



Applied nutritional investigation

Longitudinal effect of nutritional intervention on body weight: A randomized controlled trial

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ARTICLE INFO

Article History:

Received 22 December 2020

Received in revised form 16 July 2021

Accepted 19 July 2021

Keywords:

Weight loss

Obesity

Fruit

Vegetables

Intervention studies

Primary health care

Patient adherence

ABSTRACT

Objectives: This study evaluates, in the medium and long term (12, 36, and 48 mo), the effect of an intervention to promote consumption of fruit and vegetables on the body weight of Brazilian primary health care users.

Methods: A follow-up with participants ($n = 3414$) in a controlled randomized trial was performed in a primary health care service. Those in the control group performed the service's usual intervention (guided physical exercise 3 times/wk), and those in the intervention group additionally participated for 7 mo in collective activities to promote consumption of fruit and vegetables. Sociodemographic, health, and body weight data were collected by face-to-face interview at baseline and after 12 mo. At 36 and 48 mo, weight was obtained by telephone interview and was validated. Adherence to the intervention was assessed by the presence of the actions. Weight change (Δ) was measured by subtracting the weight at each follow-up time from the baseline measurement.

Results: Participants in both groups had a minor weight loss of about 0.1 kg over 12, 36, and 48 mo. The addition of an intervention for consumption of fruit and vegetables did not enhance this effect. Higher weight loss was observed in individuals with obesity classes II and III with low adherence in the intervention and after 36 mo ($\Delta = -27.1$ kg; $P = 0.024$).

Conclusions: Participating in the primary health care service contributed to a small reduction in weight, and the intervention for consumption of fruit and vegetables did not enhance this effect. However, greater weight loss was observed in participants with obesity and those who adhered to the intervention.

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Author contributions—A. C. S. L.: conceptualization, data curation, funding acquisition, investigation, methodology, project administration, supervision, designed the research, conducted the research, wrote the original draft, reviewed and edited the article. M. S. L.: data curation, designed the research, investigation, wrote the original draft, reviewed and edited the article. C. K. D.: reviewed and edited the article. P. P. F.: conceptualization, data curation, investigation, methodology, supervision, designed the research, conducted the research, formal analysis, wrote the original draft, reviewed and edited the article.

Many thanks to the Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG; APQ-00585–17, PPM-00254–15, and APQ-033376–12) and Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq; 476686/2013–0; 408136/2017–0 for research; 302978/2018–6 and ACSL productivity grant) for supporting this study. This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES)—Finance code 001. The Ministério da Saúde financed the English revision (25000.171114/2019–82). The financial support agencies had no involvement in the study design; in the collection, analysis, or interpretation of data; in the writing of the report; or in the decision to submit the article for publication. None of the authors had a personal or financial conflict of interest.

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Introduction

The world has witnessed a progressive and major increase in overweight and obesity in recent decades. Since 1980, the prevalence of obesity has doubled in more than 70 countries and has continuously increased in most other countries. In 2015, obesity affected 603.7 million adults, and high body mass index (BMI) accounted for 4.0 million deaths globally [1].

Primary health care is an ideal setting for the clinical management of obesity because weight management may require a shared sense of decision making, including the expertise of professionals from different areas. However, studies in this scenario are scarce. Multibehavioral interventions should be proposed in primary health care, and they should involve aspects that contribute to reducing energy intake and increasing energy expenditure, such as changes in diet and exercise [1–4].

Prevention and management of obesity and overweight are still challenges for health services. However, the loss of 5% to 10% of

body weight has been shown to be sufficient for reducing the risk of multiple obesity-related medical complications, such as diabetes and cardiovascular disease, and for improving overall psychological health [5,6].

In a systematic review, the approaches most applied to weight loss were energy restrictions and changes in macronutrient distribution [4]. In that direction, one potential dietary strategy is eating at least five daily portions of fruits and vegetables (FV) [2]. A study carried out with users of primary health care showed that an increase of 100 g/d of FV represented a body weight loss of 300 to 500 g after 6 mo [7]. In another study, weight change was significantly correlated with higher proportions of energy consumed from vegetables [8]. FV are low-energy-density foods and can favor weight reduction when they replace foods in the diet with higher energy density. Promotion of FV consumption can also favor changes in other behaviors that favor weight reduction, such as reducing consumption of sweetened drinks, sugar, and fast food [9]. Moreover, increased vegetable intake has been associated with reduced weight gain and reduced overweight or obesity in cohort studies [10].

Another promising strategy is the regular and targeted practice of physical activity [2]. Better weight loss results connect physical activity and dietary strategy with theory-based interventions [4]. Intervention studies have yielded positive results, but sometimes the results are not yet replicable in health care services, and few of the studies evaluate long-term changes [11]. In addition, it is still necessary to understand whether an intervention to promote adequate and healthy eating is capable of producing long-term weight loss.

The individual's behavior can be the key to the effectiveness of a long-term intervention [4]. Thus, behavior-change theories have been proposed as important tools to help participants achieve healthier behaviors, deal with their obstacles, change attitudes, and contribute to sustainable weight loss [4,12]. However, such studies are usually developed far from the participants' reality, which compromises the sustainability of the results.

So this study hypothesized that promoting FV intake with behavior-change theories could improve weight loss in individuals with obesity, and that the beneficial results could be seen in the long term. Therefore, we aimed to examine the longitudinal effects after 12, 36, and 48 mo of an intervention to promote FV consumption in body weight change in participants in Brazilian primary health care service.

Materials and methods

Study design and setting

This study was a 48-mo follow-up with participants in the Fruit and Vegetable Randomized Controlled Community Trial, conducted between 2013 and 2017 to encourage FV consumption in a representative sample of Brazilian health care service users in Belo Horizonte.

The Brazilian public health system offers various health services, including the Programa Academia da Saúde ([Health Academy Program] PAS). The PAS, the scenario of this study, offers actions to promote health, such as physical activity, at no cost to participants [13]. More than 2900 Brazilian municipalities have a PAS unit. The units are spaces with infrastructure, equipment, and human resources for the health-promotion actions, located primarily in vulnerable areas. With a goal of expanding good health, the PAS has adapted its services to local territories and adopted guiding values including autonomy and social participation. All education actions offered are conducted by primary care professionals [13].

The study was conducted in the PAS unit of Belo Horizonte, Brazil, the eighth-largest city on the South American continent, with an estimated population of 2.5 million inhabitants and a high Human Development Index value (0.810) [14]. Since 2006, the routine activities of the PAS in Belo Horizonte are physical exercises guided by a physical education instructor for 60 min, 3 times/wk [13].

Randomization and participants

The PAS units were selected via simple and stratified sampling in each stratum representing the nine administrative districts of the municipality. The inclusion

criteria for the PAS units participating were that they must be open in the morning and located in an area of medium or high vulnerability to health problems, as these constitute the predominant period and focus of operation of PAS in the municipality; they must not have been the subject of research related to food and nutrition in the previous 24 mo; and they must have been operating in November 2012, the period of the sampling process [15].

Of 50 units operating at the time of the study, 42 were found to be eligible, and 18 were selected for the study—two in each stratum, paired according to health vulnerability. After eligible units were selected, the PAS allocation group was selected using a list of random numbers. The sample comprised nine units in the control group (CG) and nine units in the intervention group (IG). The selected units were representative of medium- and high-vulnerability areas in the municipality, with a reliability of 95% and an error of less than 1.4%. More details regarding the sampling process have been given by Menezes et al. [15].

All PAS users who met the following inclusion criteria were invited to participate in the study: age 20 y or older and habituated to the activities within the PAS (participation in physical exercise in the preceding month). The exclusion criteria included pregnancy and cognitive impairment [15].

This type of intervention did not allow for blinding of participants and investigators; but the intervention was performed by all participants in the units of the IG. In all analyses, participants were kept in their original groups.

Theory-based intervention

Participants in the CG took part in the service's routine activities, including 1-h physical-activity sessions held 3 times/wk and led by a physical-education professional. The users in the IG participated in the same activities as in the CG, but they also participated for 7 mo in the intervention to promote FV intake based on the transtheoretical model and problematizing-dialogic pedagogy of Paulo Freire. During these 7 mo, participants in the CG did not receive any intervention specific for FV consumption [16].

The transtheoretical model facilitates planning and implementing actions according to individual characteristics, including perception, readiness, attitude, and motivation to undergo behavioral changes [17]. Problematizing-dialogic pedagogy by Paulo Freire was used to advance the transtheoretical model and advocate empowerment and autonomy, as proposed in the PAS [18]. In this proposal, education creates the possibility of liberation, promoting conscientious attitudes and presuming a horizontal and dialogical relationship [19].

The transtheoretical model incorporates four pillars: stages of change, change processes, self-efficacy, and decisional balance. For development of the actions in primary care to be feasible, the participants were grouped by the stages of change in FV consumption: Preaction (precontemplation and contemplation stages in three groups: individuals are not ready to change but require action to shape their motivation); Preparation (or determination stage: individuals are ready to change their behavior within 30 d); and Action (action and maintenance stages: individuals are capable of short, immediate changes, but the prevention of relapse and consolidation of gains are required) [17].

The interventions were constructed according to each grouping and using the other components of the transtheoretical model [16]. Five cognitive and five behavioral processes of change were used to understand how change occurs in stages. The interventions aimed to increase individuals' confidence in their ability to achieve the desired behavior when faced with obstacles (self-efficacy) and to increase awareness of the benefits of a healthy diet while minimizing the factors against change (decisional balance) [12].

In the Preaction and Preparation groups, we used processes of change predominantly based on cognitive changes to increase motivation and awareness about nutritional challenges. Educational activities were focused on increasing awareness of behavior and its consequences in the Preaction group. Strategies such as conversation circles, image theater, and self-portraits were used. The Preparation group focused on the signification of feelings, sensations, and thoughts related to health. In this group, the participants elaborated a plan of action to promote FV consumption. In the Action group, we focused on processes of change related to behavioral changes, including more detailed guidance on nutrition concepts [12]. The activities favored individuals' skills in changing long-term behavior and facing new difficulties, encouraging the maintenance of gains and preventing relapse. For this, we used strategies that involved cooking, social support, and the development of the ability to face new difficulties [12].

The following educational strategies were used: workshop, motivational message via postcard, telephone calls to invite participants to and remind them of group sessions, environment-based activity (particularly those concerning interactive activity in the setting, e.g., movies and culinary), education panels, and delivery of informative material [16]. These strategies had the purpose of boosting critical and problematizing thinking about concrete situations of life and existence. The intervention consisted of four group educational sessions, three postcards, and three environment-based activities for each group, plus one handout of informative material. To monitor attendance, we recorded the names of all participants taking part in each of the strategies. We sent workshop invitations to the participants in writing and via phone calls. The workshops and environment-based

activities were carried out in groups of up to 20 participants. Thus, to involve all participants in each PAS unit, activities were repeated as many times as necessary.

The theory-based intervention was planned by an interdisciplinary team comprising nutritionists, educators, and psychologists. It was performed by a team of three dietitians, who alternated between application and observation of the process, always aided by at least three graduate students in nutrition. More information regarding the nutritional intervention has been given by Menezes et al. [15].

Assessment of variables

Data at baseline and 12 mo were obtained from face-to-face interviews. In the 36- and 48-mo follow-ups, participants were interviewed by telephone. All interviews were performed by dietitians and students who were not on the intervention team.

The baseline questionnaire included sociodemographic information (sex, age, income, education, occupation, and marital status), health information (diabetes, hypertension, treatment of depression, smoking, health self-perception, body satisfaction, physical activity, stage of change), attempt to lose weight, and anthropometry (weight and height). At 12, 36, and 48 mo, we evaluated income, attempt to lose weight, and weight, which was validated [16].

Stages of change for FV intake (precontemplation, contemplation, preparation, action, and maintenance) were assessed using an algorithm proposed by Kristal et al. [20] and adapted in Brazil by Toral et al. [21]. For the analysis, the stages of change were grouped according to the performance of the nutritional intervention: Preaction (precontemplation and contemplation stages), Preparation, and Action (action and maintenance stages).

BMI was calculated by dividing the participant's measured weight at baseline and 12 mo or self-report at 36 and 48 mo (in kilograms) by the square of their measured height (in meters). Nutritional status was categorized as normal weight ($BMI \geq 18.5$ and $< 25.0 \text{ kg/m}^2$), preobesity ($BMI \geq 25$ and $< 30 \text{ kg/m}^2$), class I obesity ($BMI \geq 30$ and $< 35 \text{ kg/m}^2$), class II obesity ($BMI \geq 35$ and $< 40 \text{ kg/m}^2$), and class III obesity ($BMI \geq 40 \text{ kg/m}^2$) [22].

Adherence to the intervention was assessed by dividing the number of actions completed by the number of actions offered. Participation was computed with a record of the presence of each participant at the different activities. Adherence was classified as low ($\leq 30\%$; one to three actions), medium ($31\text{--}70\%$; four to seven actions), or high adherence ($> 70\%$; eight to eleven actions) [23].

Outcome measurements

Anthropometric assessments were conducted without coats and shoes. Weight was measured with a digital scale at baseline and 12 mo afterward. Participants' height (in centimeters) was measured using a wall-mounted stadiometer at baseline.

At 36 and 48 mo, participants were interviewed by telephone to self-report weight. Self-reported weight was valid for men and corrected for women, according to factors related to greater error [24].

The outcome was the differences obtained for body weight during the follow-up (Δkg). Weight change was assessed by subtracting the weight at each of the follow-up evaluations from baseline—for example, weight change (Δkg) at 12 mo = weight at 12 mo – weight at baseline. Changes were also evaluated as weight change percentage ($\Delta\%$)—for example, weight change percentage at 12 mo = (weight at 12 mo – weight at baseline) $\times 100$ / weight at baseline. Thus, a negative change indicated weight loss and a positive change indicated weight gain.

Statistical analysis

Mean \pm SD was calculated for all continuous variables, and frequency was used to describe qualitative variables. Differences between groups (IG and CG) for socioeconomic and health variables were evaluated using the independent sample *t* test and χ^2 test. Differences in adherence to nutritional intervention according to nutritional status were also verified using the χ^2 test.

Regression imputation was used to estimate missing data for body weight using the information from individuals (sex, age, education, and other weight measures). We do not use estimated information from one follow-up in calculations for the next follow-up interview, to avoid a possible systematic proliferation of errors. The estimated weight value for missing information was calculated as the average of 10 random values estimated by the imputation package in Stata. The imputed values for weight were compared using the mean \pm SD and the probability density distribution. The final result was satisfactory, without major differences between follow-up reporting and the probability distribution before and after imputation.

For intragroup analysis (within group), multiple linear regression models were used, with the outcome measures of weight change at different follow-up times (12, 36, and 48 mo). The models were adjusted for age, sex, education, recent weight-loss attempt and baseline weight. All models were estimated a second time following the same methodological procedures for each category of nutritional status (normal weight; preobesity; obesity class I; obesity class II and III).

The percentage of adherence to the nutritional intervention was verified according to nutritional status. Differences were tested using the χ^2 test.

To analyze the intervention's effectiveness for weight change, in intergroup (between groups) analysis we estimated multiple linear regression models, having as an outcome the measures of weight change at different follow-up times (12, 36, and 48 mo). The models were adjusted for age, sex, education, recent weight-loss attempt, baseline weight, and interaction between group and baseline weight. The models contained the indicator variable for group (CG or IG).

All models were estimated for a second time following the same methodological procedures, but now the indicator variables were CG and the different treatment categories according to adherence (low, medium, high). Finally, all previous models were repeated for each category of nutritional status (normal weight; preobesity; obesity class I; obesity class II and III), measured at baseline, aiming to show the weight change according to the initial nutritional status of the individuals, after participation in the FV consumption intervention.

From the estimated models, we verified the normality and heteroscedasticity of the residuals. When the residue was heteroscedastic, we applied residual correction (White). All models were also tested for multicollinearity.

Statistical significance was attributed when *P* values were less than 0.05. Analyses were performed using Stata 14.0. The hypotheses were specified before the data were collected. The analytical plan was prespecified, and any data-driven analyses are clearly identified and discussed appropriately.

This study was conducted according to the guidelines laid out in the Declaration of Helsinki, and all of the procedures involving human subjects were approved by the ethics committees of the university (ETIC 0339.0.203.000–09) and the City Hall (0339.0.203.000–09A). Written informed consent was obtained from all participants. The trial is registered with Brazilian clinical trials under RBR-8t7ssv.

Results

The baseline characteristics of the participants in the CG ($n = 1931$) and the IG ($n = 1483$) were not significantly different, except for age, income, and education. The average age was 56.7 ± 11.8 y, 88.1% of participants were women, 56.0% were not satisfied with their own body, and over 60.0% reported attempts at weight loss at baseline. Mean BMI was 37.8 kg/m^2 at baseline; 28.3% were classified with normal weight, 39.6% with preobesity, 20.1% with class I obesity, and 11.9% with class II or III obesity (Table 1).

Figure 1 shows that 78.0%, 68.5%, and 60.0% of CG participants completed 12, 36, and 48 mo of follow-up, respectively. For the IG the retention rate was 69.6%, 68.0%, and 60.9% at each of the follow-up times, respectively. Differences per group were observed in retention rate only at the first reevaluation (at 12 mo, $P < 0.001$; at 24 mo, $P = 0.088$; at 36 mo, $P = 0.2975$).

The adherence to nutritional intervention varied according to nutritional status. The highest proportion of individuals with high adherence was observed in participants with normal weight (51.1%). On the other hand, a greater proportion of individuals with a lower adherence rate was seen in obesity class II or III (39.4%; Fig. 2).

The intragroup comparison showed a minor negative change in weight over the follow-up term in both groups. This small change in weight was observed at all follow-up times for participants in the CG with normal weight or obesity at baseline. For the IG, weight reduction was observed only for those with class II or III obesity at 36 and 48 mo of follow-up (Table 2).

The intergroup comparison showed no difference in weight between the CG and the IG after 12, 36, and 48 mo of follow-up (Table 3).

In Tables 4 and 5, the results of the models are presented for each category of nutritional status, measured at baseline (normal weight, overweight, class I obesity, class II or III obesity), aiming to show weight change according to nutritional status at baseline and adherence to the FV consumption intervention.

Nutritional status at baseline implied different results after 12, 36, and 48 mo of follow-up. Table 4 shows that only individuals with normal weight and with medium adherence to the intervention presented significant weight reduction at 12 mo. On the other hand, individuals who participated in the intervention, had high

Table 1
Comparison of the baseline characteristics of the control and intervention groups, Fruit and Vegetable Randomized Controlled Community Trial, Belo Horizonte-MG, Brazil, 2013–2017

Variable	Total (n = 3414)		Control (n = 1931)		Intervention (n = 1483)		P*
	n	Value	n	Value	n	Value	
Age (y)	3414	56.7 ± 11.8	1931	57.0 ± 11.3	1483	56.2 ± 12.2	0.029
Education (y)	3412 [†]	7.2 ± 4.1	1930	7.5 ± 4.1	1482	6.9 ± 4.1	<0.001
Income per capita (\$)	3116 [†]	442.3 ± 405.2	1761	463.3 ± 411.8	1355	414.9 ± 395.0	<0.001
Sex							0.084
Female	3007	88.1	1717	88.9	1290	87.0	
Male	407	11.9	214	11.1	193	13.0	
Marital status							0.714
Married	2102	61.6	1196	62.0	906	61.1	
Divorced	283	8.3	151	7.8	132	8.9	
Single	483	14.1	272	14.1	211	14.2	
Widowed	545	16.0	311	16.1	234	15.8	
Occupation							0.131
Housewife	979	28.7	553	28.6	426	28.7	
Retired or pensioner	1253	36.7	710	36.8	543	36.6	
Unemployed	68	2.0	29	1.5	39	2.67	
Employed	1113	32.6	638	33.1	475	32.0	
Health self-perception							0.863
Very poor/poor/regular	966	28.3	544	28.2	422	28.5	
Good/very good	2447	71.7	1386	71.8	1061	71.5	
Diabetes							0.653
No	2831	83.1	1598	82.8	1,233	83.4	
Yes	576	16.9	331	17.2	245	16.6	
Hypertension							0.575
No	1598	46.8	912	47.3	46,29	46.3	
Yes	1,814	53.2	1018	53.7	796	53.7	
Treatment for depression							0.275
No	2744	80.5	1541	79.8	1203	81.3	
Yes	665	19.5	389	20.2	276	18.7	
Smoking							0.130
No	3220	94.3	1831	94.9	1389	93.7	
Yes	193	5.6	99	5.1	94	6.3	
Body satisfaction							0.902
Not satisfied	1913	56.0	1080	56.0	833	56.2	
Satisfied	1500	43.9	850	44.0	650	43.8	
Recent weight-loss attempt							0.204
No	1332	39.0	771	40.0	561	37.8	
Yes	2080	61.0	1158	60.0	922	62.2	
Stage of change							0.141
Precontemplation or contemplation	592	17.4	313	16.2	279	18.8	
Preparation	1209	35.4	694	36.0	515	34.7	
Action or maintenance	1611	47.2	922	47.8	689	46.5	
Physical activity (min/wk)	3276 [†]	209.3 ± 79.6	1852	208.2 ± 77.1	1424	210.8 ± 82.6	0.352
Nutritional status							0.855
Normal weight	968	28.3	555	28.7	413	27.8	
Preobesity	1352	39.6	755	39.10	597	40.3	
Class I obesity	688	20.2	395	20.46	293	19.8	
Class II or III obesity	406	11.9	266	11.7	180	12.1	

Values are expressed as mean ± SD or percentage

*Between-groups comparison: Student's *t* test for continuous variables and χ^2 test for categorical variables.

[†]Two missing data for education; 4278 missing for income per capita; and 138 missing for physical activity.

adherence, and were in class I of obesity at baseline showed greater weight reduction. Already for those with class II and III obesity at baseline, weight reduction varied according to the degree of adherence to the intervention and the follow-up time (Table 5).

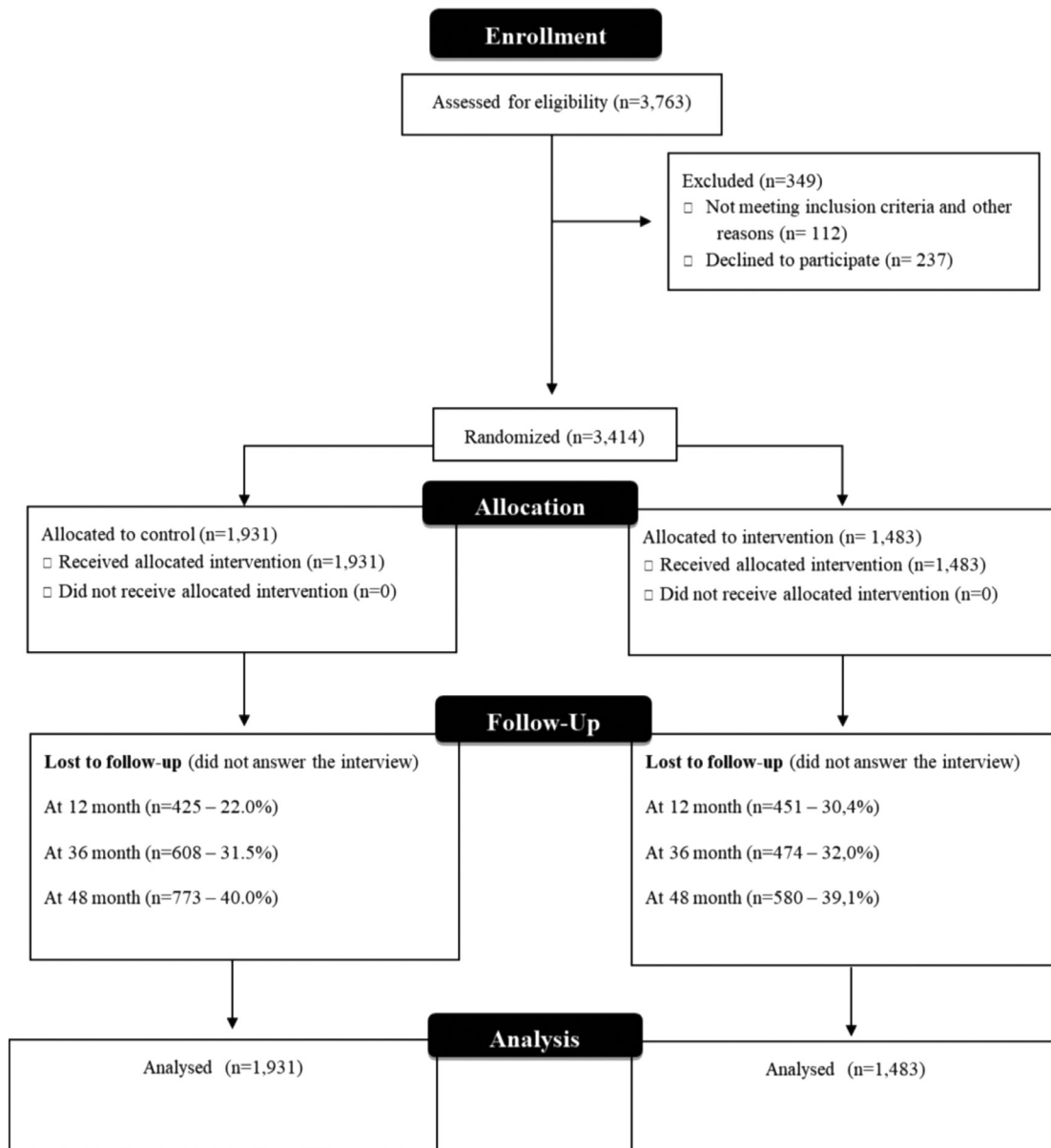
Discussion

An ongoing exercise intervention offered to health care primary users induced a minor weight loss, and an intervention to promote FV consumption did not enhance this effect for participants in general. However, the body weight loss over time occurred differently according to the initial nutritional status of the individuals and their adherence to the intervention.

To our knowledge, this is the first longitudinal study to evaluate the effect of an intervention performed at a primary health care

service, based on the readiness for change, at different times of follow-up (12, 36, and 48 mo). The small weight change observed during the follow-up in both groups shows the potential of physical exercise in primary care. Participants from the CG and the IG were users of a health service that offers physical exercises 3 times/wk for 60 min. Physical exercise helps to promote weight loss [25], especially because it improves physical fitness [26].

Promoting physical exercise in primary health care results in multiple benefits. In addition to the more active routine, users report better health perceptions, reduced use of medications, and improved eating habits. It is believed that once they are participating in health promotion programs, people can significantly increase their chances of adopting healthy lifestyles for the sake of their well-being [27–29]. Participation in the service was also important in preventing users from gaining weight. The



Note: PAS = Programa Academia da Saúde, in Portuguese.

Fig. 1. Flow diagram of the Fruit and Vegetable Randomized Controlled Community Trial. Belo Horizonte-MG, Brazil, 2013 to 2017.

prevalence of obesity has been increasing all over the world [30,31]. Therefore, actions to promote health and control chronic non-transmissible diseases that act on risk factors are important [2,31].

The intervention to promote FV consumption did not increase the reduction in body weight for all participants. The intervention's effect on weight change was different according to nutritional status at baseline and adherence. Another intervention study carried out with obese individuals in the PAS showed a reduction of 1.4 kg after 6 mo of individual nutritional intervention for weight loss [32]. Depending on baseline nutritional status and adherence to the intervention, there is a verifiable weight reduction ranging from 1.9 to 27 kg, reaching up to 27% of initial body weight. A review study of weight-loss interventions showed an average reduction of 5% (or 4–5 kg) in body

weight, and trials using cognitive therapy and motivational interviewing showed decreases greater than 10% [4]. Weight loss $\geq 5\%$ in individuals with obesity induces favorable changes in numerous cardiovascular risk factors and improves the quality of life [5,8,9].

The differences in weight change by baseline nutritional status may be a reflection of the focus on weight change, which may be greater in people with a higher degree of obesity than in those who are preobese. However, this hypothesis needs to be tested. In addition, specific characteristics of participants with different nutritional status can explain the observed effect. To better understand these possible differences, we described the sociodemographic characteristics according to nutritional status in the supplementary material. It is worth mentioning that in order to minimize these possible effects, the analyses were adjusted for individual characteristics (sex, age,

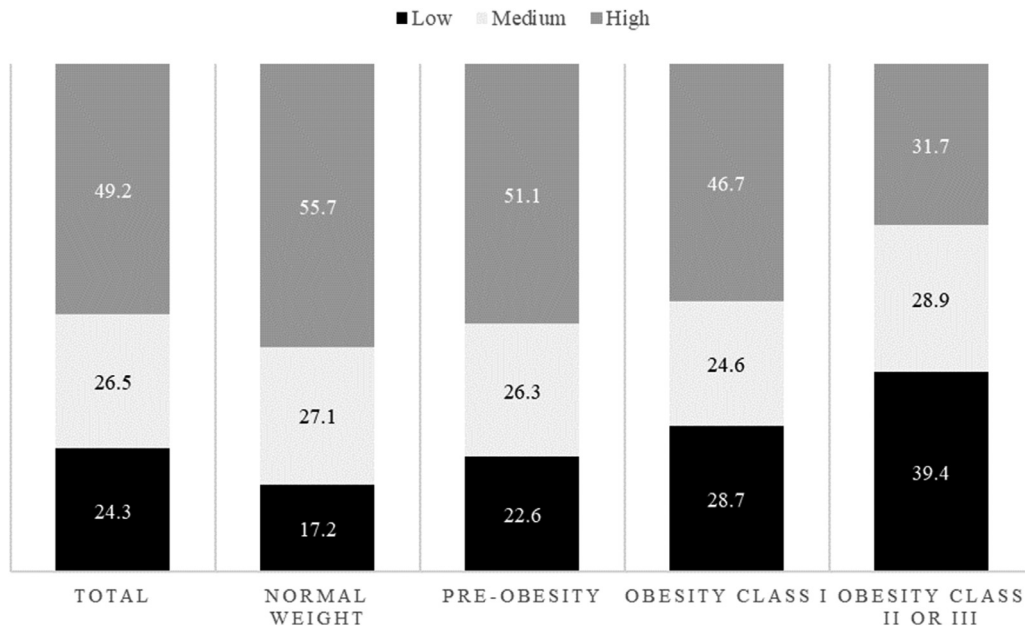


Fig. 2. Adherence to the nutrition intervention according to nutritional status, Fruit and Vegetable Randomized Controlled Community Trial, Belo Horizonte-MG, Brazil, 2013–2017. Low adherence, $\leq 30\%$ participation; medium adherence, 31–70% participation; high adherence, $> 70\%$ participation. $\chi^2: P < 0.001$.

and education), including a recent attempt at weight loss assessed at each of the follow-up times.

Our results show how individuals with higher levels of obesity could benefit from group interventions to promote adequate and healthy food habits. The results reinforce that the effect of behavioral interventions on body weight is slow; it needs to be assessed in follow-up and reinforced by actions of encouragement to result in better adherence and better weight-loss results. Previous studies have often shown that the effect on weight loss is stronger during the intervention and then gradually decreases—that is, weight is being partially regained [33,34]. These findings are typically from studies that use intensive programs for weight loss, with caloric restriction, dietary prescription [33], or formula-based diets [34]. However, for adults with obesity, it is important to consider various options for nutritional intervention, and they must be flexible [35]. Our intervention did not prescribe any diet. We worked on concepts and healthy eating practices that can contribute to reducing non-chronic diseases. As we said earlier, strategies such as promoting adequate and healthy food can have long-term results [36].

However, there is still little evidence on the long-term effect of this type of intervention, and further studies are needed [35].

Another important aspect of this study is its performance within a public health service. Even after the end of the intervention, users could continue to participate in the guided physical exercise and health-promotion activities of the PAS. Continuity of intervention is not common in most trials [4]. This can enhance new changes in the long term and support the maintenance of healthy behaviors.

Adherence to nutritional interventions can vary from 22.7% to 56.0% [18,28,33,34]. In this study, most participants showed high adherence ($> 70\%$) to the intervention. One previous publication that assessed the barriers and facilitators of adherence to the intervention showed participants reporting that the development of the intervention in the service routine was a facilitator for adherence. Issues such as living next to the health care service and the strategy offered, preferably in the habitual time of attendance, were reported as facilitators [23]. The methodology used in the intervention was also differential, according to participants. The highlighted aspects were the form of an

Table 2

Change in weight by group after 12, 36, and 48 mo of follow-up, Fruit and Vegetable Randomized Controlled Community Trial, Belo Horizonte-MG, Brazil, 2013–2017

Variable	Control											
	Weight change (Δ kg)						Mean weight change (%)					
	12 mo	P	36 mo	P	48 mo	P	12 mo	P	36 mo	P	48 mo	P
Effect*												
Total	-0.108	<0.001	-0.097	0.001	-0.097	<0.001	-0.111	<0.001	-0.129	<0.001	-0.148	<0.001
Normal weight	-0.046	0.018	-0.003	0.166	-0.042	0.197	-0.106	0.005	-0.128	0.006	-0.173	0.005
Preobesity	-0.023	0.204	-0.012	0.583	-0.032	0.250	-0.030	0.251	-0.057	0.077	-0.089	0.019
Class I obesity	-0.052	0.055	-0.074	0.024	-0.093	0.007	-0.054	0.082	-0.113	0.006	-0.128	0.002
Class II and III obesity	-0.237	0.004	-0.207	0.027	-0.154	0.009	-0.199	<0.001	-0.182	<0.001	-0.149	<0.001
Intervention												
Effect*												
Total	-0.050	<0.001	-0.066	<0.001	-0.077	<0.001	-0.070	<0.001	-0.123	<0.001	-0.141	<0.001
Normal weight	-0.006	0.830	-0.053	0.136	-0.030	0.381	-0.039	0.434	-0.184	0.013	-0.149	0.014
Preobesity	0.002	0.916	-0.012	0.675	-0.026	0.333	-0.008	0.772	-0.064	0.125	-0.089	0.021
Class I obesity	0.037	0.296	0.021	0.650	0.018	0.703	0.052	0.238	0.003	0.954	0.000	0.999
Class II and III obesity	-0.072	0.085	-0.076	0.032	-0.108	0.008	-0.096	0.024	-0.101	0.004	-0.144	0.001

*Estimated effect on body weight in the intragroups comparison; adjusted for age, sex, education, and recent weight-loss attempt.

Table 3

Effect of nutritional intervention on weight change after 12, 36, and 48 mo of follow-up, Fruit and Vegetable Randomized Controlled Community Trial, Belo Horizonte-MG, Brazil, 2013–2017

Variable*	12 mo	P	36 mo	P	48 mo	P
According to group [†]						
Weight change (Δkg)	-2.326	0.146	-1.146	0.528	-0.403	0.763
Mean weight change (%)	-1.789	0.119	0.074	0.959	0.1778	0.896
According to adherence to intervention [‡]						
Low adherence						
Weight change (Δkg)	-1.229	0.491	0.046	0.985	-0.667	0.722
Mean weight change (%)	-0.524	0.759	0.562	0.814	-0.803	0.708
Medium adherence						
Weight change (Δkg)	-3.564	0.098	-1.947	0.395	-0.863	0.651
Mean weight change (%)	-2.702	0.135	0.132	0.960	-0.197	0.927
High adherence						
Weight change (Δkg)	-2.254	0.175	-1.579	0.399	-0.111	0.945
Mean weight change (%)	-1.957	0.146	-0.484	0.776	0.744	0.687

*Estimated effect on body weight in the comparison between control and intervention groups.

[†]Adjusted for initial weight, interaction between group and initial weight, age, sex, education, and recent weight-loss attempt.

[‡]Adjusted for initial weight, interaction between initial weight and adherence, sex, education, and recent weight-loss attempt.

invitation to attend the educational activities (postcard and telephone call), duration of meetings (60 min), the flexibility to participate at different times, punctuality, promotion of empowerment and interactivity, and use of simple and feasible guidelines for everyday life.

Adherence to treatment is one of the main determinants of its success, and it is influenced by multiple factors, such as recognition of risk behaviors and the development of self-care [37]. However, individuals with class II or III obesity had lower adherence. A review of determinants of adherence to lifestyle intervention has shown lower baseline BMI to be among the main predictors of adherence [38], but this is still controversial in the literature [35]. Another aspect sometimes cited and negatively associated with adherence was the participants' dissatisfaction with their body weight. People with obesity and dissatisfaction with their body weight may have low motivation for change, and this can reduce their adherence to the intervention [23,39].

It is important to remember that the objective of the nutritional intervention performed in this trial was to stimulate the consumption of FV, which may have affected the adherence of individuals with obesity. Obesity was not directly discussed during the

intervention. Therefore, the approach may not have been attractive because it did not directly address the problem of being overweight. In addition, individuals often stop attending the PAS because of job demands, starting a new job, or personal or family problems [23].

There are some limitations to this study. First, it was not designed to verify the effect of the intervention on obesity. Randomization was performed for the PAS units, paired with the vulnerability of the territory, and not for individuals. In each PAS unit, all users were invited to participate (there was no internal selection). Thus, there could be differences between the characteristics of the individuals despite the fact that PAS users are very similar (older people with non-chronic diseases, retirees, and women) regardless of unit [32,39]. It is worth emphasizing that many users are referred to the service to treat obesity and that actions to promote FV consumption are important in this context. So we performed the analyses to verify the effect of the intervention according to nutritional status and thus support our hypothesis that people with obesity respond differently to this type of intervention.

Differences in educational levels, income, and age were observed between participants in the CG and the IG at baseline. CG participants were older and had higher education and income. It should be noted that despite the statistical difference, the means of age, education, and income are very close between the CG and the IG (differences of 0.3 y, 0.3 y, and \$2100, respectively). Even so, all analyses were adjusted by these differences to minimize the effect on the results.

The great predominance of women in our participants can also be understood as a limitation. However, this is the feature in the PAS [32,39]. Studies with men are necessary, considering their high prevalence of obesity and associated factors. In addition, efforts should be made to increase male participation in health services, since men traditionally participate less in initiatives to promote health, prevention, and treatment of diseases. Factors that may affect weight were not assessed, such as the use of medications and the weekly frequency of participation in the routine PAS activities. And after the nutritional intervention of 7 mo, participants could continue in the usual activities of the PAS for the entire follow-up, which may have affected the final result. However, these situations occurred in both the CG and the IG.

Attrition reached 40% in both groups, reflecting the challenge of conducting an intervention without offering payment to participants and the difficulty of carrying out long-term follow-up. However, this attrition rate was lower than those found in other

Table 4

Effect of nutritional intervention on weight change after 12, 36, and 48 mo of follow-up, according to baseline nutritional status (normal weight and preobesity), Fruit and Vegetable Randomized Controlled Community Trial, Belo Horizonte-MG, Brazil, 2013–2017

Variable*	Normal weight						Preobesity					
	12 mo	P	36 mo	P	48 mo	P	12 mo	P	36 mo	P	48 mo	P
According to group [†]												
Weight change (Δkg)	-2.469	0.099	0.355	0.843	0.660	0.770	-0.886	0.560	0.761	0.688	0.718	0.729
Mean weight change (%)	-3.714	0.164	1.603	0.616	2.067	0.603	-0.558	0.805	1.271	0.652	1.297	0.669
According to adherence to intervention [‡]												
Low adherence												
Weight change (Δkg)	-1.906	0.513	3.21	0.357	4.466	0.310	-0.919	0.732	3.124	0.351	-3.512	0.576
Mean weight change (%)	-2.225	0.668	5.350	0.789	8.151	0.298	-1.068	0.789	4.033	0.418	-2.785	0.604
Medium adherence												
Weight change (Δkg)	-4.826	0.040	-3.424	0.224	-3.797	0.286	-1.041	0.660	-1.691	0.569	-1.033	0.848
Mean weight change (%)	-8.830	0.048	-3.690	0.687	-6.724	0.287	-0.114	0.974	-1.181	0.789	-0.379	0.936
High adherence												
Weight change (Δkg)	-1.357	0.454	1.679	0.440	2.126	0.438	-0.741	0.689	1.069	0.645	3.463	0.473
Mean weight change (%)	-1.743	0.590	8.684	0.144	5.344	0.273	-0.663	0.810	1.430	0.678	1.620	0.663

*Estimated effect on body weight in the comparison between control and intervention groups.

[†]Adjusted for initial weight, the interaction between group and initial weight, age, sex, education, and recent weight-loss attempt.

[‡]Adjusted for initial weight, the interaction between initial weight and adherence, sex, education, and recent weight-loss attempt.

Table 5
Effect of nutritional intervention on weight change after 12, 36 and 48 mo of follow-up, according to baseline nutritional status (class I, II, or III obesity), Fruit and Vegetable Randomized Controlled Community Trial, Belo Horizonte-MG, Brazil, 2013–2017

Variable*	Class I obesity						Class II or III obesity					
	12 mo	P	36 mo	P	48 mo	P	12 mo	P	36 mo	P	48 mo	P
According to group [†]												
Weight change (Δ kg)	-4.581	0.121	-8.532	0.019	-8.346	0.017	-2.525	0.667	-11.221	0.141	-6.945	0.436
Mean weight change (%)	-5.162	0.163	-11.558	0.012	-10.354	0.017	-4.144	0.524	-10.843	0.208	6.225	0.517
According to adherence to intervention [‡]												
Low adherence												
Weight change (Δ kg)	-9.978	0.025	-10.658	0.052	-8.579	0.103	-2.431	0.792	-27.101	0.024	-12.53	0.371
Mean weight change (%)	-12.539	0.024	-15.591	0.025	-10.658	0.101	-4.845	0.634	-27.639	0.041	-14.507	0.339
Medium adherence												
Weight change (Δ kg)	2.165	0.642	-5.978	0.300	-3.617	0.512	-21.010	0.062	-8.211	0.570	-9.426	0.578
Mean weight change (%)	3.659	0.529	-7.442	0.307	-4.007	0.555	-27.234	0.028	-17.168	0.292	-10.562	0.564
High adherence												
Weight change (Δ kg)	-6.014	0.128	-10.375	0.034	-13.183	0.005	-1.050	0.576	-10.435	0.229	-8.713	0.396
Mean weight change (%)	-6.778	0.170	-13.327	0.031	-16.060	0.006	1.127	0.880	-12.006	0.222	-7.274	0.513

*Estimated effect on body weight in the comparison between control and intervention groups.

[†]Adjusted for initial weight, the interaction between group and initial weight, age, sex, education, and recent weight-loss attempt.

[‡]Adjusted for initial weight, the interaction between initial weight and adherence, sex, education, and recent weight-loss attempt.

intervention studies [40,41]. Additionally, missing data imputation were used to minimize the effect of loss. Finally, this type of intervention did not allow blinding of the participants and professionals involved.

The exercise intervention offered for health care primary users induced a minor weight loss, and the intervention to promote FV consumption enhanced this effect when the results were analyzed according to initial nutritional status. In addition, the high adherence rate of the 7-mo intervention and 4-y follow-up suggest that it is possible to engage people in behavioral programs delivered in a public health context.

Participation in a primary care service, like the PAS, contributed to a small reduction in weight, and the FV consumption intervention did not enhance this effect among participants in general. However, individuals with obesity and who adhered to the intervention were different, highlighting the importance of actions to promote healthy eating for this group. These results are important for improving obesity care and directing treatment actions, especially in view of the scarcity of obesity management strategies. Furthermore, adherence to the intervention is fundamental for better results; so more studies are needed to identify strategies to promote adherence and to identify their effect on interventions, given the reality of public health attention and the complexity of obesity.

Acknowledgments

Many thanks to the team of the Research Group on Nutrition Interventions (GIN/UFMG) at the Universidade Federal de Minas Gerais, who conducted the community trial and who organized the database; Mariana Martiniano for language review; Júlia Almeida and Instituto Olhar for support for statistical analysis; and the users of the Programa Academia da Saúde and employees of the Belo Horizonte City Hall, who contributed to the realization of this study.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.nut.2021.111436.

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