group can be seen in Supplement 1.

Outcomes

The primary outcome was change in body weight at 8-weeks. Measurements were originally planned to be at eight-weeks but high reports of COVID-19 infections by study participants during the holiday season resulted in a delay of two weeks (10-weeks). Secondary outcomes of body size and composition, biochemical variables and health-related quality of life were also measured at 10-weeks. Baseline measurements were assessed from November 1 to 12, 2021, and final measurements from January 24 to February 2, 2022. The outcome assessors were blinded to treatment allocation status (TJMC and ALMP). Techniques and details about how measures were taken for each outcome can be consulted in Supplement 1.

Statistical analysis

Statistical analysis was performed with one-way ANOVA tests for parametric samples or Kruskal-Wallis tests for nonparametric samples, using statistical software NCSS 10 (Number Cruncher Statistical System for Windows, Kaysville, UT, USA). All analyses were performed using the intention-to-treat approach and, secondarily, with those who completed all measurements.

RESULTS

Thirty-two participants were recruited and randomized to the three different intervention groups: WWDH Program (n = 10), RF5:2 (n = 11) and control group (n = 11). Figure 1 shows the flow diagram of study participants. At the end of the study measurements, a retention of 78.1 % of the participants was achieved.

Participants were predominantly female (65.6 %), with a mean age ± standard deviation of 38.1 ± 11.3 years, and BMI of 30.4 ± 3.84 kg/m^2. There were no significant differences between groups at baseline in any of the characteristics as was expected due to the randomization process (Table 1). Table 2 shows the results of the variables analyzed by the ITT approach. Results for weight change at 10 weeks showed no difference between groups (WWDH: -0.10 ± 1.81, 95 % CI -1.40 to 1.19; RF5:2: 0.92 ± 1.18, 95 % CI 0.12 to 1.71 and control group: 0.15 ± 1.68, 95 % CI from -0.98 to 1.28) (Figure 2), though a positive trend was observed for the WWDH group and a negative trend for the RF5:2 group, both compared to the control group. For secondary outcomes, no differences were observed between the groups.

Analysis by those who completed all study measurements also showed no difference between groups in body weight change at 10 weeks or in any of the secondary outcomes evaluated (Figure 3). During the 10-week study period, no adverse effects were reported by study participants.

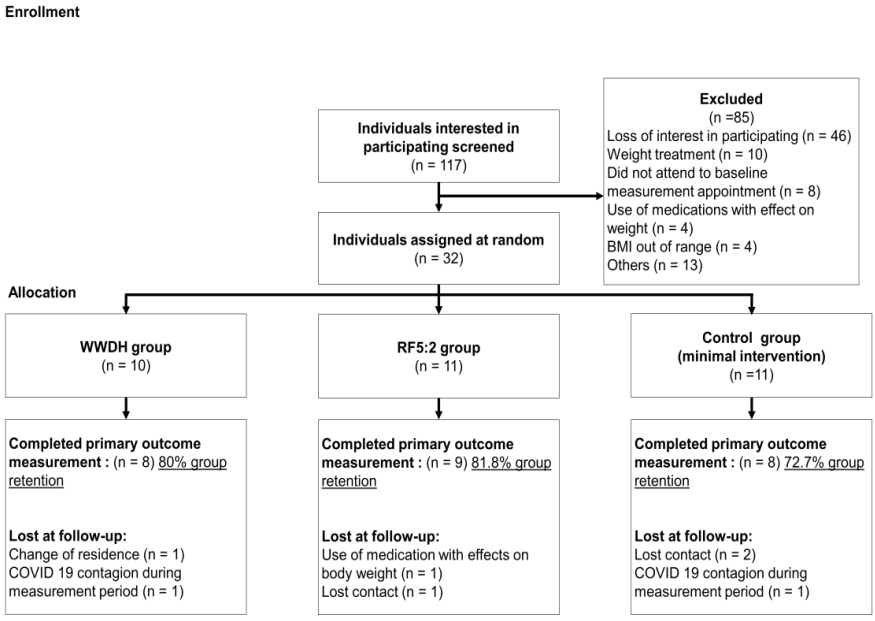

Figure 1. Flow diagram of study participants. Abbreviations: WWDH: Watch your Weight During the Holidays, RF5:2: Relative Fasting 5:2.
Figura 1. Diagrama de flujo de los participantes del estudio. Abreviaturas: CPDFD: grupo Cuida tu Peso Durante las Fiestas Decembrinas, AR5:2: grupo Ayuno Relativo 5:2, Control: grupo Control.

Table 1. Baseline characteristics of participants.
Tabla 1. Características basales de los participantes.

Outcome	WWDH group (n= 10)	RF5:2 group (n= 11)	Control group (n= 11)	P Value
Sex n (Femenine %)	7 (70.0)	7 (63.6)	7 (63.6)	0.94
Age (years)	37.5 (11.5)	39.7 (12.5)	38.1 (11.3)	0.84
Weight (kg)[a]	77.1 (68.8, 97.4)	77.1 (69.4, 109)	87.0 (79.1, 99.5)	0.58
BMI (kg/m2)	29.5 (3.60)	30.8 (4.98)	30.7 (2.87)	0.69
Waist circumference (cm)	97.5 (11.8)	100 (15.8)	101 (9.37)	0.71
Fat mass (kg)	31.3 (7.68)	35.0 (9.49)	35.1 (7.02)	0.49
Fat free mass (kg)[a]	43.3 (40.8, 67.5)	42.1 (39.9, 54.1)	49.2 (44.5, 64.7)	0.68
Systolic blood pressure (mm/Hg)	124 (12.3)	118 (11.9)	120 (14.5)	0.62
Diastolic blood pressure (mm/Hg)	82.1 (10.1)	78.2 (9.74)	79.1 (11.1)	0.68
Biochemical outcomes				
Fasting glucose (mg/dL)	89.6 (10.1)	81.3 (10.2)	84.4 (12.1)	0.21
Total cholesterol (mg/dL)	186 (40.7)	213 (50.6)	186 (44.8)	0.30
LDL cholesterol (mg/dL)	117 (32.0)	134 (36.9)	114 (38.8)	0.39
HDL cholesterol (mg/dL)	42.9 (6.69)	47.6 (9.61)	43.0 (7.18)	0.32
Triglycerides (mg/dL)	129 (64.5)	157 (134)	145 (66.6)	0.84
Health-related quality of life outcomes				
Physical function[a]	95.0 (85.0, 100)	95.0 (83.7, 100)	89.1 (85.0, 100)	0.92
Physical problems[a]	100 (68.7, 100)	100 (93.7, 100)	100 (50.0, 100)	0.47
Pain	80.2 (15.5)	89.5 (10.3)	80.2 (16.8)	0.27
Social function	83.7 (15.6)	85.0 (17.4)	79.5 (18.7)	0.75
Mental health	72.0 (14.3)	77.6 (17.6)	70.1 (13.8)	0.52
Emotional problems	56.6 (38.6)	70.0 (39.9)	60.6 (29.1)	0.69
Vitality	62.5 (16.8)	62.0 (23.7)	64.0 (16.4)	0.96
Perception of general health	69.5 (15.7)	77.5 (14.9)	65.4 (20.3)	0.28
Health changes over time	65.0 (24.1)	62.5 (21.2)	61.3 (30.3)	0.94

Baseline characteristics of participants, expressed as mean (percentage) or mean (standard deviation), one-way ANOVA test; and [a]median (percentiles 25 and 75), Kruskal-Wallis test.
Abbreviations: WWDH: Watch your Weight During the Holidays, RF5:2: Relative Fasting 5:2.

Table 2. Changes in outcomes from baseline to 10-weeks of follow-up.
Tabla 2. Cambios en las variables desde el inicio hasta las 10 semanas de seguimiento.

Outcome	WWDH group (N= 10)	RF5:2 group (N= 11)	Control group (N= 11)	P value
Weight (kg)	-0.10 (-1.40, 1.19)	0.92 (0.12, 1.71)	0.15 (-0.98, 1.28)	0.30
BMI (kg/m2)	-0.04 (-0.51, 0.42)	0.34 (0.05, 0.63)	0.06 (-0.32, 0.45)	0.27
Waist circumference (cm)	-0.36 (-1.71, 0.99)	0.14 (-0.92, 1.21)	-0.97 (-2.43, 0.49)	0.39
Fat mass (kg)[a]	0.12 (-0.31, 1.80)	0.56 (-0.02, 1.67)	0.12 (0.00, 0.45)	0.57
Fat free mass (kg)[a]	-0.63 (-1.71, 0.14)	0.05 (-0.33, 0.66)	0.16 (0.00, 0.81)	0.57
Systolic blood pressure (mm/Hg)	1.00 (-6.53, 8.53)	2.00 (-2.29, 6.29)	4.54 (1.41, 7.67)	0.57
Diastolic blood pressure (mm/Hg)	-3.40 (-8.87, 2.07)	-0.45 (-5.59, 4.68)	-1.18 (-5.75, 3.39)	0.57
Biochemical outcomes				
Fasting glucose (mg/dL)[a]	0.00 (-4.00, 2.00)	0.00 (0.00, 12.0)	0.00 (0.00, 10.0)	0.16
Total Cholesterol (mg/dL)[a]	28.6 (5.41, 51.7)	16.2 (-21.6, 54.1)	8.45 (-12.4, 29.3)	0.13
LDL cholesterol (mg/dL)[a]	20.5 (0.00, 35.7)	0.00 (-1.00, 14.0)	0.00 (-4.00, 27.0)	0.11
HDL cholesterol (mg/dL)[a]	0.00 (0.00, 8.75)	0.00 (0.00, 13.0)	0.00 (0.00, 4.00)	0.92
Triglycerides (mg/dL)[a]	0.00 (-29.0, 33.5)	0.00 (-8.00, 8.00)	0.00 (-45.0, 12.0)	0.77
Health-related quality of life outcomes				
Physical function[a]	0.00 (-1.25, 6.25)	0.00 (0.00, 5.00)	0.00 (0.00, 0.00)	0.49
Physical problems[a]	0.00 (-6.25, 6.25)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.93
Pain	5.44 (-10.0, 14.5)	-5.90 (-20.7, 8.94)	5.00 (-1.14, 11.1)	0.31
Social function[a]	0.00 (-18.7, 15.6)	0.00 (0.00, 0.00)	0.00 (0.00, 12.5)	0.56
Mental health	-2.40 (-11.3, 6.56)	-2.18 (-8.46, 4.10)	4.36 (-0.93, 9.66)	0.22
Emotional problems	-30.0 (-53.7, -6.28)	6.05 (-21.9, 34.0)	6.07 (-10.7, 22.8)	0.03[b]
Vitality	-1.00 (-10.6, 8.65)	10.0 (-0.62, 20.6)	-1.36 (-6.58, 3.85)	0.07
Perception of general health[a]	-2.50 (-10.0, 6.25)	0.00 (-5.00, 10.0)	0.00 (-5.00, 0.00)	0.65
Health changes over time	-7.50 (-26.4, 11.4)	4.54 (-15.1, 24.1)	-9.09 (-20.4, 2.23)	0.38

Changes in outcomes from baseline to 10-weeks of follow-up, expressed as mean (percentage) or mean (standard deviation), one-way ANOVA test; and [a]median (percentiles 25 and 75), Kruskal-Wallis test.
[b] Statistically significant differences with one-way ANOVA test, without differences with Bonferroni test.
Abbreviations: WWDH: Watch your Weight During the Holidays, RF5:2: Relative Fasting 5:2.

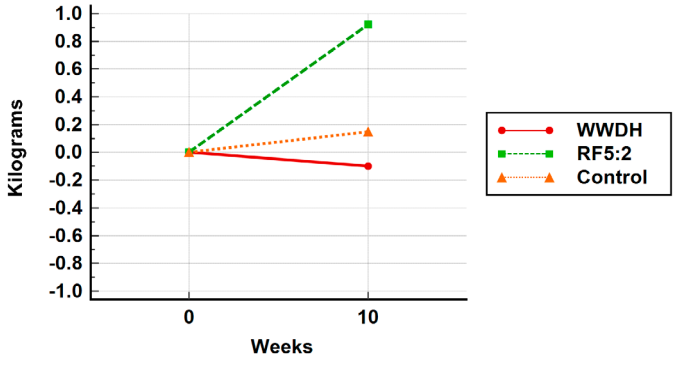

Figure 2. Body weight changes during the holiday season from baseline to 10-weeks, Intention-to-Treat approach analysis. Abbreviations: WWDH: Watch your Weight During the Holidays group, RF5:2: Relative Fasting 5:2 group, Control: Control group.
Figura 2. Cambios en el peso corporal durante las fiestas decembrinas desde el inicio hasta las 10 semanas, análisis con abordaje de Intención de Tratar. Abreviaturas: CPDFD: grupo Cuida tu Peso Durante las Fiestas Decembrinas, AR5:2: grupo Ayuno Re-lativo 5:2, Control: grupo Control.

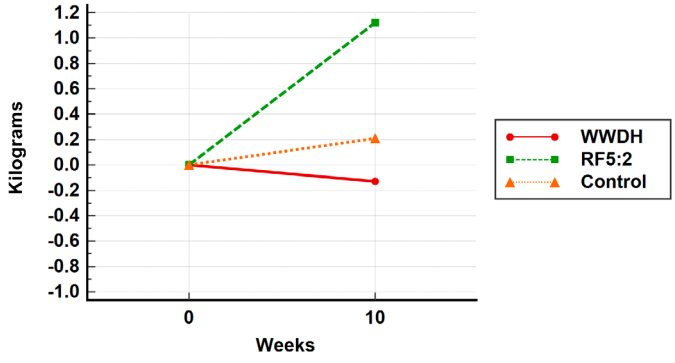

Figure 3. Changes in body weight during the holiday season at 10-weeks in participants who completed the study measurements. Abbreviations: WWDH: Watch your Weight During the Holidays group, RF5:2: Relative Fasting 5:2 group, Control: Control group.
Figura 3. Cambios en el peso corporal durante las fiestas decembrinas a las 10 semanas de seguimiento de los participantes que terminaron las mediciones del estudio. Abreviaturas: CPDFD: grupo Cuida tu Peso Durante las Fiestas Decembrinas, AR5:2: grupo Ayuno Relativo 5:2, Control: grupo Control.

DISCUSSION

This pilot study showed non-significant positive effects on weight gain prevention in favor of the WWDH group, compared to the RF5:2 and the control groups. The positive result of the WWDH group was a bit less than expected, compared to other studies on the prevention of weight gain during the holiday season. A systematic scoping review showed that intervention studies during this holiday period have achieved significant weight loss, mostly in favor of the intervention group (Zorbas *et al*., 2020). The review showed weight losses from 0.13 kg to 1.30 kg in the intervention groups and weight gains from 0.09 to 1.10 kg in the control groups (Zorbas *et al*., 2020). The effect of the RF5:2 group was opposite to what we expected and showed a similar behavior to the control groups of previous studies. We are not sure if this is due to this type of intervention not being culturally acceptable in Mexican participants, as it has not been tested previously outside of high-income countries (Harris *et al*., 2018; Cioffi *et al*., 2018), or whether it was due to the difficulty of maintaining normal eating habits on the five non-fasting days during the holiday season.

The data from this study will allow the implementation of this methodology in a definitive randomized controlled trial with a larger sample size. Given the results obtained by the RF5:2 intervention during this period, we have removed this intervention from the definitive study (NCT05580926). We also intend to use face-to-face rather than online sessions for the WWDH intervention, and remove the last individual session in the intervention group. Finally, considering the data from this pilot study (mean differences and SDs from WWDH and RF5:2, assuming that the RF5:2 group acted as a control group) and taking into account other published studies (Mason *et al*., 2018; Kaviani *et al*., 2019), it was possible to calculate a sample size of 64 participants for a definitive study (32 in each arm).

Among the strengths of our pilot study is that, to our knowledge, is the first randomized controlled trial seeking to prevent December holiday body weight gain remotely and during the COVID-19 pandemic. It is also the first in this period in a population outside of the United States of America and the United Kingdom. Among the limitations of our study was the presence of the uncertain pandemic outlook, which we believe strongly affected the retention of study participants which may have negatively affected the ability of the participants to adhere to the interventions, particularly the RF5:2 intervention. Likewise, the small sample size typical of a pilot or exploratory study could be taken as a limitation, but it fulfilled its purpose in proving that the intervention was feasible (while suggesting areas for improvement) and allowed the calculation of a sample size for a definitive study.

In conclusion, the results of this study showed that a trial aimed at preventing weight gain during the December holiday period is feasible in Mexican adults, having retained 78.1 % of the participants. It also showed that, while the WWDH intervention was promising, the RF5:2 intervention was not promising in Mexican adults during this period.

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CONFLICTS OF INTEREST

The authors declare that there is no support from any organization for the work presented; no financial relationship with any person who may have an interest in the work submitted in the previous three years; and there are no other relationships or activities that have influenced the work submitted.

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SUPPLEMENT 1

Interventions

The three different intervention arms are described below according to the guide and checklist of the Template for Intervention Description and Replication (TIDieR) (Hoffmann *et al*., 2014).

Watch Your Weight During the Holidays Program: This intervention group included self-monitoring strategies (self-weighing, diet monitoring and physical activity), and nutrition counseling and education. The nutritional consultation and education mainly sought to prevent weight gain during the holidays, by reporting nutritional needs according to their body composition, in addition to the use of digital materials that contained information on low-energy menus, "10 tips to lead a healthy lifestyle and how to self-monitor your weight, diet and physical activity." In addition, participants in this group received a weighing scale to achieve self-monitoring of body weight from the beginning of the study intervention until the end of the 8-weeks follow-up. Participants who completed the 8-weeks measurements received this weighing scale as gift.

The basis of this strategy was the theory of self-regulation. This theory mentions that the change in behavior occurs when the person monitors the current state of their own actions and compares them with a reference goal or "gold standard" established goal (Boutelle, 2006; Orehek *et al*., 2017). The difference between the two behaviors involves the participant in a "feedback loop", which adjusts their behavior to achieve the goal (Boutelle, 2006). When the person perceives that there are differences between the current and desired state, they begin to take actions to reduce them. For this, self-regulation obeys two basic processes: 1) The evaluation process, which occurs when the person makes comparisons, and 2) the locomotion process (actions to move forward) (Orehek *et al*., 2017). Establishing clear objectives is essential in the approach of self-regulation. Once goals are identified, the ability to track behavior, or self-control, becomes essential, as attention to internal and external cues leads to greater control of behavior. Self-monitoring of food intake, physical activity and weight are ways in which the participant can evaluate their own current behavior and compare it with a standard (Boutelle, 2006).

Systematic reviews show that self-regulation can be an effective strategy in preventing body weight gain. Also, they mention that the best way to impact prevention using this technique is with the implementation of low intensity interventions that incorporate face-to-face and non-face-to-face strategies (self-monitoring of weight and nutritional information) (Lemmens *et al*., 2008; Hutfless *et al*., 2013; Lombard *et al*., 2009).

The intervention took place during the last two weeks of the month of November 2021 until the first two weeks of the month of January 2022. During the intervention period, participants were offered one individual and one group Zoom video call session with a maximum duration of 30 minutes for each session, which were led by two of the members of the study staff (DEGM and TJMC). DEGM and TJMC have a bachelor's degree in Nutritional Sciences as well as a Master of Health Sciences degree. Between November 17 and 19 the participants were contacted in an individual video call to inform them of their assigned group and to give initial instructions about how to perform their self-monitoring strategies (self-weighing, diet monitoring and physical activity monitoring) and receive information about their nutritional status, in relation to their body composition. Also, in this individual session another individual session with a nutritionist was scheduled for one of the first two weeks of the month of January. In the group video call session (November 26) they were trained and given supplementary material with strategies for self-monitoring (body weight, diet, and physical activity), information on healthy lifestyles, as well as information about the energy contained in festive meals and their equivalent in minutes of physical activity or steps per day (Mason *et al*., 2018). In the case that any participant missed the group videocall session, a link to a video recording of the group session was sent by message via WhatsApp or e-mail.

It was recommended that participants weigh themselves at least twice a week, as a form of self-monitoring of weight, from the beginning of the intervention. Participants had access to weekly formats with boxes where they could fill in the data obtained for each day of self-monitoring of weight, report their energy restriction and minutes of physical activity. In addition, participants were encouraged to restrict the energy they consumed for at least two days of the week, in order to compensate in case that they overconsumed calories ("posadas" or various social meetings, Christmas, New Years, etc.). For this, the participants were informed about the recommended energy consumption according to their needs and were given printed menus with low calorie diets (1200 - 1600 kcal / day) to follow for at least two days of the week.

In the January individual session with the nutritionist, the participants with overweight were not denied weight loss counseling, if they requested it. This counseling used the same intervention pattern as described above. Both the group and individual sessions were implemented in a video call, using Zoom as a video call platform.

During December 7, 21 and January 4 participants had short contact through messages through WhatsApp, telephone texts, calls or e-mail with DEGM to talk about their adherence to the intervention, possible adverse effects that they were experiencing, or any other topic related to this study.

Relative 5:2 Fasting: Participants in this group received eating recommendations to follow 5:2 intermittent fasting. This intermittent fasting approach has been shown to be a potential strategy to avoid weight gain (Harris *et al*., 2018).

Intermittent energy fasting has two popular variants: 5:2 intermittent fasting and alternate days of fasting. One of the most common strategies is 5:2 intermittent fasting, which involves 5 days of regular food consumption (with ad libitum consumption patterns) exchanged with 2 consecutive or non-consecutive fasting days per week –maximum energy consumption of 500 kcal for women and 600 kcal for men– with a period without energy intake of 12 to 21 hours per day (Harris *et al*., 2018; Cioffi *et al*., 2018). In the context of the country where the intervention will take place, a fast, for most people, means not consuming the first meal of the day (breakfast or meal eaten before noon). This intervention group was named Relative Fasting 5:2 (referring to 5:2 intermittent energy fasting), and the participants in this group were able to decide whether their fast was before or after noon.

In studies of the management of obesity, it has been observed that using 5:2 intermittent energy fasting gives a weight loss similar to that obtained with conventional caloric restriction (hypocaloric diets) (Cioffi *et al*., 2018). In a meta-analysis of studies where intermittent fasting is compared with a group without weight loss treatment, a difference in body weight loss of 4.14 kg ± 2.16 kg (P <0.001) is obtained (Harris *et al*., 2018).

The mechanism of action of intermittent fasting for weight loss is not only in the pronounced energy restriction on days with calorie restriction, but is also found in the production of ketone bodies in the liver from fatty acids as a result of spending more than 10 hours without energy intake (de Cabo y Mattson, 2019). These ketone bodies are not only used for energy production purposes for some tissues and organs, but also act as powerful signaling agents in cells and functions of different organs. It is believed that one of the functions of ketones is to regulate appetite. However, the mechanism of action remains uncertain (de Cabo y Mattson, 2019; Liu *et al*., 2020).

This intervention group included one individual session between November 17 and 19 and a group video call session on November 26, with a maximum duration of 30 minutes each. The sessions were led by the same two members of the study committee (DEGM and TJMC).

As in the aforementioned group, during the first individual video call session, participants scheduled an additional individual meeting with a nutritionist for between January 3 and 14.

In the group session the participants received information on how to perform the 5:2 relative fasting. They were given low-calorie menus of 550 kcal and 660 kcal, for women and men respectively, which were to be applied on fasting days, as has been done in similar studies (Cioffi *et al*., 2018). The composition of the macronutrients in the diet were in accordance with the recommendations of a healthy diet (Great Britain Panel on Dietary Reference, 1991). The fasting was held twice a week and on the remaining five days, the participants did not have any type of energy restriction (it was ad libitum). They only received the general recommendation to adhere to a healthy dietary pattern.

As in the previous intervention group, the individual video call session with the nutritionist followed the group approach (Relative Fasting 5:2). Participants with overweight were not denied weight loss counseling at these sessions if requested. In cases where guidance was requested, it followed the same themes as this intervention group. Both the group and individual sessions were implemented in a video call, using Zoom as the video call platform.

Like the previous group, participants in this group received three short contacts through WhatsApp messages, telephone texts, calls or e-mail with DEGM to talk about their adherence to the intervention, possible adverse effects that they were experiencing, or any other topic related to this study. These short contacts were scheduled for December 8, 22, and January 5.

Control group (minimal intervention): Participants in this group received online information and a PDF file brochure during an individual video call session at the beginning of the 8-week period (from DEGM). This information was about leading a healthy lifestyle. In addition, the brochure contained information on healthy eating based on the Mexican Standard for health promotion and education for healthy eating in Mexico (NOM-043-SSA2-2012) (Norma Oficial Mexicana, 2013). Apart from this, participants in this group did not receive any contact with interventionists in our study. The only additional contact they had with a member of the project committee (DEGM) was to schedule the measurements corresponding to 8 weeks.

Explanation for choosing the comparator

Due to our interest in evaluating the effect, feasibility, and acceptability of two interventions that had not been previously evaluated in terms of their intensity, components and population, the control group received a much less intensive intervention, but with positive components for the health of the participants. In several previous studies in the area, very low intensity interventions have been used as comparators (Mason *et al*., 2018; Kaviani *et al*., 2019; Hirsh *et al*., 2019).

General proceedings and recommendations

The three individual measurement sessions were in person at the Nutrition Health Promotion Center located on the ground floor of the 7J building of the School of Nutritional Sciences of the University of Sonora.

In all interventions, participants were recommended to perform at least 150 minutes of physical activity a week. During the 8-week period, participants in any of the intervention groups were told to avoid following interventions with an effect on body weight unrelated to those in their study group. In case of presenting conditions during the intervention period that required immediate action on body weight, they were not contraindicated but participants were requested to declare them to the project committee. However, during the same 8-week period, they were able to exercise or improve their diet on their own initiative if they so wished

(without support from healthcare providers, health professionals, nutritional coaches, personal trainers, etc.). Once the period of measurements at 8 weeks of the participants in each intervention group had concluded, the participants were able to perform any other change or activity with an effect on body weight that could benefit their health. These changes or activities other than the interventions delivered could be made accompanied or not by a health care professional.

Criteria for discontinuing the intervention

Those participants who presented a medical condition or received any treatment that had significant implications on body weight during the protocol, who received any intervention outside the protocol during the 8 weeks of the Holidays, or who decided to abandon the intervention or withdrew their informed consent were discontinued from the intervention.

Program cost

Participants did not pay for the program. Patient materials for intervention sessions or individualized nutrition sessions when applicable were provided free of charge. Participants were only responsible for buying the foods for their diet.

Measurements of the study variables

For all face-to-face measurements, COVID-19 recommendations for medical appointments were followed. For this scenario, WHO suggested collecting all possible data by telephone or other non-face-to-face means. If a visit was necessary, it was recommended to have disinfectant gel, medical or surgical masks for all study participants, respect the distance between people, take care of ventilation and avoid agglomerations (Organización Mundial de la Salud, 2020).

Following the above recommendations, participants were measured for primary and secondary variables using a combination of face-to-face measurements and online forms during the first two weeks of November for baseline measurements. Afterwards, the variables were measured again, following the same recommendations, at the end of the 8 weeks intervention. These measurements were conducted during the last two weeks of January.

For each of the measurements, the participants were required to fast for 8 to 12 hours and to have at least 2 hours without water intake, for body composition and body size measurements, preferably with empty intestines and bladder. In addition, participants were instructed to not perform vigorous physical activity during the 24 hours prior to measurements.

Data collection methods

The study measurements took place during the initial phase, and at 8 weeks at the Nutrition Health Promotion Center (assessed by TJMC) and the Clinical Biochemistry Laboratory of the University of Sonora (obtained by ALMP), by outcome assessors from our research team (blinded to group assignment). Due to the pandemic of COVID-19, the measurements body weight, body size, blood pressure, and collection of the blood sample took place in the Nutrition Health Promotion Center and the Biochemistry Laboratory of the University of Sonora, following the above WHO recommendations for face-to-face medical appointments. The paper forms for health-related quality of life, scales of satisfaction, adherence to intervention and sociodemographic information were obtained in the outdoors space near the Nutrition Health Promotion Center.

Primary measurement

Body weight. It was measured with a digital SECA scale, model 284 (Seca Gmbh & Co. Hammer Steindamm 9-25, Germany, capacity 300 ± 0.05 kg) following a standard technique (Cameron N, 2004).

Secondary measurements

Body fat. Was estimated with a SECA MBCA electrical bioimpedance equipment (Medical Body Composition Analyzer, SECA gmbh & Co. Kg Hammer Steindamm 9-25).

Body size measurements. Height was measured with a SECA stadiometer, model 284 (Seca Gmbh & Co. Hammer Steindamm 9-25, Germany, Capacity 30-220 cm). The waist circumference was measured at the umbilical level with a fiberglass anthropometric tape (GÜLICK, 0 to 150 cm) (Cameron N, 2004).

Blood pressure. Measurement was performed in duplicate using a digital sphygmomanometer (Omrom, model HEM-907XL) following the technique proposed by the American College of Cardiology (ACC) / American Heart Association (AHA) (Whelton *et al*., 2017).

Analysis of biochemical parameters. The biochemical parameters to be measured were the following: fasting glucose, total cholesterol, LDL cholesterol, HDL, triglycerides. The biochemical parameters tests of the study were conducted in the Laboratory of Clinical Biochemistry of Medicine of the University of Sonora using standardized techniques (RANDOX®, Crumlin, UK).

Health-related quality of life. It was evaluated with the SF-36 survey (Zúniga *et al*., 1999).

Percentage of retention / attrition of participants. The retention percentage was obtained by dividing the people who attended for the 8-week measures among those who started the intervention multiplied by 100. The dropout percentage was obtained by the difference in the number of subjects who started and finished the intervention divided by the number of subjects who started the intervention.

Other measurements

Sociodemographic variables. Sociodemographic variables measured included: age, gender, employment and marital status, educational level and approximate monthly household income. These were measured using a questionnaire through a video call.

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