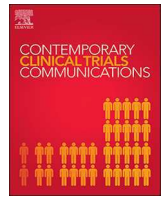




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## Promoting fruit and vegetable consumption: Methodological protocol of a randomized controlled community trial



Mariana Carvalho de Menezes, Raquel de Deus Mendonça, Nathália Luíza Ferreira, Larissa Morelli Ferraz Guimarães, Aline Cristine Souza Lopes\*

Federal University of Minas Gerais, Avenida Alfredo Balena, 190, Room 316, Belo Horizonte, 30130-100, Brazil

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## ABSTRACT

This study aimed to develop community educational activities in Brazilian primary health care settings. A randomized controlled community trial was conducted to encourage fruit and vegetable consumption (FV-RCT) in a representative sample of consumers aged 20 years or older in a Brazilian city. The fruit and vegetable consumption was classified according to the transtheoretical model's stages of change, reflecting different degrees of readiness for change. The educational activities were based on the transtheoretical model and a problematizing-dialogic pedagogy, planned by an interdisciplinary team, using information collected in a qualitative pilot study. The actions were conducted over seven months, and baseline data were collected from 1483 participants. The educational strategies included workshops interspersed with motivational messages conveyed via postcard, interactive environment-based activities, and informative material. In the workshops, different techniques were used - conversation circles, image theatre, self-portraits, cooking and art as experience. The applied intervention based on the chosen theories implied in a refinement of the intervention, but, nevertheless, proved to be feasible for large population groups and to the scenario of health services. Thus, this interdisciplinary FV-RCT study represents an effort to advance methodological issues and provide theoretical subsidies for actions.

### 1. Introduction

Documents of the World Health Organization have highlight the need for countries to commit themselves to the proposition and implementation of effective, integrated, sustainable evidence-based public policy for the prevention and control of chronic non-communicable diseases (NCDs) and associated risk factors, mainly by strengthening primary health care [1,2].

The scientific community has presented alternatives; however, the interventions proposed constitute a heterogeneous set of methods, with different combinations of intensity, time and behaviours evaluated (compromising reproducibility), generally resulting in minimal changes to lifestyles and participants health [3]. Few studies have been conducted in the context of health services, despite their importance in providing a practical solution [4]. In addition, behaviour-based interventions do not explain the theories used and how each construct was applied [5,6]. We have few methodological articles, which would

favour reproduction of methods and consequently verify the consistency of findings. With respect to participants, researches have shown a low participation rate; most studies do not observe participants' attitudes and perceptions concerning diet and health and disregard the fact that some people are not ready to introduce changes [7].

To overcome these issues, the use of educational theories is fundamental. The theories promote reflection, guiding action, and facilitating the understanding of interactions that constitute human behaviour [8]. The methods and theories used should facilitate the planning of distinguished interventions, respecting participant characteristics such as environment, culture, perception, attitude, difficulties, and motivation to accomplish behaviour change [7].

Despite the importance of these issues, most published epidemiological studies focus on the effects of interventions on a certain behaviour or disease, without providing sufficient explanation concerning the methods used or their application in real-life contexts [9]. Hence, we have a gap regarding the understanding of educational theories and

Abbreviations: CG, control group; FV, fruit and vegetable; HAP, Health Academy Program; IG, intervention group; TM, transtheoretical model

\* Corresponding author. Department of Nutrition, Nursing School Federal University of Minas Gerais, Avenida Alfredo Balena, 190, Room 316, Belo Horizonte, Minas Gerais, 30130-100, Brazil.

E-mail addresses: [marysnut@gmail.com](mailto:marysnut@gmail.com) (M.C.d. Menezes), [raqueldmendonca@gmail.com](mailto:raqueldmendonca@gmail.com) (R.d.D. Mendonça), [nathnutricaoufmg@gmail.com](mailto:nathnutricaoufmg@gmail.com) (N.L. Ferreira), [larissamfg@gmail.com](mailto:larissamfg@gmail.com) (L.M.F. Guimarães), [alinelopesenf@gmail.com](mailto:alinelopesenf@gmail.com), [aline@enf.ufmg.br](mailto:aline@enf.ufmg.br) (A.C.S. Lopes).

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practices, and the knowledge and reapplication of methods.

In this way, this study will present the methodology of an innovative intervention proposal in the promotion of fruit and vegetable (FV) consumption in adult consumers, based on individuals' perceptions of their consumption habits, using different theories. To our knowledge, this study is one of the first Randomized Controlled Community Trial for FV promotion (FV - RCT) held in the health service system of a low-income country; proposing to jointly evaluate the process and the effectiveness of the intervention, with a considerable sample.

In consideration of the key role of methodological choices in planning and developing educational activities, this study aimed to present the protocol of the FV - RCT, a community educational nutrition intervention, provided in Brazilian primary health care. The main objective of the FV - RCT study was to evaluate, among a vulnerable population, the effectiveness of a nutrition intervention on FV consumption. In this article, we describe the methods and present baseline data and preliminary results.

## 2. Material and methods

### 2.1. Study setting and participants

The study was conducted in Belo Horizonte, Brazil, the eighth-largest city on the South American continent, with an estimated population of 2,375,151 inhabitants and a high Human Development Index value (0.810) [10].

One of the characteristics of the public health system in Brazil is heavy investment in primary care. The system is divided into different health services, such as basic health units and the Health Academy Program (HAP). The HAP, which was the scenario examined in this study, focuses on the promotion of health care by encouraging physical activity, leisure, and healthy eating, and other activities at no cost to participants [11]. The practice of physical exercise is guided by a physical education instructor and is offered for 60 min, three times a week per class.

The FV - RCT study was conducted in the HAP scenario: a randomized controlled community trial to encourage FV consumption in a representative sample of service users.

The HAP centres were selected via stratified cluster sampling in each of nine strata representing the nine administrative districts of the municipality. In each geographic stratum, formed according to the nine administrative regions of the municipality, two units were selected from low-income areas in the municipality and randomly assigned to the intervention (IG) or control group (CG).

Therefore, 18 centres were included in the study, nine with participants in the IG, and nine with participants in the CG; these centres were representative of the municipality, with reliability of 95% and error of less than 1.4%.

In each selected centre, participants in the study included all aged 20 years or older and habituated to the activities within the centres (e.g., regular participation in physical exercise in the preceding month). Pregnant women and individuals with cognitive difficulties preventing research participation were excluded from the study.

Participants in the IG and CG participated in the routine activities of HAP, which included physical activities, for three times a week during one hour. The CG did not participate in any activity related to nutritional intervention. During intervention development, we investigated and recorded educational activities related to nutrition and FV consumption among participants in the CG and IG, regardless whether these were conducted by the research team. We found that no further specific action of FV consumption was released for the CG until the follow-up evaluation at seven months.

### 2.2. FV - RCT intervention group

An important step in planning the FV - RCT intervention was the pilot study that had been previously conducted in order to examine the

practices, barriers, facilitators, and social representations related to FV consumption. It allowed the activities adaptation according to participants' subjective needs [12] and identification of the shortcomings that should compose the activities. These shortcomings were related to food portions; nutritional information about FV (vitamins and minerals); and means of overcoming obstacles to changing FV consumption, which were associated with cost, flavour, family support, time required to buy and prepare food; and difficulties in access to quality FV.

The educational activities for intervention were developed by a trained interdisciplinary team consisting of dietitians, educators, and psychologists with expertise in health education. In order to standardize methodology, intervention development was performed by a team of three dietitians, who alternated between application and observation of the process, aided by at least three graduate students in Nutrition at all times.

Invitations to attend the workshops were made in writing and by telephone, one week in advance, with up to three contact attempts made on different days; thereafter, the invitation was left with a family member. Furthermore, physical educators in the centres propagated intervention during exercise classes.

The interdisciplinary team defined educational strategies and listed those that would be appropriate for the theoretical framework used.

### 2.3. Theoretical intervention approach

Educational activities were established based on problematizing-dialogic pedagogy of Paulo Freire [13], the pillars of the transtheoretical model (TM) [7], information gained via a qualitative pilot study [12] and literature review involving the factors associated with FV consumption.

The TM includes four pillars: stages of change, processes of change, self-efficacy, and decisional balance. The model facilitates the planning and implementation of various actions according to individuals' specific characteristics including perception, availability, attitude, and motivation to make behavioural changes [7,14].

Regarding stages of change, motivation for change defines phases that guide action planning and development. In the precontemplation stage, individuals do not intend to change their behaviour in the foreseeable future. In the contemplation stage, individuals recognize the need to change but require action to shape their motivation. In the preparation stage, individuals are ready to change their behaviour within 30 days. In the action stage, individuals are capable of short, immediate changes for a period of up to six months. In the maintenance stage, individuals' behaviour was changed more than six months previously, requiring the prevention of relapse and consolidation of gains [7].

To establish feasibility of intervention development in primary care service, the participants were regrouped as follows according to the stages of change with respect to FV consumption: preaction (precontemplation and contemplation stages), preparation stage, and action (action and maintenance stages).

The interventions were constructed according to each grouping, using the other components of TM. There are five cognitive and five behavioural processes of change. These processes underlie the understanding of how change occurs in stages. Cognitive processes are more effective in the preaction and preparation stages; and educational activities should focus on increasing awareness of behaviour and its consequences. The behavioural processes are directed to the action stages; providing more specific and detailed information [7]. Interventions also aimed to (1) increase individuals' confidence in their ability to achieve the desired behaviour when faced with obstacles (self-efficacy) [15] and, (2) increase awareness of the benefits of a healthy diet while minimizing the factors against change (decisional balance) [15].

Problematizing-dialogic pedagogy, proposed by Paulo Freire, was chosen for intervention development, to advance the TM and advocate autonomy and empowerment, as proposed in the HAP [8,13]. In this

proposal, education creates the possibility of liberation, which promotes conscientious attitudes and presumes a horizontal and dialogical relationship between participants, which is aimed at knowledge exchange instead of a relationship in which one is superior to the other [13].

#### 2.4. Observers' team and analysis plan

The observation of the intervention was made through an observation questionnaire. The questions were previously tested in a HAP centre not participating in the research in order to make the necessary adjustments to its application. The observation questionnaire recorded theme, objective (and if it was reached), number of participants, duration, description of how the action occurred, problems, participants doubts, satisfaction of participants and how was the participation of the subjects involved in the activities. It was performed by four trained dieticians.

Also, considering evaluation of intervention effectiveness, initial and final face-to-face interview was performed by trained staff (dieticians or students of nutrition). The primary endpoint is change in FV consumption (grams) during follow-up. Secondary endpoints include mediating variables related to the main outcome: knowledge of FV season/crop; FV availability at home; and behaviour (stages of change, self-efficacy, and decisional balance).

In this study we present the descriptive statistics for participant's characteristics at baseline. The future analysis plan includes between-group differences for participants and non-participants at follow-up; and within-group changes. In order to analyze the impact on the primary outcome, generalized estimating equation will be used to examine the change in FV consumption. This analytic method examines time-varying dependent variables in relation to time-varying (variables that change over time) and time-constant (variables that do not change over time).

The study was approved by the University Ethics Research Committee (No. 0537.0.0203.000–11) and City Hall (No. 0537.0.0203.410–11A) and registered in the Brazilian Registry of Clinical Trials (RBR-9h7ckx; website: [www.ensaioclinicos.gov.br/rg/RBR-9h7ckx/](http://www.ensaioclinicos.gov.br/rg/RBR-9h7ckx/)). This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all participants were informed about the objectives and methods of the study via letter and signed the written consent prior to participation.

### 3. Results

#### 3.1. FV - RCT intervention group: participants' characteristics

From 3414 participants of 18 HAP centres, educational activities were developed for 1483 participants (43.4%) (9 HAP centres were IG) and implemented for seven months, in blocks of three centres.

Table 1 presents baseline characteristics of participants. FV - RCT intervention group participants were mostly women (87.0%), adults with low education and income, and with a high prevalence of NCDs. However, most reported being in group action, with a high average of FV consumption (360.0 g) (Table 1).

#### 3.2. Educational strategies

The following strategies were defined: workshop, motivational message via postcard, environment-based activity associated with the panel setting (particularly those concerning the interactive activity in the setting, e.g., movies and culinary), and delivery of informative material. All strategies were tailored according to the transtheoretical model (TM)'s stages of change, with the exception of the informative material and environment-based activities.

The educational activities addressed the following topics: health and food consumption; purchase, seasonality, and cost of FV; preserving

**Table 1**  
Baseline characteristics of participants of group intervention (n = 1483).

| Characteristics                                 | n    | Value               |
|---|------|---------------------|
| <b>Sex (%)</b>                                  |      |                     |
| Female  | 1291 | 87.0                |
| <b>Age (years)</b>                              | 1483 | 56.6 ± 12.2         |
| <b>Family income per capita (\$)</b>            | 1349 | 301.3 (96.5; 888.9) |
| <b>Education (years)</b>                        | 1482 | 6.9 ± 4.1           |
| <b>Marital status (%)</b>                       |      |                     |
| Married   | 906  | 61.1                |
| Divorced  | 132  | 8.9                 |
| Single  | 211  | 14.2                |
| Widow   | 234  | 15.8                |
| <b>Profession (%)</b>                           |      |                     |
| Housewife                                       | 426  | 28.7                |
| Retired   | 543  | 36.6                |
| Unemployed                                      | 39   | 2.6                 |
| Employed  | 475  | 32.0                |
| <b>Body mass index (Kg/m<sup>2</sup>)</b>       | 1415 | 27.9 ± 4.7          |
| <b>Waist circumference (cm)</b>                 | 1414 | 86.8 ± 10.9         |
| <b>Diseases (%)</b>                             |      |                     |
| Hypertension                                    | 796  | 53.7                |
| Diabetes  | 245  | 16.6                |
| Dyslipidemia                                    | 644  | 43.8                |
| <b>Stages of change Fruit and Vegetable (%)</b> |      |                     |
| Preaction                                       | 279  | 18.8                |
| Preparation                                     | 515  | 34.7                |
| Action  | 689  | 46.2                |
| <b>Fruit and Vegetable consumption (g/day)</b>  | 1462 | 360.0 (97.1; 720.0) |

After performing Shapiro–Wilk test to assess normality of the quantitative variables, variables with normal distribution were presented in mean and standard deviations; and variables with non-normal distribution in median and interquartile ranges. Income - Brazilian Real to Dollar (\$): 2.25 was the average exchange rate during the data collection period.

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.

Fig. 1 shows the timeline for educational strategies development. The educational strategies used in the activities (workshops, postcard with motivational messages, interactive environment-based activities and informative material) are presented in Fig. 2, showing their theoretical and developmental characteristics.

In the workshops different techniques were used, as described below:

- **Conversation circles:** Are characterized by space for dialogue, communication, and the exchange of experiences and information. The main objective is the development of the participant's autonomy via problematization, socialization of knowledge, and reflection on actions to promote empowerment [16].
- **Image theatre:** Uses mainly concrete images to express emotions. One's own or another person's gestures constitute language and express feelings, problems, and ideas. The images constructed by the body are participants' creations, which facilitate the expression of thoughts, since images are easier to create than words [17].
- **Self-portrait:** Assists the construction of one's identity in relation to the community, the neighbourhood, the city, the world, and one's emotions. When someone draws yourself, he/she is doing his/her self-portrait, which may arouse many questions [18].
- **Cooking:** Facilitates the appreciation of cultural, social, and symbolic dimensions of feeding, embracing a moment of experience and the exchange of that experience. The cooking workshop allows one to be closer to individuals' daily lives, establishes contact with food, preparation of recipes, and tasting different preparations, which can provide new alimentary possibilities [19].
- **Art as experience:** Helped to construct the educational strategies, permeating the encounter with the unexpected in the context of the

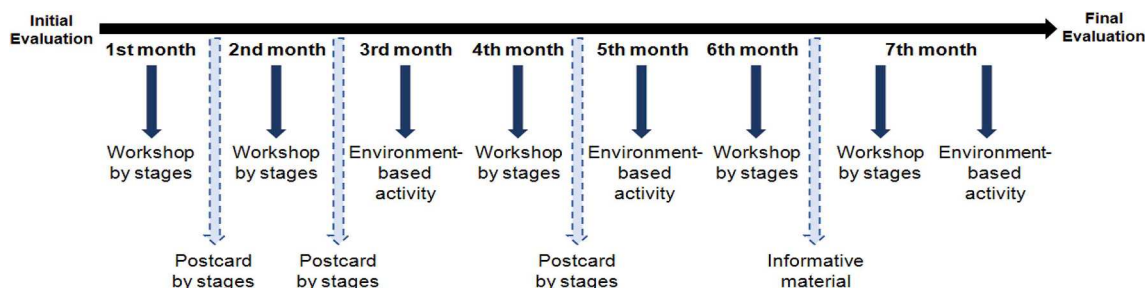


Fig. 1. Timeline for educational strategies development.

participants' lives, trying to evoke and/or renew the meaning of food in their lives, involving different emotions (pleasure, frustration, sadness and joy) and cover the subject in its totality [20,21].

3.3. Educational strategies according to the transtheoretical model

The activities were developed with the completion of 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. To monitor the frequency with which users participated in FV - RCT intervention, the names of all participants were recorded.

Fig. 3 describes the educational strategies performed according to the TM, their objectives, techniques and materials.

In the preaction group, the activities aimed to promote knowledge about healthy eating and to show its benefits; to provide to individuals tools to analyze their own diet; to increase awareness of the behaviour and its consequences; increase self-confidence in adopting healthy eating; and assist in identifying barriers to change and map out joint strategies to overcome them. In this group, strategies such as conversation circles, image theatre and self-portrait, were used to enhance the expression of feelings, sensations and thoughts, as well as reflection on

the possibility of behaviour change (Fig. 3).

The preparation group focused on the signification of feelings, sensations and thoughts related to health. Participants elaborated a “plan of action” to be achieved within 30 days and were assisted to achieve feasible objectives related to FV intake, without being overburdened with excessive targets. Other strategies included self-portrait and sensory exploration of FV (Fig. 3).

In the action group, the activities provided individualized detailed materials; and favoured individual's skills in changing long-term behaviour and facing new difficulties, encouraging the maintenance of gains and prevention of relapse. The strategies involved cooking; social support; to develop ability to face new difficulties; thus, stimulating to promote and maintain changes achieved (Fig. 3).

4. Discussion

In order to conduct an intervention to promote FV consumption in health service, it was necessary to use different educational strategies aligned according to the chosen theories. This effort, although exhaustive because it involved a large contingent of people, proved feasible and apparently important to promote sustainable changes in participants' diet.

| Educational Strategy                     | Theoretical characteristics   | Developmental characteristics   |
|--|---|---|
| Workshop                                 | <ul style="list-style-type: none"> <li>- Structured group work</li> <li>- Focus on a central topic</li> <li>- Consideration of the social context</li> <li>- Addressing the subject in a comprehensive manner, considering their ways of thinking, feeling, and acting<sup>27</sup>.</li> <li>- Three basic stages: introduction and discussion of the topic, creation of strategies and targets, and conclusion</li> </ul>   | <ul style="list-style-type: none"> <li>- Differentiation according to the transtheoretical model stages</li> <li>- Use of different techniques according to themes: Conversation circles, image theatre, self-portrait, and cooking</li> <li>- Duration: 60 minutes</li> <li>- Number of participants: maximum of 20</li> </ul>   |
| Postcard                                 | <ul style="list-style-type: none"> <li>- Motivational messages to stimulate participation in activities and adoption of healthy eating habits, specifically according to the stages of change</li> </ul>  | <ul style="list-style-type: none"> <li>- Differentiation according to the transtheoretical model stages                             <ul style="list-style-type: none"> <li>• Preaction: importance of self-care</li> <li>• Preparation: importance of planning change</li> <li>• Action: encouraging positive thoughts regarding fruit and vegetable consumption</li> </ul> </li> </ul>   |
| Interactive environment-based activities | <ul style="list-style-type: none"> <li>- Only strategy performed for all individuals simultaneously: the sharing of ideas favours dialogue, joint production of knowledge, problematization, and process of change</li> <li>- Promotion of reflection on fruit and vegetable consumption</li> <li>- Discussion time for problematic situations and making room for dialogue, expression, and autonomy</li> <li>- Meeting with the unexpected in the routine physical activity</li> <li>Example: exposure of a basket with fruit and vegetables for a week in the centre, modifying the environment with an unusual object and promoting the dramatization of food deterioration. The discussion stimulated the reflection about consumption, self-care health promotion and the relation present between the process of food deterioration with health-disease process, discussing the importance of eating habits to achieve the health potential</li> </ul> | <ul style="list-style-type: none"> <li>- Changes to physical space for services, using different techniques such as inclusion of unusual materials (basket with fruit and vegetables; supermarket trolley with a mirror inside); film with tasting of a culinary dish; and a food festival</li> <li>- Panels aimed at reinforcing themes performed and displaying meeting records (pictures):                             <ul style="list-style-type: none"> <li>• each panel was exhibited for one month</li> <li>• form of communication between the research team and users in the intervals between activities</li> </ul> </li> </ul> |
| Informative Material                     | <ul style="list-style-type: none"> <li>- Resolving users' questions</li> <li>- Dialogue with the family and community</li> </ul>  | <ul style="list-style-type: none"> <li>- Providing reliable information concerning the following issues:                             <ul style="list-style-type: none"> <li>• importance of consuming fruit and vegetables</li> <li>• purchase, sanitization, storage of fruit and vegetables</li> <li>• healthy recipes</li> </ul> </li> <li>- Colourful booklet with four folds</li> </ul>  |

Fig. 2. Description of educational strategies.

| Grouping             | Activities   |   |  |   |
|----------------------|--|---|--|---|
|                      | Educational strategy   | Objectives  | Technique  | Material  |
| Activities in common | Workshop: "Who are we?"  | <ul style="list-style-type: none"> <li>Introduce participants to the stages of change and activities</li> <li>Know the participants and their expectations with respect to the activities</li> </ul>  | Conversation circles   | Doll and images that could represent the participants' life contexts  |
|                      | Interactive environment-based activity, "Fruit and vegetables (FV), why?"  | <ul style="list-style-type: none"> <li>Reflect on the concept of health associated with healthful eating</li> <li>Discuss the importance of eating FV</li> </ul>  | Inclusion of an extraneous object in the HAP centre for a week   | Panel and basket of (initially fresh) FV                              |
|                      | Interactive environment-based activity, "FV, where and how?"               | <ul style="list-style-type: none"> <li>Reflect on obstacles (purchases and costs) to FV consumption and strategies to overcome them</li> </ul>  | Inclusion of an extraneous object in the HAP centre for a week   | Supermarket cart with a mirror  |
|                      | Interactive environment-based activity, "FV in my life today and forever!" | <ul style="list-style-type: none"> <li>Reflect on obstacles to FV consumption, focusing on taste, time, media, and personal relationships</li> <li>Discuss the importance of healthy eating</li> </ul>  | Short film with tasting of healthy food preparation  | - Material for projection, film, a healthy food preparation and Panel |
|                      | Informative Material: "Savouring FV"                                       | <ul style="list-style-type: none"> <li>Enable access to reliable information concerning nutritional value, portions, shopping, sanitization, storage, and FV preparation</li> </ul>   | -  | Printed material  |
|                      | Gastronomic Festival   | <ul style="list-style-type: none"> <li>Exchange recipes and experiences</li> <li>Sample preparations with healthy and affordable FV</li> <li>Encourage FV consumption</li> <li>Last day of FV - RCT intervention</li> </ul>   | Competition involving election of the top three culinary preparations  | Evaluation sheets for preparation                                     |
| Preaction            | Postcard 1   | <ul style="list-style-type: none"> <li>Encourage participation in activities</li> </ul>   | Motivational message: "Your health in first place. Participate in the activities."   | Graphic resources   |
|                      | Workshop, "What does health mean to you?"                                  | <ul style="list-style-type: none"> <li>Reflect on the individual's perception of the concept of health</li> </ul>   | Image theatre  | -   |
|                      | Postcard 2   | <ul style="list-style-type: none"> <li>Stimulate self-care guided by the concept of health</li> </ul>   | Motivational message: "Taking care of your health is an act of love for yourself!"   | Graphic resources   |
|                      | Workshop, "FV, where to start? Increasing the Pros I"                      | <ul style="list-style-type: none"> <li>Discuss determinants of food choice and their relationship to health</li> <li>Reflect on autonomy in healthy food choices, focusing on FV</li> </ul>   | Conversation circles   | Scales and weights  |
|                      | Postcard 3   | <ul style="list-style-type: none"> <li>Encourage self-care</li> </ul>   | Motivational message: "The future is important, because it is where I am going to live."   | Graphic resources   |
|                      | Workshop, "GV, where to start? Increasing the Pros II"                     | <ul style="list-style-type: none"> <li>Expose the importance of consuming FV</li> <li>Discuss strategies to overcome obstacles to FV consumption</li> </ul>   | Self-portrait  | Paper, pencil, paste, paint, brush, and figures                       |
| Grouping             | Activities   |   |  |   |
|                      | Educational strategy   | Objectives  | Technique  | Material  |
| Preparation          | Postcard 1   | <ul style="list-style-type: none"> <li>Encourage participation in activities</li> </ul>   | Motivational message: "Your health in first place. Participate in the activities."   | Graphic resources   |
|                      | Workshop, "Health and Healthy Eating"                                      | <ul style="list-style-type: none"> <li>Reflect on determinants of health and their relationship to alimentation</li> <li>Discuss the importance of consuming FV and their association with health</li> </ul>  | Self-portrait  | Paper, pencil, paste, paint, brush, and figures                       |
|                      | Postcard 2   | <ul style="list-style-type: none"> <li>Encourage the adoption of healthful eating</li> </ul>  | Motivational message: "To be healthy, start taking care of your nutrition today."  | Graphic resources   |
|                      | Workshop, "Planning my nutrition"  | <ul style="list-style-type: none"> <li>Recognize the importance of planning behaviour change</li> <li>Discuss obstacles to change</li> <li>Produce a plan of action</li> </ul>  | Conversation circles   | Plan of action  |
|                      | Postcard 3   | <ul style="list-style-type: none"> <li>Encourage FV consumption and execution of an action plan</li> </ul>  | Motivational message: "Have you taken care of your health today? How about eating more FV? Do not put off until tomorrow what you can do today!" | Graphic resources   |
|                      | Workshop, "Laboratory of tastes"   | <ul style="list-style-type: none"> <li>Try FV using sensory perception</li> <li>Discuss means of increasing FV consumption</li> <li>Encourage FV consumption</li> </ul>   | Conversation circles   | Eye-mask, dark box, and food  |
| Action               | Postcard 1   | <ul style="list-style-type: none"> <li>Encourage FV consumption</li> </ul>  | Motivational message: "Your life more delicious and colourful! This is possible ... include FV in every meal!"                                   | Graphic resources   |
|                      | Workshop: "Knowing FV portions"  | <ul style="list-style-type: none"> <li>Reflect on the benefits of FV</li> <li>Discuss strategies to increase FV consumption</li> </ul>  | Conversation circles   | Cards with pictures of FV portions                                    |
|                      | Postcard 2   | <ul style="list-style-type: none"> <li>Address the FV consumption associated with self-care</li> </ul>  | Motivational message: "Your health on a daily basis! Consume fruit in snacks and greens and vegetables at lunch and dinner!"                     | Graphic resources   |
|                      | Workshop: "Savouring FV - Part I"  | <ul style="list-style-type: none"> <li>Discuss the importance of support from family, friends, and neighbours to increase and/or maintain FV consumption</li> <li>Discuss FV consumption and preparation techniques</li> <li>Sample low-sugar FV preparation</li> </ul> | Culinary workshop  | Food and different types of sugar and sweetener                       |
|                      | Postcard 3   | <ul style="list-style-type: none"> <li>Encourage positive thoughts regarding fruit and vegetable behaviour</li> </ul>   | Motivational message: "FV for a healthy life. Have you eaten any of these foods today?"  | Graphic resources   |
|                      | Workshop: "Savouring FV - Part II"   | <ul style="list-style-type: none"> <li>Discuss FV consumption and preparation techniques</li> <li>Sample preparation of FV with little salt or oil</li> </ul>   | Culinary workshop  | Food  |

Fig. 3. Educational strategies according to the groupings based on the Transtheoretical Model stages of change.

Theoretical and methodological choices regarding lifestyle interventions should encourage dialogical and emancipatory educational activities that promote independent and voluntary healthy lifestyles. There is a need to overcome proposals for actions that merely *intervene* without *promoting* health. Educational activities planned and developed through listening, dialogue, and joint production of knowledge, favour citizenship and autonomy, complying with health promotion principles [22].

The planning and development of intervention passes through several stages that should be discussed within an interdisciplinary team. This process includes local reality, the individuals involved, social representations, and the definition of educational theory and methodology, which guides the selection and construction of educational strategies.

The FV-RCT intervention revealed participants in a vulnerable situation, with low socioeconomic condition and high prevalence of NCDs, showing the importance of lifestyle intervention. Socioeconomically disadvantaged individuals typically demonstrate low quality dietary intake, live in neighbourhoods with lower access to healthy food and are more likely to develop NCDs [23]. The innovative HAP service represents an important initiative to promote health, prevent, and control prevalence of NCDs in populations with high social vulnerability. The FV-RCT intervention took into consideration important factors that affect food behaviours, such as social determinants, culture, food and social environment, possible cognitive difficulties, appropriate language in its development, between others.

In addition, the FV-RCT intervention was implemented mainly for women participants. The gender imbalance affects external validity of the study, which should be generalized mainly for the primary health care setting. It is well documented in literature that most participants of healthcare services in Brazil are women, which is an issue out of the control of researchers. This is likely due to service access (which can hinder the permanence of the economically active public) and also

cultural (while women are more attentive to health issues, men are more resistant to seeking primary care and prevention actions) [24–26].

The use of educational theories may impose challenges. It is worth to highlight the ones related to the application of the TM, which was used in this study. There was a need for all individuals classified according to the five stages of change to participate in the educational activities, including those in the action and maintenance stages, which increased the complexity of intervention logistics, mainly because of the numbers of activities and participants involved. Some studies have examined only those individuals considered at risk of the target behaviour (i.e., those in the preaction stage) [22,27]. However, individuals in the action and maintenance stages should also be included, considering that some of their eating behaviours might require improvement [28], and they may be subject of relapse, particularly in view of today's obesogenic environment.

In this study, FV - RCT intervention were performed by the preaction, preparation, and action subgroups; this could have limited the educational activities developed, leading to the exclusion of approaches addressing these stages from each group. However, it is worth to note that 711 meetings in nine centres of health services were required to conduct considering the three groups, which raises the question as to whether it is viable and applicable to perform specific activities for the five stages in the context of primary care. It should also be noted that individuals in the early and late stages are sufficiently similar to allow the use of similar processes of change and strategies related to decisional balance and self-efficacy.

Intervention to promote the health of individuals, families, and communities should be prioritized in the context of health services, enabling the application of scientific evidence to practice situations that echo improvements in the health of the population under real-life conditions, to the detriment of studies performed under ideal, unviable conditions in the human context [9]. In this way, careful and systematic planning associated with institutional commitment, community

mobilization, and focus on critical behaviours have been shown to be essential.

For the appropriate use of educational theories in the development of health actions, certain methodological steps must be employed. Special attention should be paid to interdisciplinary planning and the theoretical alignment of the professionals responsible for their implementation. The theoretical development of educational strategies is extremely important considering the challenge of training qualified facilitators aligned with the educational strategies proposed [29]. The interdisciplinary approach facilitates the articulation of knowledge and enrichment of skills, strengthening professionals and enhancing educational activities [22,30].

To ensure advancement of health-promotion interventions, it is fundamental the expansion of vehicles that allows the dissemination of methodology and detailed description of actions. This disclosure could be accomplished by publishing methodological studies and sharing the strategies and techniques developed, including their particularities and specificities, provided that they ensure the researchers authorship. Access to the methodology of health actions facilitates the reapplication of studies, resulting in verification of the results consistency and identification of valid and reproducible methods in different contexts.

We also highlight the potential for these studies to support new research that contributes to improve effectiveness of actions and public policies, which is a pressing global need.

## 5. Conclusion

The applied intervention based on the chosen theories implied in a refinement of the intervention with the inclusion of different educational strategies, which consider the context involved in the objective investigated. But, nevertheless, the intervention proved to be feasible for large population groups and to the scenario of health services.

Thus, this interdisciplinary FV-RCT study represents an effort to advance methodological issues and provide theoretical subsidies for actions. It can provide detailed information for lifestyle intervention and has the potential to make a substantial contribution to the development of nutrition interventions that are applicable to and attractive for populations, especially those at public health system.

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## 6. Number registration

RBR-9h7ckx in Brazilian Registry of Clinical Trials.

## Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.conctc.2018.04.003>.

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**Update**

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## Erratum regarding missing Declaration of Competing Interest statements in previously published articles

Declaration of Competing Interest statements were not included in the published version of the following articles that appeared in previous issues of Contemporary Clinical Trials Communications.

The appropriate Declaration/Competing Interest statements, provided by the Authors, are included below.

- 1 “Evaluating the effectiveness and reliability of the Vibrant Soundbridge and Bonebridge auditory implants in clinical practice: Study design and methods for a multi-centre longitudinal observational study” [Contemporary Clinical Trials Communications, 2018; 10: 137–140] <https://doi.org/10.1016/j.conctc.2018.03.007>.

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- 2 “Treatment of trauma related anger in operation enduring freedom, operation Iraqi freedom, and operation New Dawn veterans: Rationale and study protocol” [Contemporary Clinical Trials Communications, 2018; 12: 26–31].

<https://doi.org/10.1016/j.conctc.2018.08.011>.

Declaration of competing interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

- 3 “Different ways to estimate treatment effects in randomised controlled trials” [Contemporary Clinical Trials Communications, 2018; 10: 80–85]. <https://doi.org/10.1016/j.conctc.2018.03.008>.

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- 4 “Recruitment & retention program for the NeuroNEXT SMA Biomarker Study: Super Babies for SMA!” [Contemporary Clinical

Trials Communications, 2018; 11: 113–119] <https://doi.org/10.1016/j.conctc.2018.07.002>.

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- 5 “Two-step recruitment process optimizes retention in FLEX clinical trial” [Contemporary Clinical Trials Communications, 2018; 12: 68–75]. <https://doi.org/10.1016/j.conctc.2018.09.005>.

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- 6 “Design of an experimental protocol to examine medication non-adherence among young drivers diagnosed with ADHD: A driving simulator study” [Contemporary Clinical Trials Communications, 2018; 11: 149–155]. <https://doi.org/10.1016/j.conctc.2018.07.007>.

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- 7 “Exercise training as S-Klotho protein stimulator in sedentary healthy adults: Rationale, design, and methodology” [Contemporary Clinical Trials Communications, 2018; 11: 10–19] <https://doi.org/10.1016/j.conctc.2018.05.013>.

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- 8 “Extensions of the mTPI and TEQR designs to include non-monotone efficacy in addition to toxicity for optimal dose determination for early phase immunotherapy oncology trials” [Contemporary Clinical Trials Communications, 2018; 10: 62–76]. <https://doi.org/10.1016/j.conctc.2018.01.006>.

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- 9 “Meal-exercise challenge and physical activity reduction impact on immunity and inflammation (MERIT trial)” [Contemporary Clinical Trials Communications, 2018; 10: 177–189] <https://doi.org/10.1016/j.conctc.2018.05.010>.

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- 10 “A randomized preference trial of cognitive-behavioral therapy and yoga for the treatment of worry in anxious older adults” [Contemporary Clinical Trials Communications, 2018; 10: 169–176] <https://doi.org/10.1016/j.conctc.2018.05.002>.

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- 11 “Promoting fruit and vegetable consumption: Methodological protocol of a randomized controlled community trial” [Contemporary Clinical Trials Communications, 2018; 10: 131–136] <https://doi.org/10.1016/j.conctc.2018.04.003>.

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- 12 “An initiative using informatics to facilitate clinical research planning and recruitment in the VA health care system”

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- 13 “Reduce bladder cancer recurrence in patients treated for upper urinary tract urothelial carcinoma: The REBACARE-trial” [Contemporary Clinical Trials Communications, 2018; 9: 121–129] <https://doi.org/10.1016/j.conctc.2018.01.007>.

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- 14 “Master protocol trials in oncology: Review and new trial designs” [Contemporary Clinical Trials Communications, 2018; 12: 1–8]. <https://doi.org/10.1016/j.conctc.2018.08.009>.

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- 15 “Embedded Motivational Interviewing combined with a smartphone app to increase physical activity in people with sub-acute low back pain: Study protocol of a cluster randomised control trial” [Contemporary Clinical Trials Communications, 2019; 17: 100511] <https://doi.org/10.1016/j.conctc.2019.100511>.

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