British Journal of Nutrition (2024), 132, 1255–1266 doi:10.1017/S0007114524002241

Weight loss maintenance in primary health care: a randomised controlled trial

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(Submitted 17 January 2024 – Final revision received 22 August 2024 – Accepted 10 September 2024 – First published online 5 November 2024)

Abstract

This study evaluates the maintenance of a clinically meaningful weight loss (≥ 5 %) after 12 and 36 months of participation in an intervention to promote fruit and vegetable (FV) consumption. A randomised controlled trial was conducted in a primary health care service. For 7 months, participants in the control group (CG) and in the intervention group (IG) performed guided physical exercise three times/week; the IG also participated in collective activities to promote FV consumption. This study selected participants (*n* 267) who showed clinically meaningful weight loss after nutritional intervention. Sociodemographic, health and body weight data were collected in a face-to-face interview at baseline (T0) and after intervention (T1). Participants were reassessed after 12 (T2) and 36 months (T3) by telephone interview, and the self-reported weight was corrected. The outcome measures weight changes at three time points: M1, comparing T2 with T1; M2, comparing T3 with T2; and M3, comparing T3 with T1. The generalised estimating equation, adjusted for individual characteristics, was used. Participants in the CG showed an increase of 4·2 kg ($P < 0·001$) at M1 and 4·6 kg ($P < 0·001$) at M3, while IG individuals showed an increase of 3·6 kg ($P < 0·001$) at M1 and 3·8 kg ($P < 0·001$) at M3. The between-group analyses show the effect of nutritional intervention on the maintenance of weight loss at M2 ($P = 0·033$). Although CG and IG participants increased in weight, the nutritional intervention was associated with maintenance over the long term. This reveals the importance of the promotion of FV consumption for body weight maintenance.

Keywords: **Weight loss maintenance: Intervention studies: Primary health care: Programme evaluation**

Obesity is a global health problem with increasing prevalence and is associated with an increased risk of developing several chronic diseases[1]. Obesity can impact the quality of life in different dimensions, such as personal health, occupational health, social belonging, among others[2]. The WHO[3] defines quality of life as a subjective assessment of a person's perception of their reality in relation to their goals and through the lens of their culture and value system. In this context, the impact on the quality of life of people with obesity may also occur as a consequence of feeling stigmatised and excluded, which increases their risk of developing anxiety and depression[4].

A variety of dietary, physical activity, behavioural, pharmaceutical and surgical treatments are currently available to treat overweight and obesity. Diet, exercise and behavioural interventions are particularly useful tools and can be used in a variety of service contexts[5]. One potential dietary strategy that has been proposed is eating at least five daily portions of fruits and vegetables (FV). FV are low-energy-density foods and can promote weight loss when they substitute higher energy density foods, such as ultra-processed foods, in one's diet, especially when associated with the practice of physical exercises[6,7].

However, to manage obesity and co-morbidities effectively, evidence-based and interdisciplinary care that meets individual needs[8,9] is recommended. In other words, effective interventions must emphasise person-centred outcomes that take into account the full complexity of the disease, its risk factors, and an overall quality of life. The literature points out that a 5 % weight loss can represent an effective management of obesity at a population level, primarily due to its significant clinical health benefits. However, a mere 2 % weight loss can already show

Abbreviations: FV, fruits and vegetables; TTM, Transtheoretical Model; PAS, Health Academy Program (Programa Academia da Saúde, in Portuguese); CG, control group; IG, intervention group.

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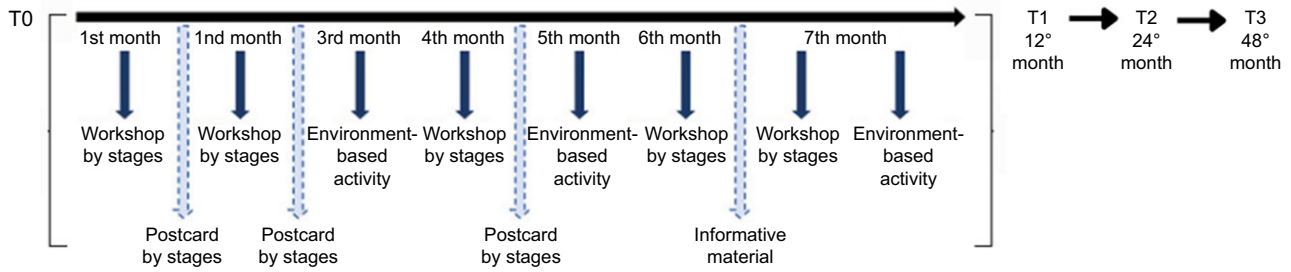

Fig. 1. Timeline for educational strategies development and participants' evaluation. Data: Adapted to Menezes *et al.* 2018. Note: T0, Pre-intervention (baseline); T1, Post-intervention; T2, 12 months after intervention T3, 36 months after intervention; M1, weight loss maintenance at T2 compared with T1; M2, weight loss maintenance at T3 compared with T2; M3, weight loss maintenance at T3 compared with T1.

cardiovascular improvement, but some co-morbidities and complications may require even greater weight loss[10].

Significant and moderate weight loss (~5 %) rely on key contributors, including behavioural theories, dietary approaches using energy restrictions and interventions delivered by dietitians and psychologists[5]. However, most of the interventions are only temporarily effective in maintaining a 5 % weight loss. Less than one-fifth of all people who achieve a clinically meaningful weight loss are able to maintain it after one year; 85 % regain the previous body weight (return to baseline) after two years; and more than 95 % lose the benefit of the intervention after 3 years[11,12]. These effects may vary with the severity of the initial obesity, the intensity of the intervention, the presence of maintenance interventions, among other characteristics[13].

One of the main reasons for the high rate of body weight regain is a series of physiological and behavioural adaptations to weight loss that result in an increase in appetite, a suppression of energy expenditure, and a reduction of satiety. The use of restrictive diets and low adherence or transient strategies is another reason that may explain the difficulty in maintaining weight loss[14,15]. Thus, preventing weight increase after weight loss continues to be the major challenge for interventions and obesity management[11].

Long-term weight management is extremely challenging due to interactions among our biology, our behaviour, and the obesogenic environment. Specific barriers include poor adherence to behavioural interventions and physiological adaptations that promote weight regain. Thus, behavioural change theories have been proposed as important tools for promoting adherence and helping participants achieve healthier behaviour and attitudinal changes that contribute to sustained weight loss [11,16,17]. In this sense, theories that identify an individual's readiness to change may be useful, as the majority of pple are not ready to change their behaviour and will therefore not be able to follow traditional action-oriented diet programmes. One example is the Transtheoretical Model (TTM), which suggests that behavioural change is complex and takes place in stages, which are mediated by cognitive and behavioural change processes and are dependent on self-efficacy and proper choices concerning eating habits. However, few studies have assessed the maintenance of weight loss after behavioural interventions in public health services [17,18].

There is, therefore, a gap in the literature concerning what happens in the medium to long term to people who have achieved clinically meaningful weight loss after taking part in interventions based on TTM[5,11,13]. Understanding what happens to these people's body weight can tell us whether or not the use of such strategies actually helps to maintain clinically meaningful weight loss. In addition, it is important to consider nutritional interventions delivered through public health services to ensure the applicability of interventions in real contexts[5]. In this light, this study evaluated the maintenance of clinically meaningful weight loss after 12 and 36 months of participation in an intervention to promote FV consumption, conducted in a Brazilian primary health care service. It is believed that analysing this objective will provide an opportunity to test whether or not interventions to promote FV can lead to clinically meaningful weight loss over the long term.

Methods

Study design and setting

This study used data from a follow-up of a Randomised Controlled Community Trial to promote FV consumption, which was conducted between 2013 and 2017 in a large Brazilian city. Data were collected from participants at baseline (T0), after the nutritional intervention (T1) and after 12 (T2) and 36 months (T3) of the intervention (Fig. 1).

Belo Horizonte, Brazil, is 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)[19]. It is also a national reference in the primary health care organisation. Since 2006, the municipality counted on a health promotion service in the Public Health network[20], called the Health Academy Program (*Programa Academia da Saúde* – PAS), which was incorporated into the national public health system in 2013. Because of their relevance as a free health promotion and chronic disease control service[20], the PAS units were chosen as the setting for the present study.

Participants and recruitment

The random sample was stratified by the nine administrative districts in the municipality of Belo Horizonte. The PAS units that met the following criteria were considered to be eligible: (1) 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, respectively, for

PAS in the municipality; (2) did not participate in research related to food and nutrition in the previous 24 months; and (3) was in operation in November 2012, which is the timeframe for the sampling process[21].

Among 50 units that were operating during the study, 42 were found to be eligible and 18 were randomly selected for the study, two at each stratum and paired according to health vulnerability. Using a random numbers list, one unit from each administrative district was selected to receive the nutritional intervention (intervention group – IG), while the other unit in the district was designated as a control group (CG). Thus, there were nine units in the CG and nine units in the IG. The sampling process was developed by a statistician who did not participate in the other phases of the trial. The selected units were representative of the medium and high vulnerability areas in the municipality, with a 95 % CI and an error of less than 1·4 %[21].

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

All PAS users who met the following inclusion criteria were invited to participate in the study: age 20 years or older, who frequently attended the activities within the PAS (participation in physical exercise in the preceding month). The exclusion criteria included pregnancy and individuals with cognitive impairment[21]. More details regarding the sampling process are available in Menezes *et al.*[21].

The 18 PAS units sampled included 3763 users, 237 (6·3 %) refused to participate in the study and 112 (3·0 %) were excluded, totalling 3414 (90·7 %) interviewed at baseline. At T1, 2538 participants were reassessed (loss of 25·6 %), at T2, 2332 (loss of 31·7 %) and at T3, 2061 (loss of 39·6 %). For this study, only Randomised Controlled Community Trial participants who presented clinically meaningful weight loss after participation in nutritional intervention were selected (see item *Clinically Meaningful Weight Loss*).

Routine activity in Programa Academia da Saúde

Participants from the IG and CG participated in routine service activities throughout the study period (48 months). The activities included one-hour physical activity sessions held three times a week, which were led by a physical education professional who included aerobic activities, walks and muscle strengthening exercise with light loads.

During the Randomised Controlled Community Trial, participants in the CG received no intervention that was specific to FV consumption and it was monitored through monthly contact with the health professional responsible for the unit[22].

Intervention to promote fruits and vegetables consumption

The participants in the IG participated for seven months in an intervention to promote FV consumption. The intervention was constructed according to TTM, and the problematising-dialogic pedagogy by Paulo Freire was used to advocate empowerment and autonomy, as proposed in the PAS[23]. In this proposal, education creates the possibility of freedom, which promotes conscientious attitudes and presumes a horizontal and dialogical relationship[22].

TTM facilitates planning and the implementation of actions according to individual characteristics, including perception, readiness, attitude and motivation to undergo behavioural changes. This incorporates four pillars: stages of change, change processes, self-efficacy and decisional balance.

Five cognitive and five behavioural processes of change were used to understand how change occurs in stages. The interventions sought to increase individuals' confidence in their ability to achieve the desired behaviour when faced with obstacles (self-efficacy) and to increase awareness of the benefits of a healthy diet while minimising the factors against change (decisional balance)[24]. For the development of the actions in primary health care to be feasible, the participants were grouped according to the following stages of change in FV consumption: Pre-action (Stages of change from Precontemplation and Contemplation); Preparation (Stages of change from Preparation); and Action (Stages of change from Action and Maintenance)[22,24]. There were 279 participants in the Pre-action Group (18·8 %), 515 (37·7 %) in the Preparation Group, and 689 (46·2 %) in the Action Group. The characteristics of the groups and interventions offered are presented in Table 1.

In the Pre-action and Preparation groups, we used processes of change predominantly based on cognitive changes to increase motivation and awareness concerning nutritional challenges. Educational activities were focused on increasing one's awareness of behaviour and its consequences in the Pre-action group. Strategies, such as conversation circles, image theatre, and self-portraits, were used. The Preparation group focused on the meaning of feelings, sensations and thoughts related to health. In this group, the participants elaborated an action plan to promote FV consumption. In the Action group, focus was placed on processes of change related to behavioural changes, including more detailed guidance on nutrition concepts. The activities favoured individuals' skills in changing long-term behaviour 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[22] (Table 1).

The educational strategies that were used included workshops that were performed in a group of up to 20 participants, motivational messages via postcards, telephone calls to invite the participants to and remind them of the group sessions, environment-based activities (particularly those concerning an interactive activity, e.g. movies and culinary), education panels, and the delivery of educational materials (Fig. 1)[22]. The activities were developed through the 10 different workshops, which were held on 540 different occasions, and four interactive environment-based activities, which were repeated 171 times. In addition, 4449 postcards and 1483 educational materials were distributed[22].

The groups were fixed, i.e. the participants were always the same and the sessions took place in the same place and on previously defined days and times. To monitor the frequency with which users participated in the intervention, the names of all participants were recorded for all actions carried out[22].

Table 1. Characteristics of nutritional intervention groups

Intervention groups	Stage of changes	Participants characteristics	Processes of change used in nutritional intervention	Examples of Educational strategies		
				Educational Strategy	Objectives	Technique
Pre-action	Precontemplation and Contemplation	Individuals are not ready to change, but they require action to shape their motivation	Cognitive: to increase motivation and awareness about nutritional challenges	Workshop, 'what does health mean to you?'	Reflect on the individual's perception of the concept of health	Image theatre
				Workshop, 'FV, where to start? Increasing the Pros'	Discuss determinants of food choice and their relationship to health Reflect on autonomy in healthy food choice, focusing on FV	Conversation circle
Preparation	Preparation	Individuals are ready to change their behaviour within 30 d	Cognitive: awareness about nutritional challenges Behavioural: planning for change	Workshop 'Health and Health Eating'	Reflect on determinants of health and their relationship to food consumption	Self-report
				Workshop 'Planning my food consumption'	Recognise the importance of planning behaviour change Discuss obstacles to change Produce a plan of action	Conversation circles
Action	Action and Maintenance	Individuals who are capable of short, immediate changes, but for whom preventing relapse and consolidating gains are required	Behavioural: favoured individuals' skills to change long-term behaviour and face new difficulties, which encouraged the maintenance of gains and prevention of relapse	Workshop 'Knowing FV portions'	Reflect on the benefits of FV consumption Discuss strategies to increase FV consumption	Conversation circle
				Workshop 'Savouring FV'	Discuss FV consumption and preparation techniques Sample preparation of FV with little salt or oil	Culinary workshop

Data: Menezes *et al.* 2018[22].

The educational activities covered the following topics: health and food consumption; purchase, seasonality and cost of FV; preserving the nutritional and sensory quality (from acquisition to consumption) of FV; guidelines for diversifying methods of preparation and consumption; sensory characteristics; portions; nutritional information; and family support. Our intervention addressed different behavioural aspects that may influence FV consumption, including the replacement of ultra-processed foods with fruits and vegetables. The quantitative guidance for FV consumption was based on the WHO recommendation of 400 g/d[25].

The FV intervention was planned by an interdisciplinary team, consisting of dietitians, educators, and psychologists who did not participate in data collection. This was performed by three dietitians and a post-graduate student, who alternated managing the groups. They also counted on support from three undergraduate students from the Nutritional Sciences department. The entire team received specific training to develop the intervention and followed detailed scripts created by the team responsible for developing the intervention. Further information regarding the nutritional intervention can be seen in Menezes *et al.*[22].

Assessment of variables

All interviews were performed by dietitians and students who were not on the intervention team. The interviews were periodically trained to perform face-to-face data collection at each PAS unit, which was monitored by data collection supervisors. All data at baseline (T0) and after the nutritional intervention (T1) were obtained from face-to-face interviews in the PAS unit. After 12 and 36 months of the nutritional intervention (T2 and T3), participants were interviewed by telephone.

The T0 questionnaire included sociodemographic information (sex, age, income, education, occupation and marital status), health information (self-heath perception, body satisfaction, physical activity), recent weight loss attempts and anthropometry (weight and height). At T1, T2 and T3, we evaluated the participants' income, recent weight loss attempts, and body weight (online Supplementary material 1).

In T0 and T1, the weight was measured using a digital scale. The participants' height (in metres) was measured using a wall-mounted stadiometer at T0. Anthropometric assessments were conducted without coats and shoes. At T2 and T3, participants were interviewed by telephone to self-report weight, which was adjusted according to the validation study[26].

Clinically meaningful weight loss

Weight change was assessed by subtracting the weight after the intervention (T1) from the baseline measure (T0):

$$\%\ weight\ change = \frac{weight\ at\ T1 - weight\ at\ T0}{weight\ at\ T0 \times 100}$$

Participants with a weight loss that was greater than or equal to 5 % were considered to have clinically meaningful weight loss. This cut-off point is used to control obesity, as it represents a significant improvement in the individual's health and quality of life[10].

Maintenance of clinically meaningful weight loss

Among people who had clinically meaningful weight loss (greater than or equal to 5 %), the weight change maintenance at T2 and T3 was evaluated. Thus, three maintenance measures were obtained from the following calculations: Maintenance 1 (M1) = weight at T2 − weight at T1; Maintenance 2 (M2) = weight at T3 − weight at T2; and Maintenance 3 (M3) = weight at T3 − weight at T1. Weight variation that was negative or equal to zero was considered to represent maintenance of clinically meaningful weight loss, and a positive result indicated an increase in weight by the participant.

Data analysis

To assess the nutritional status, the BMI was calculated by dividing one's weight (in kilograms) by the square of their measured height (in metres) at T0. The nutritional status was categorised as BMI ≥ 18·5 and < 25·0 kg/m^2 (eutrophy), BMI ≥ 25 and < 30 kg/m^2 (pre-obesity), and BMI ≥ 30 and < 35 kg/m^2 (obesity Class I); BMI ≥ 35 and < 40 kg/m^2 (obesity Class II), or BMI ≥ 40 kg/m^2 (obesity Class III)[27].

Data imputation analysis was used for body weight using the individuals' information (sex, age, education, and other weight measures) to estimate missing data. The estimated weight value for missing information was calculated as the average of ten random values that were estimated using the imputation package in Stata. The estimated data from one time point were not considered when estimating a second missing measure to avoid the proliferation of errors. The method used has the advantage of taking into account the variability between imputations and limiting the underestimation of sampling variability when compared with other imputation methods that impute values from the centre of the distribution (median method) or a single value (normal value method). At a simple level, if there is not much information in the observed data (used in the imputation model) about the missing values, the imputations will be highly variable, leading to high SE in the analyses. By contrast, if the observed data are highly predictive of the missing values, the imputations will be more consistent across imputations, resulting in smaller, but still accurate, SE[28]. To ensure the quality of the imputed data, data sensitivity analysis was performed comparing the sample with and without imputation. No differences were found in the mean, SD and probability distribution before and after imputation. The results showed the quality of the procedure carried out, which had z high degree of consistency with the collected information.

The mean and SD were calculated for all continuous variables, and the frequency was used to describe qualitative variables. The participants' characteristics were presented according to GC and IG. Differences between the groups at baseline were evaluated using an independent sample *t* test, the chi-square test and Fisher's exact test.

The average participant weight is described for each follow-up period (T0, T1, T2 and T3). The comparison of weight at each follow-up time point by group was assessed using a paired

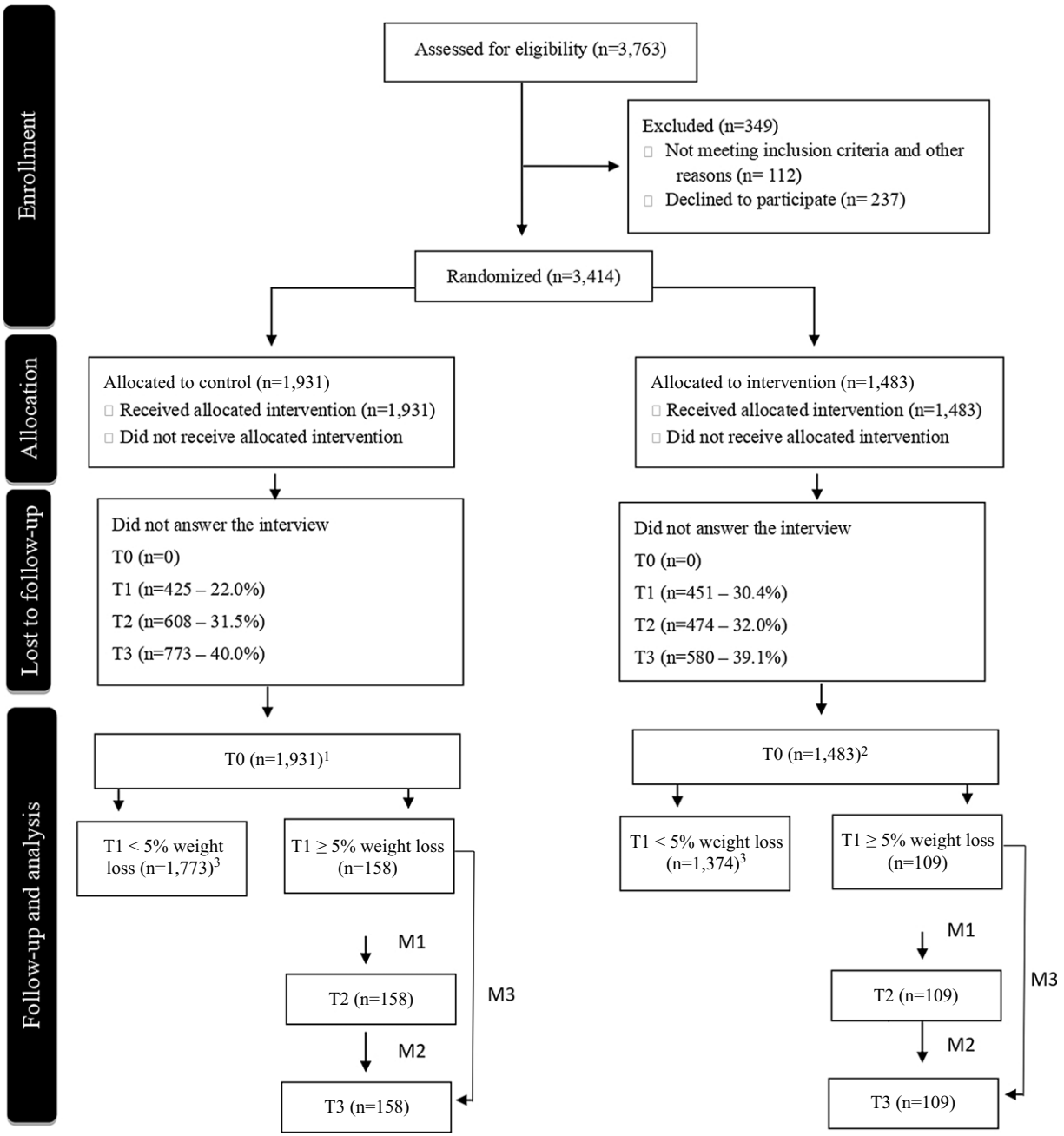

Fig. 2. Flow diagram. Fruit and Vegetable Randomised Controlled Community Trial. Belo Horizonte-MG, Brazil. 2013–2017. Note: T0, Pre-intervention (baseline); T1, Post-intervention; T2, 12 months after intervention T3, 36 months after intervention; M1, weight loss maintenance at T2 compared with T1; M2, weight loss maintenance at T3 compared with T2; M3, weight loss maintenance at T3 compared with T1. [1]Only participants with 5 % weight loss at T1 were included in the analyses (*n* 158).

Student's *t* test. The weight change for each evaluated moment (M1, M2 and M3) was also described. In within-group analysis, the change in weight by group was estimated using the generalised estimating equation. The models were adjusted for age, sex and income.

The generalised estimating equation was used to examine the maintenance of beneficial effects from the intervention on the basis of weight. This analytic method was used to examine the associations of time-varying and time-constant independent variables with a time-varying dependent variable (e.g. weight). Results were adjusted for sex, age and income.

Statistical significance was attributed when p-values were less than 0·05. Analyses were performed using Stata 14.0.

Results

After the nutritional intervention, 267 participants (7·8 %) showed a weight loss of 5 % or more (CG = 158; IG = 109) (Fig. 2). There were no significant differences in socio-demographic and health characteristics between the participants in the CG and the IG, except for income. Participants with

https://doi.org/10.1017/S0007114524002241 Published online by Cambridge University Press

Table 2. Baseline characteristics of participants with a weight loss of 5 % or more after nutritional intervention in the control (*n* 158) and intervention groups (*n* 109). Fruit and vegetable randomised controlled community trial. Belo Horizonte-MG, Brazil. 2013–2017

	Total (*n* 267)			Control (*n* 158)			Intervention (*n* 109)			
		Values		*n*	Values		*n*	Values		
Variables	*n*	Mean	SD		Mean	SD		Mean	SD	*P*-value
Age[§] (years) SD	267	55·5	12·0	158	56·0	11·1	109	54·9	13·2	0·46*
Education[§,‖] (years) SD	267	6·9	3·8	158	7·1	3·7	109	6·6	4·0	0·27*
Income per capita[§,‖] (dollar) SD	249	425·58	405·16	147	476·22	490·04	102	352·60	216·44	0·02*
	n	%		*n*	%		*n*	%		
Gender (%)										
Female	238	89·5		142	89·9		97	90·0		0·05†
Men	28	10·5		16	10·1		12	11·0		
Marital status (%)										
Married	152	56·9		92	58·2		60	55·0		0·76†
Divorced	26	9·7		14	8·9		12	11·0		
Single	41	15·4		22	13·9		19	17·4		
Widowed	48	18·0		30	19·0		18	16·5		
Occupation (%)										
Housewife	84	31·5		54	34·2		30	27·5		0·48‡
Retired or pensioner	95	35·6		56	35·4		39	35·8		
Unemployed	7	2·6		5	3·2		2	1·8		
Employed	81	30·3		43	27·2		38	34·9		
Self-health perceptions (%)										
Very poor/poor/regular	83	31·1		56	35·4		27	24·8		0·06†
Good/very good	184	68·9		102	64·6		82	75·2		
Body satisfaction (%)										
Not satisfied	187	70·0		113	71·5		74	67·9		0·52†
Satisfied	80	30·0		45	28·5		35	32·1		
Recent weight loss attempt										
No	81	30·3		48	30·4		33	30·3		0·98†
Yes	186	69·7		110	69·6		76	69·2		
		Mean	SD		Mean	SD		Mean	SD	
Physical activity[§,‖] (min/week) SD	145	214·45	78·8	89	208·7	59·0	56	223·6	102·7	0·27*
	n	%		*n*	%		*n*	%		
Nutritional status (%)										0·72†
Normal weight	48	19·3		30	20·13		18	18·2		
Pre-obesity	85	34·3		47	31·5		38	38·4		
Obesity class I	77	31·0		49	32·9		28.	28·3		
Obesity class II or III	38	15·3		23	15·4		15	15·15		

Note: only users with 5 % or more of weight loss after nutritional intervention. SD, SD.
*Student *t* test; †Chi-squared test; ‡Fischer test. §Presented by means. ‖Two missing data for education; 4278 missing data for income per capita; and 138 missing data for physical activity.

clinically meaningful weight loss (5 % or more) after the nutritional intervention were 89·5 % women; 70 % of whom were not satisfied with their body, 69·7 % of whom described a recent weight loss attempt, and only 19·3 % of whom were eutrophic (Table 2).

The mean weight, adjusted for individual characteristics, for CG participants was 68·4 kg, 72·6 kg and 73·1 kg at T1, T2 and T3, respectively. For IG participants, the mean weight was 66·3 kg, 67·5 kg and 68·0 kg, respectively (Fig. 3).

Adjusted within-group analysis showed a weight increase in participants with clinically meaningful weight loss at T2 compared with T1 and T3 compared with T1. Participants in the CG showed an increase of 4·2 kg ($P < 0·001$) at M1 (maintenance in T2 compared with T1) and 4·6 kg ($P < 0·001$) at M3 (maintenance in T3 compared with T1). Those from the IG showed an increase of 3·6 kg ($P < 0·001$) at M1 (maintenance in T2 compared with T1) and 3·8 kg ($P < 0·001$) at M3 (maintenance in T3 compared with T1) (Table 3).

The adjusted between-group analysis for assessing weight maintenance at each time point is shown in Table 4. No significant differences were observed in weight maintenance for M1 and M3, when comparing CG and IG. However, for M2 (maintenance in T3 compared with T2), the final adjusted mean weight for participants in the CG was 73·4 kg, while for those in the IG it was 69·7 kg, a difference of 3·6, which was deemed to be statistically significant ($P = 0·033$).

Discussion

PAS participants who achieved clinically meaningful weight loss were unable to sustain it over the long term, given that 12 and 36 months after the collective intervention to promote FV consumption, the participants had regained the weight. However, the nutritional intervention was important for better results in weight maintenance in the last 36 months, when compared with 12 months.

The hypothesis of this study was that the promotion of FV consumption associated with physical exercise would induce weight loss by causing a decrease in total energy intake with an

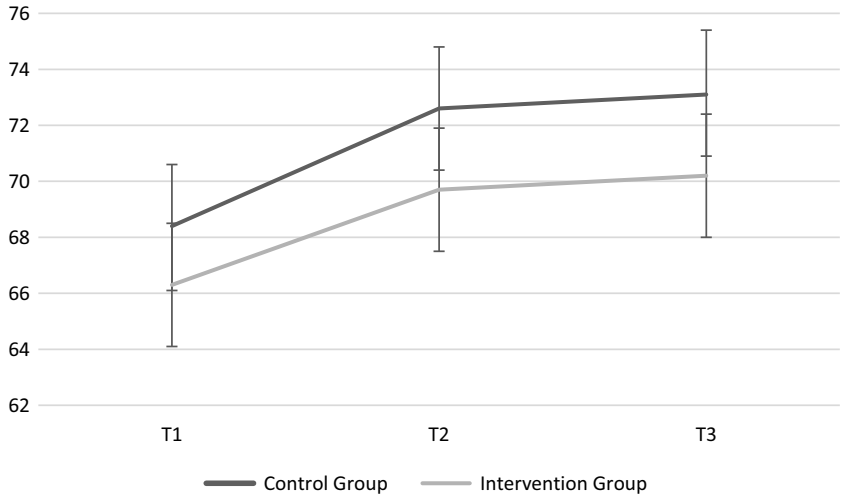

Fig. 3. Weight at Each Follow-up Period After the Nutritional Intervention (n=267). Fruit and Vegetable Randomized Controlled Community Trial. Belo Horizonte-MG, Brazil. 2013-2017. Note: T0, Pre-intervention (baseline); T1, Post-intervention; T2, 12 months after intervention T3, 36 months after intervention; M1, weight loss maintenance at T2 compared with T1; M2, weight loss maintenance at T3 compared with T2; M3, weight loss maintenance at T3 compared with T1. [1]Only participants with 5 % weight loss at T1 were included in the analyses (*n* 158).

increase in energy expenditure and that the weight loss would be sustained over the long term because of changes in food consumption and the permanence of participants in the health promotion service. All of these factors could contribute to clinically meaningful weight loss. What we observed partially confirmed our hypothesis. The IG participants showed unfavourable changes in weight when compared with the CG, but only at the last follow-up of the study. Thus, the intervention contributed to the maintenance of clinically meaningful long-term gains, but with limitations. The within-group comparison showed weight gain in the CG and IG, when comparing data from immediately after the intervention (T1) with 12 months of follow-up (T2), and when comparing the weight immediately after the intervention (T1) with the 36 months of follow-up (T3). Additional weight loss was observed when comparing 12 months (T2) and 36 months (T3) of follow-up.

The behavioural intervention was shown to be beneficial for the participants over the long term. In previous results, we showed that the nutritional intervention was effective in increasing FV at 12 months in those with a lower intake at baseline and in those who reported consuming FV as recommended[29]. One effect of the intervention on fruit intake at 36 months was identified among those with adequate baseline FV intake[30]. The positive impact of the intervention may have favoured the results shown here in terms of a clinically meaningful maintenance of weight loss.

The clinically meaningful maintenance of weight loss observed in our study is similar to other interventions, including interventions based on the TTM for sustained weight loss[18,31]. However, because of the variety of interventions used and the small number of trials, the evidence still remains inconclusive. In an intervention that included qualitative and quantitative dietary changes to induce weight loss and increased physical activity levels, weight loss was maintained for 30 months, but the intervention lost its effect after 48 months[32]. A recent review of weight maintenance estimated that between 60·5 % and 88·0 % of participants were estimated to be able to achieve this goal over a period of 28 to 68 months. However, the criteria for assessing and determining weight maintenance varied, and a loss of 3 % to 10 % of the initial weight is commonly used[11].

In the within-group analysis, the body weight of the CG and IG participants increased during the follow-up period. It should be noted that the participants were mainly women with low income and education, and the extrapolation of the results to other populations should be conducted with caution. In a follow-up study of participants from the National Weight Control Registry in the USA, women and those with less education had more weight variation than other groups[33]. Socioeconomic factors were associated with the method used to lose and maintain weight, given that women and people with a lower income and education tended to choose faster weight loss methods[34]. However, the use of restrictive diets, meal replacements and other weight loss methods are associated with faster and greater weight regain[4,11,17].

Several factors may be associated with maintaining weight loss, such as the availability of healthy foods at home, eating breakfast regularly, increasing vegetable consumption and reducing sugary and fatty food consumption[11,16,17]. Psychological factors and participating in physical activity have also been identified as important determinants[11,17,35]. However, low adherence remains a challenge. To meet these needs, interventions to improve adherence to physical exercise and a healthy diet are needed, not only with a behavioural focus but also with policy measures to change the obesogenic environment. Behavioural strategies that include understanding cognitive function and developing behavioural skills can help overcome the biological challenges of weight loss. The variety of behavioural strategies associated with maintaining weight loss suggests that there is no single approach that will work for everyone. Instead, it is necessary to use a combination of

Table 3. Change in weight during follow-up of participants with clinically meaningful weight loss (*n* 267) after the nutritional intervention. Fruit and vegetable randomised controlled community trial. Belo Horizonte-MG, Brazil. 2013–2017

	Effect intragroup (Kg)											
Groups	M1 (not adjusted)	*P*-value*	M1 (adjusted)†	*P*-value	M2 (not adjusted)	*P*-value*	M2 (adjusted)†	*P*-value	M3 (not adjusted)	*P*-value*	M3 (adjusted)†	*P*-value
Control	4·0	< 0·001	4·2	< 0·001	0·4	0·23	0·48	0·193	4·5	< 0·001	4·6	< 0·001
Intervention	3·6	< 0·001	3·6	< 0·001	0·4	0·42	0·49	0·393	4·0	< 0·001	3·8	< 0·001

Note: Only for participants with weight loss of 5 % or more after the nutritional intervention. M1, weight loss maintenance at T2 compared with T1; M2, weight loss maintenance at T3 compared with T2; M3, weight loss maintenance at T3 compared with T1.
*Intragroup comparison: paired Student's *t* test. †Estimated effect on body weight in the intragroup comparison, adjusted by age, sex and income per capita.

Table 4. Effect of nutritional intervention on weight maintenance (*n* 267). Fruit and vegetable randomised controlled community trial. Belo Horizonte-MG, Brazil. 2013–2017

Maintenance of weight loss	Control group				Intervention group				Between-group difference			Between-group difference*		
	PW (Mean)	CI (95 %)	FW (Mean)	CI (95 %)	PW (Mean)	CI (95 %)	FW (Mean)	CI (95 %)	Coef.	CI (95 %)	*P*-value	Coef.	CI (95 %)	*P*-value
M1	68·8	66·5, 71·0	73·0	70·8, 75·0	66·0	63·8, 68·3	69·2	66·7, 71·7	–2·7	–6·0, 0·5	0·102	–2·9	–6·2, 0·35	0·081
M2	72·8	70·6, 75·1	73·4	71·3, 75·5	69·6	67·3, 71·9	69·8	67·2, 72·3	–3·2	–6·5, 1·2	0·057	–3·6	–7·00, –0·29	**0·033**
M3	68·8	66·5, 71·0	73·4	71·3, 75·6	66·0	63·8, 68·3	69·7	67·2, 72·2	–2·7	–6·0, 0·6	0·105	–2·9	–6·3, 0·37	0·082

Note: Only for participants with weight loss of 5 % or more after the nutritional intervention. PW, previous weight; FW, follow-up weight; Coef, Coefficient (β); M1, weight loss maintenance at T2 compared with T1; M2, weight loss maintenance at T3 compared with T2; M3, weight loss maintenance at T3 compared with T1.
* Adjusted for sex, age, income per capita. Bold: significant, p-value <0.05

strategies that are selected according to the individual's characteristics and individual-centred goals and changes in the environment that favour healthy food consumption and physical activity[11].

The aim of this study is not to evaluate the effectiveness of a treatment for obesity in the short, medium and long term, but rather to evaluate the effect of an intervention to promote FV consumption in maintaining clinically healthy weight loss. The treatment of obesity requires a broad approach that focuses on its different determinants and that does not use weight loss or weight maintenance as the sole measure of success. Even in the absence of weight loss, lifestyle improvements can have an impact on one's quality of life[8,9].

The realistic magnitude of long-term weight loss is significantly less than expected by patients and healthcare professionals. Even the highest quality short-term interventions are unlikely to produce sustained positive outcomes without ongoing intervention and support[36]. Our intervention did not include long-term nutritional strategies, which may have prevented us from achieving better results. Strategies such as continuous weight monitoring, goal setting and encouraging experiences may favour weight maintenance[11]. However, previously unsuccessful experiences are the main challenge[11].

Physical exercise should be emphasised as a highly effective weight maintenance strategy for those individuals who are able to implement and maintain regular activity[15]. Therefore, it is important to include physical exercise in programmes to achieve a clinically meaningful maintenance of weight loss, such as that conducted in our study. However, a high rate of loss to follow-up was observed (25·6 % at T1, 31·7 % at T2 and 39·6 % at T3), due to non-adherence of the PAS for the practice of physical exercise. Understanding what motivates individuals to be more active and the psychological, biological and environmental issues that can facilitate a more active lifestyle are required[15].

The importance of PAS in building a healthy environment should be highlighted. Unlike other health services, PAS advocates a positive perspective, offering activities for people with different lifestyles, with the potential to expand the participation of groups that, in general, are not served by health services[36]. In addition to the practice of physical exercise three times a week, users undergo biannual physical reassessments that include information on health behaviours, physical fitness and weight monitoring. The routine participation of individuals in the PAS also seems to favour a greater bond with the professional and continuous care, which is essential for the success of health interventions. For individuals with overweight, obesity and other chronic noncommunicable diseases, long-term follow-up is an important predictor of weight reduction, as are weight maintenance and the control of co-morbidities[11]. Therefore, their participation in PAS can be used as a strategy to manage obesity and control co-morbidities, in addition to promotion and health surveillance[36].

The literature shows the importance to promote FV consumption for weight loss[6,7,15,17]. However, studies often show that the effect on weight loss is stronger when using intensive weight loss programmes with caloric restrictions, dietary prescriptions[37,38,39] or formula-based diets[37,39]. The treatment of obesity requires a broad approach that focuses on its different determinants and that does not use weight loss or weight maintenance as the sole measure of success. Even in the absence of weight loss, lifestyle improvements can have an impact on one's quality of life and can have long-term results[12]. Therefore, the intervention proposed in the context of the PAS approaches behavioural aspects that can have sustainable effects, but their results should be interpreted with caution.

There are some limitations to this study. CG participants had a higher income when compared with IG participants, but all analyses were adjusted by these differences to minimise their impact on the results. The results of this study may reflect characteristics of the participants who were predominantly women with a low education level. However, this is a feature of PAS[36,40]. Efforts should be made to increase male participation in health services because men traditionally participate less in initiatives to promote health, prevention, and disease treatment.

High attrition was found in both groups, which reflects the challenge of conducting an intervention without offering remuneration to subjects and the difficulty of performing a long-term follow-up. Responding and non-responding participants differed in terms of sociodemographic characteristics (online Supplementary material 2) and may reflect the characteristics of the service, such as the morning shift operation, which makes it difficult for workers to participate. However, this attrition rate was lower than those found in other intervention studies[40,41]. Additionally, imputation techniques were used to minimise the impact of loss. In addition, few participants had an initial weight loss of 5 %. This substantially reduced the size of our final sample, which may well be due to the fact that the intervention was not focused on body weight loss, but rather on the promotion of FV consumption.

However, this is the first study that we have identified in the literature that followed individuals with successful weight loss over a 36-month period in primary health care from a middle-income country. These results address an important gap in knowledge about the effectiveness of interventions to promote adequate and healthy eating to maintain weight loss.

The change in clinically meaningful weight loss was associated with the intervention only after 36 months, which implies long-term benefits of the intervention. Therefore, behavioural interventions to promote adequate and healthy eating can contribute to clinically meaningful weight loss and should be included in the routine of health services. Thus, this study is important in documenting the possibility of achieving long-term clinically meaningful weight loss with a service that offers health promotion programmes including guided physical exercise and intervention on eating behaviour. However, further studies are needed to observe more reliable outcomes, including the understanding of one's satisfaction with weight loss on an individual basis, taking into account the individual's overall health, as well as the focus on reducing the consumption of ultra-processed foods.

Therefore, our results showed the importance of health promotion and PAS as a health surveillance intervention and for clinically meaningful weight loss. Expanding the programme and encouraging the participation of individuals who have already lost weight may help to maintain the health benefits for these people.

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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 data collection and organised the database.

This study is funded by Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG) (APQ-00585-17, PPM-00254-15; 21618/2013; 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) to support this study. This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) – Finance code 001 and the Programa de Pós-Graduação em Saúde Pública of Universidade Federal de Minas Gerais (English review). The financial support agencies had no involvement in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

P. P. F.: Analysis and interpretation of data; drafting of the manuscript; data collection and input; review of the final version and approval for publication. M. S. L.: Analysis and interpretation of data; drafting of the manuscript; data collection and input; review of the final version and approval for publication. A. C. S. L.: Conception and design; interpretation of data; critical review of the manuscript; obtaining funding; administrative, technical and material support; review of the final version and approval for publication.

The authors declare none.

Supplementary material

For supplementary material/s referred to in this article, please visit https://doi.org/10.1017/S0007114524002241

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