



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 practices, and the knowledge and reapplication of methods.

In this way, this study will present the methodology of an

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 (M.C.d. Menezes), raqueldmendonca@gmail.com (R.d.D. Mendonça), nathnutricaoufmg@gmail.com (N.L. Ferreira), larissamfg@gmail.com (L.M.F. Guimarães), alinelopesenf@gmail.com, aline@enf.ufmg.br (A.C.S. Lopes).

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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

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