

# Methodological course of a community controlled trial in health care services: a translational epidemiological research on Nutrition

## Percurso metodológico de ensaio comunitário controlado em serviço de saúde: pesquisa epidemiológica translacional em Nutrição

Mariana Carvalho de Menezes<sup>1</sup>  
Bruna Vieira de Lima Costa<sup>1</sup>  
Nathália Luiza Ferreira<sup>1</sup>  
Patrícia Pinheiro de Freitas<sup>1</sup>  
Raquel de Deus Mendonça<sup>1</sup>  
Mariana Souza Lopes<sup>1</sup>  
Melissa Luciana de Araújo<sup>1</sup>  
Larissa Morelli Ferraz Guimarães<sup>1</sup>  
Aline Cristine Souza Lopes<sup>1</sup>

<sup>1</sup> Universidade Federal de Minas Gerais, Departamento de Nutrição, Escola de Enfermagem, Grupo de Pesquisas de Intervenção em Nutrição. Belo Horizonte-MG, Brasil.

*Financial support:* Conselho Nacional de Desenvolvimento Científico e Tecnológico-CNPq (granting no.476686/2013-0) e Fundação de Amparo à Pesquisa de Minas Gerais-Fapemig (APQ-033376-12, 21618/2013 e PPM-00254-15).

Correspondence  
Aline Cristine Souza Lopes  
E-mail: alinelopesenf@gmail.com

### Abstract

*Objectives:* To discuss and exemplify the methodology of a translational epidemiological research in the area of Nutrition. *Methodology:* A randomized controlled community-based trial to encourage the consumption of fruits and vegetables in a representative sample of the Health Gym Program of Belo Horizonte, MG. *Results and Discussion:* The methodological course consisted of the following stages: 1) A liaison with managers and professionals of the service and community; 2) Control and quality assurance of data collection; 3) A community educational action based on the transtheoretical model of behavior change (TTM) and Paulo Freire's dialogic and problematizing pedagogy; 4) Transfer to the community, managers and professionals. In the 18 centers investigated, 3,414 individuals were interviewed, a figure lower than that reported by local management (n = 5,778; -34.9%) and service center (n = 4,517; -16.7%). The majority were women, older adults with low schooling. The educational action included 540 workshops, 171 actions in the environment, distribution of 4,449 postcards and 1,483 participants, in order to reach the 1,483 participants in the intervention group. Search results were presented to the managers and banners were sent for discussion at the centers. *Conclusions:* This research showed that the accomplishment of translational population studies with quality is possible, being primordial the link with the service and the community, besides the continuous adaptation of its planning. It is intended, therefore, to provoke a reflection on the need of conducting studies on health care services, a scenario that has not yet been explored.

**Keywords:** Translational Medical Research. Uses of Epidemiology. Health Care Services; Primary Health Care. Nutrition.

Registry of Clinical Trials: RBR-9h7ckx at the Brazilian government Registry of Clinical Trials

## Resumo

*Objetivos:* Discutir e exemplificar o percurso metodológico de pesquisa epidemiológica translacional na área de Nutrição. *Metodologia:* Ensaio comunitário aleatorizado controlado de incentivo ao consumo de frutas e hortaliças em amostra representativa do Programa Academia da Saúde de Belo Horizonte-MG. *Resultados e Discussão:* O percurso metodológico constou das etapas: 1) Vinculação com gestores e profissionais do serviço e comunidade; 2) Controle e garantia de qualidade da coleta de dados; 3) Ação educativa comunitária, pautada no Modelo Transteórico, na pedagogia dialógica e problematizadora de Paulo Freire; 4) Devolutiva à comunidade, gestores e profissionais. Nos 18 polos investigados, foram entrevistados 3.414 indivíduos, número inferior ao informado pela gestão local (n=5.778; -34,9%) e central do serviço (n=4.517; -16,7%). A maioria eram mulheres, adultos mais velhos e com baixa escolaridade. A ação educativa incluiu 540 oficinas, 171 ações no ambiente, distribuição de 4.449 postais e 1.483 fôlderes, de forma a atingir os 1.483 participantes do grupo intervenção. Resultados da pesquisa foram apresentados para os gestores e enviados *banners* para discussão nos polos. *Conclusões:* A pesquisa mostrou que a realização de estudos translacionais populacionais com qualidade é possível, sendo primordial o vínculo com o serviço e a comunidade, além da adequação contínua de seu planejamento. Pretende-se, assim, provocar a reflexão sobre a necessidade de conduzir estudo em serviços de saúde, cenário ainda pouco explorado.

**Palavras-chave:** Pesquisa Médica Translacional. Aplicações da Epidemiologia. Serviços de Saúde. Atenção Primária à Saúde. Nutrição.

**Número de registro do ensaio clínico:** RBR-9h7ckx no Registro Brasileiro de Ensaio Clínicos

## Introduction

In view of the advancement of health problems without a satisfactory solution, such as chronic diseases, it is up to epidemiology, as a branch of medical science, to advance in the application of the scientific evidences, valuing its historical commitment to the improvement of populations' health and its collective and social nature.<sup>1</sup> To cover this gap, there is a translational epidemiology.<sup>2,3</sup>

Translational epidemiology suggests the conduction of epidemiological studies that evaluate the applicability and effectiveness of interventions under real life conditions.<sup>3-5</sup> Translational application of knowledge is seen in government initiatives in Brazil, such as monitoring and evaluation of the agreement with the food industry to reduce the sodium content in ultra-processed foods and the implementation of Brazilian government Health Gym Program (PAS, in the Portuguese abbreviation).<sup>6</sup> However, to the best of our knowledge, there is little in the way of conducting and publishing epidemiological translational research, especially in health services. A study<sup>7</sup> has identified that it takes about 17 years for only 14% of scientific results obtained in research to be applied in health services routine practices. Thus, health care continues to be based on the history of practice, assumptions and beliefs to the detriment of scientific evidence.

This is an alarming data for countries such as Brazil, which has a universal health care system that serves about 190 million people<sup>8</sup> with a strong investment in Primary Health Care (PHC) and it is indispensable that translational research explore this scenario. Carrying out translational epidemiological studies contributes to the production of scientific evidence relevant to publicly funded health care. It can support new research on health services, exemplifying the logistic and methodological aspects of the implementation of health care actions and of process and impact assessments. And it provides knowledge for planning and improving health care programs and policies.<sup>1,3,9</sup> Considering this scenario, this article proposes to discuss and exemplify the performance of translational epidemiological research on nutrition conducted in the context of Primary Health Care (PHC) services in Brazil.

## Methodology

A randomized controlled community trial conducted in Brazilian government Health Gym Program (PAS, in the Portuguese abbreviation), a Primary Health Care (PHC) service in Brazil, shall be presented. PAS has been created nationally in 2011 as a proposed health care promotion environment. It consists of physical sites, referred to as centers, with infrastructure and human resources qualified for providing guidance on corporal practices, physical and leisure activities, promotion of healthy and adequate diets, among other activities.<sup>6</sup>

In the Brazilian city of Belo Horizonte, in the state of Minas Gerais, PAS has been implemented in 2006 and presently has 64 centers distributed in nine regional administrative units. The choice

of this research scenario was due to the fact that the program encourages translational research in the development of effective interventions and consonant with local realities, in addition to being a recent health care promotion service.

Based on this, and according to scientific evidence, a randomized community controlled trial with PAS centers services users in Belo Horizonte was conducted. To ensure the study scientific efficiency, careful planning was carried out in two stages – the link with the service and the population – and the data effective control and quality assurance, with sampling definition and calculation, instruments preparation and testing, data collection and subsequent processing.

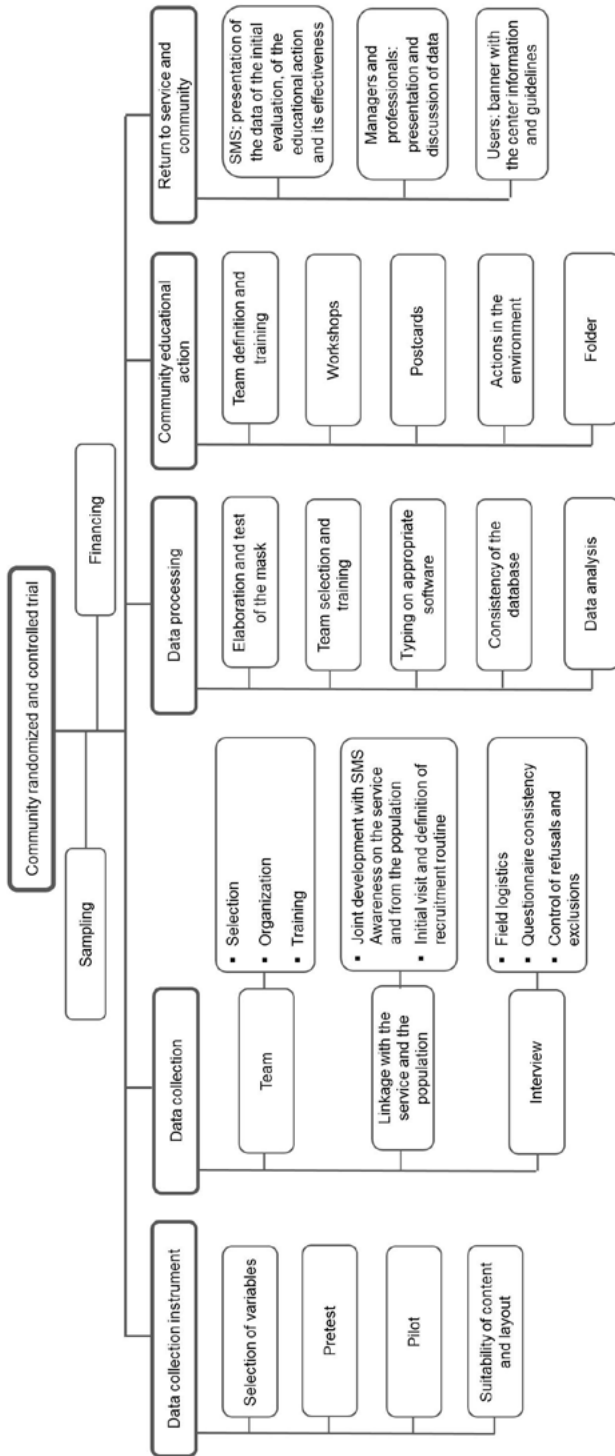
All steps of the research were recorded in a field manual, which presented the description of the logistics for data collection, form of filling the instruments used and selection and training of the team (Figure 1). The document was made available for consultation in all fields of data collection.

The third stage consisted of structuring community educational actions. Detailed scripts were created for carrying out the activities and didactic materials were developed. All the information obtained from the study was returned to the PAS and the community involved, constituting the fourth and last step of the methodological course adopted (Figure 1).

To accomplish the sampling process and identify the individuals to be surveyed, three different data sources were used: a) “registered users,” those that are frequent at the centers or have been temporarily removed, obtained from data from the PAS management, performed by the Municipal Department of Health; b) “frequent users,” those regular at the center activities, according to local service coordinators (physical educators); and c) “users identified in the field,” identified at the centers by the research team. To verify possible differences between these data sources, delta percentages were calculated by using the formula:  $[Source X - (Source A / Source X) * 100]$

This article shall also present sociodemographic information about the interviewees, such as gender, age and income, aiming to characterize the PAS users’ profile since it is a service still undergoing consolidation in the country. The number of users of the centers services and their age were presented in mean and standard deviation and the income as median and interquartile range. Student’s t-test and Pearson’s chi-squared test were used to compare the information among the centers ( $p < 0.05$ ).

The study was conducted within the standards required by the Declaration of Helsinki (DoH) and was approved by the Research Ethics Committees (REC) of the university (0537.0.0203.000-11) and the municipality (0537.0.0203.410-11 A) and registered at Brazilian government Registry of Clinical Trials (RBR-9h7ckx) in accordance with the criteria required by the *International Committee of Medical Journal Editors (ICMJE)* and by the World Health Organization (WHO). The users of the PAS centers services were clarified about the research methods and signed the Informed Consent Form (ICF).



**Figure 1.** Search quality control flow

Note: SMS: Municipal Department of Health (SMS, in the Portuguese abbreviation)

## Results

A translational research focused on the development of community educational actions to encourage the consumption of fruits and vegetables was carried out. This topic was chosen because it is effectively related to health care promotion and necessary, considering results of a priori surveys in Brazil and the world.

Below are the steps for performing a translational research, namely: A connection with services, professionals and community; data quality control and assurance; development and application of community educational actions; and transfer to service, professionals and community.

### A connection among services, professionals and the community

The link with the service was given by the project presentation and discussion with the Municipal Department of Health's technical references, even before raising financial resources. Subsequently, information on research and field logistics was presented for PAS technical references and regional and local coordinators.

In all centers, the research, the interview process and the importance of the users' participation were presented and the recruitment routine for interviewing professionals was defined. Then, all individuals aged 20 or older were invited to participate, except for pregnant women and those with reduced mental or cognitive capacity that would make it impossible for them to respond to the questionnaire.

This stage was critical to adjust the research methodology and define the data quality control process according to the centers different realities, consolidating the relationship between the university and health care services.

### Data quality control and assurance

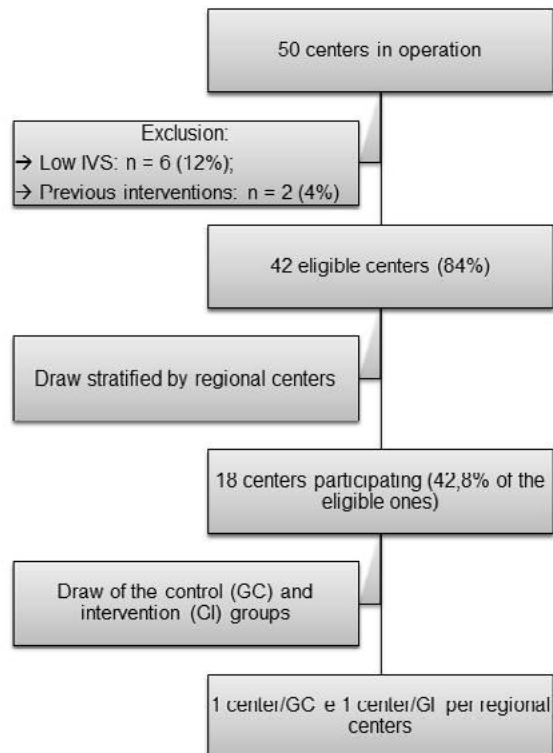
#### *Sample process*

To accomplish the sampling process, managers provided information on the services operation and database with sociodemographic variables in order to verify the sample representativeness.

Sampling by simple cluster of the PAS centers to be investigated was performed, stratified by the nine administrative regional units of the municipality. The inclusion criteria were: morning operation; being located in an area of medium and high/very high vulnerability to health (PAS' predominant characteristics in the municipality); not having participated in research related to

food and nutrition in the last two years; and being in operation in November 2012, the period of accomplishing the sample process; totaling 42 eligible centers (Figure 2).

In each geographic stratum, formed by the administrative regions, two centers were selected ( $n = 18$ , 42.8% of the eligible centers) paired according to the territory's vulnerability to health [Health Vulnerability Index (IVS, in the Portuguese abbreviation) – *this is a composite index that covers aspects related to sanitation, housing, education, income and health. The index high values indicate high vulnerability/risk and are intended to highlight epidemiological inequalities of distinct social groups*].<sup>10</sup> The centers were randomly assigned to a control group, individuals who participated only in the routine activities of the service (physical exercises, three times a week for an hour) and an intervention group that also received the community educational actions prepared by the research group. The sample was representative of the PAS centers with medium and high/very high vulnerability of the municipality, presenting 95% confidence level and 1.4% error (Figure 2).



**Figure 2.** Flowchart of the sample process.

Note: IVS: Health Vulnerability Index (IVS, in the Portuguese abbreviation); GC: Control group (GC, in the Portuguese abbreviation); GI: Intervention group (GI, in the Portuguese abbreviation).

## Data collection instrument

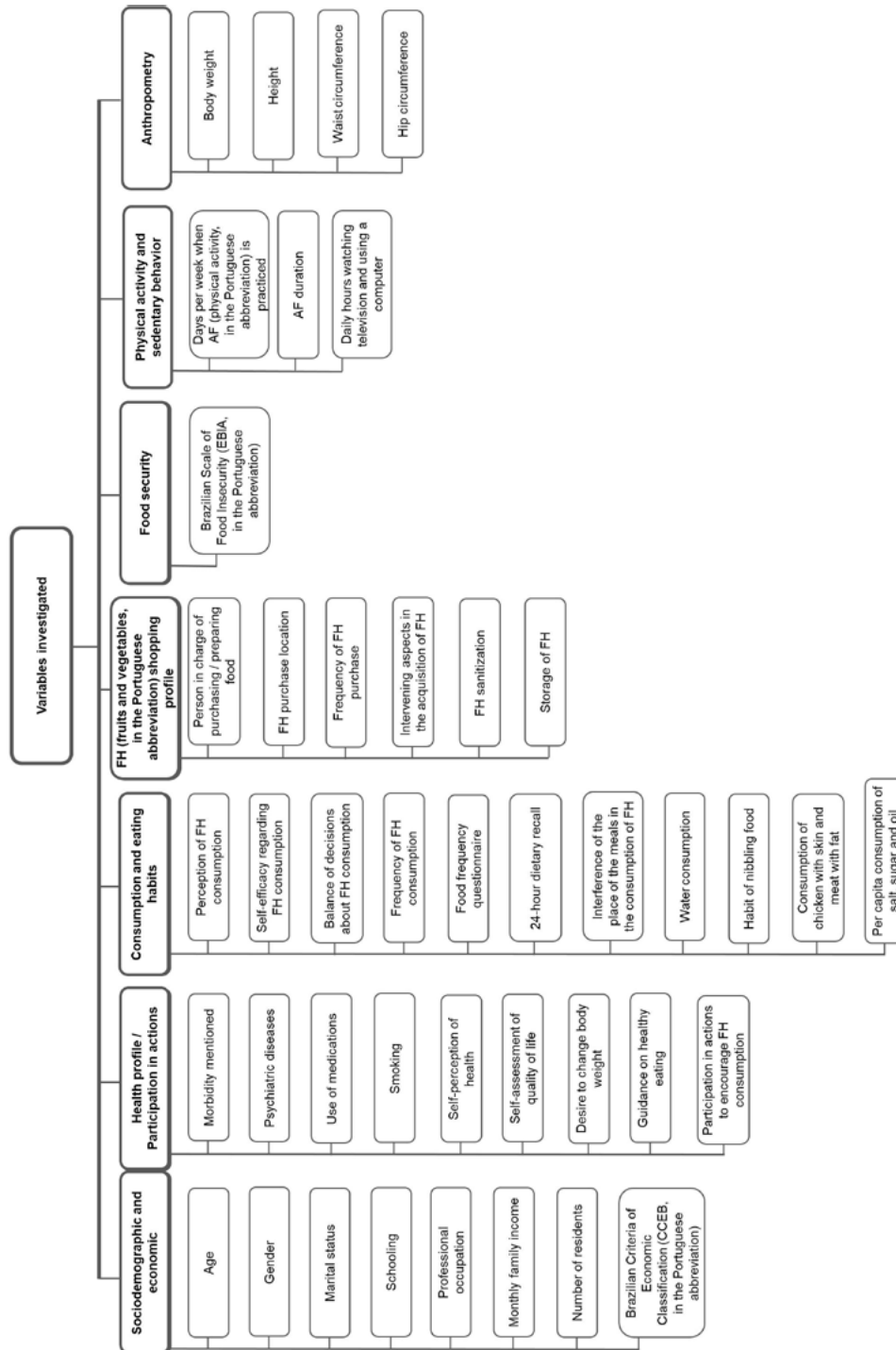
The questionnaire was based on national surveys such as the Brazilian Ministry of Health's Surveillance of Risk Factors and Protection for Chronic Diseases by Telephone Inquiry (VIGITEL, in the Portuguese abbreviation),<sup>11</sup> the Brazilian government Family Budget Survey (POF, in the Portuguese abbreviation)<sup>12</sup> and the Brazilian government Household survey on risk behavior and morbidity reported from noncommunicable diseases and aggravations,<sup>13</sup> besides previous experience of the research group.<sup>14-16</sup>

Sociodemographic and economic data; food and nutrition security; health conditions and perception; quality of life (QOL); practice of physical activities; food consumption and eating habits [Food frequency questionnaire (FFQ) and two 24-hour dietary recall (24HR) associated with a home measurement kit<sup>17</sup>]; and behavior evaluated by the transtheoretical model of behavior change (TTM) (Figure 3) were all investigated. Commercial establishments used for purchasing fruits and vegetables and hygienic-sanitary procedures used were also questioned about. Anthropometric measurements were also obtained.

The instrument was submitted to a pretest and a pilot study. There was a need to adapt the linguistic content, remove repetitive questions, restructure the layout and include guidelines for the interviewer as well as to develop response cards for difficult-to-understand variables and instructional cards for the interviewers. The pilot study included subjects of both genders with characteristics similar to those of the sample of interest, having been performed during 15 days between June and July 2012.

However, in the first weeks of data collection, there was a need to review the order of the questions in order to improve the fluidness of the questionnaire and to suppress questions still considered repetitive.





**Figure 3.** Variables investigated.

Note: AF: Physical activity (AF, in the Portuguese abbreviation); FH: Fruits and vegetables (FH, in the Portuguese abbreviation).

## Baseline data collection and reassessment

Data collection from baseline occurred between February 2013 and June 2014, with an average duration of four months of research at each center. Working with our own data collection team was the option due to the epidemiological design used and its implementation in health care services. These aspects demand specific knowledge and sensitivity for an effective action with the services professionals and users. The data collection team consisted of a coordinator (researcher in charge), a general supervisor and field supervisors (nutritionists;  $n = 1$  and  $n = 9$ , respectively) and interviewers (health care professionals and nutrition academics,  $n = 31$ ), totaling 43 individuals. The general supervisor would be in charge of maintaining constant communication with the research coordination and field supervisors, acting as a reference for solving doubts and answering to demands. Field supervisors were responsible for organizing the interviews and data collection, analyzing the questionnaires consistency and training the team as well as weekly sending the collection control worksheet.

Interviewers' training sessions were semiannual and included explanations about the research objectives, user-approach techniques, applying the information letter and an Informed Consent Form (ICF), simulation of interviews and registration of anthropometric measures. To avoid errors and methodological inconsistencies, new interviewers would be inserted in the field only after observation of the interview and supervised application of the instrument. When considered fit, they would begin the interviews, which were daily observed, discussing critical nodes.

The interview, both at the baseline and in the reevaluation, was carried out in two moments. The first one, lasting about 40 minutes, consisted of applying most of the questionnaire and a 24-hour dietary recall (24HR), in addition to scheduling the second part of the interview for a non-consecutive day. In the second moment, the implementation of a new dietary recall lasting approximately five minutes.

After completing each interview, the field supervisor would analyze its consistency, returning the questionnaire to the interviewee if any clarification were needed. From the interviews completed and checked, a field report would be weekly prepared and sent to the general supervisor and team coordinator. The user would be identified in the service for the interview and if they were not located in three attempts the center coordinator would be questioned about their attendance and a telephone call would be made, up to three times in different days and times. If after all these attempts the user would not be found, they would be considered infrequent and therefore excluded. If located but lacking three appointments in a row they would also be excluded.

For cases of exclusion and refusal, sociodemographic data available at the service (telephone contact, gender, age, marital status and occupation) would be recorded. When the user answered the first part of the interview but was not located to answer the second part, the second dietary recall would be carried out by telephone. In cases of refusal, this information would be recorded.

At the reassessment stage after about seven months, users not located at the center, according to the protocol mentioned above, would be interviewed by telephone about reasons for leaving the service, changes in physical exercise practices, consumption of fruits and vegetables and body weight.

## Data processing

*Microsoft Access* database management system (DBMS) version 7.0 was used for digitizing the information. The entire data processing stage was supervised and typists ( $n = 7$ ) were semiannually trained.

After completing the typing process, the database was consistently analyzed. For that, a descriptive analysis of the data and identification of atypical values were performed by checking the physical questionnaire.

The number of users interviewed, compared to those informed by the service, revealed differences. In general, the number of participants reported by the centers local coordinators (Source B) was higher than that of the Municipal Department of Health (Source A) (delta = 27.9%). And those identified in the research were lower in both (Source A: delta = -16.7% and Source B: delta = -34.9%, respectively), according to Table 1.

The field survey showed that 3,773 users were frequent in the 18 centers investigated (Control Group  $n = 2,159$  and Intervention Group  $n = 1,604$ ). Of these, 3,414 (90.7%) were interviewed, with 237 refusals (6.3%, being 7.8% in the control group and 4.3% in the intervention group) and 112 exclusions (3.0%, being 2.8% in the control group and 3.2% in the intervention group), as shown in Table 1.

Table 2 shows the socioeconomic characteristics of the respondents, according to the center investigated. The majority of users were female, with mean ages between 52.1 and 63.4 years, schooling between 5.4 and 10.6 years of study and median per capita income between BRL 500.00 and BRL 1,305.67 (Table 2).

**Table 1.** Information provided by the service and obtained in the field. Belo Horizonte, MG, 2014.

Center	Number of users			Delta percentage*			People interviewed (n)		Data collected		
	Registered (A)	Frequent (B)	Identified (C)	B - A	C - A	C - B	n	%	Refusals	Exclusions	
A1	189	202	161	6.9	-14.8	-20.3	150	5	3.1	6	3.7
A2	243	512	256	110.7	5.3	-50.0	229	21	8.2	6	2.3
B1	170	157	141	-7.6	-17.1	-10.2	137	1	0.7	3	2.1
B2	267	350	242	31.1	-9.4	-30.9	196	32	13.2	14	5.8
C1	328	290	222	-11.6	-32.3	-23.4	195	13	5.9	14	6.3
C2	262	311	178	18.7	-32.1	-42.8	154	19	10.7	5	2.8
D1	112	167	109	49.1	-2.7	-34.7	104	1	0.9	4	3.7
D2	353	421	311	19.3	-11.9	-26.1	294	11	3.5	6	1.9
E1	202	255	158	26.2	-21.8	-38.0	151	1	0.6	6	3.8
E2	317	399	250	25.9	-21.1	-37.3	244	5	2.0	1	0.4
F1	210	341	139	62.4	-33.8	-59.2	127	6	4.3	6	4.3
F2	311	416	259	33.8	-16.7	-37.7	236	21	8.1	2	0.8
G1	164	259	125	57.9	-23.8	-51.7	113	7	5.6	5	4.0
G2	207	233	191	12.6	-7.7	-18.0	143	38	19.9	10	5.2
H1	267	390	293	46.1	9.7	-24.9	281	9	3.1	3	1.0
H2	217	263	225	21.2	3.7	-14.4	215	9	4.0	1	0.4
I1	380	370	256	-2.6	-32.6	-30.8	225	26	10.2	5	2.0
I2	318	450	247	41.5	-22.3	-45.1	220	12	4.9	15	6.1
<b>Total</b>	<b>4,517</b>	<b>5,778</b>	<b>3,763</b>	<b>27.9</b>	<b>-16.7</b>	<b>-34.9</b>	<b>3,414</b>	<b>237</b>	<b>6.3</b>	<b>112</b>	<b>3.0</b>

\* Delta percentage B - A =  $\frac{\text{source B} - \text{source A}}{\text{source A}} \times 100$ ; Delta percentage C - A =  $\frac{\text{source C} - \text{source A}}{\text{source A}} \times 100$ ; Delta percentage C - B =  $\frac{\text{source C} - \text{source B}}{\text{source B}} \times 100$ .

**Table 2.** Socioeconomic characteristics according to centers for the Brazilian government Health Gym Program (PAS, in the Portuguese abbreviation). Belo Horizonte, MG, 2014.

PAS center	Data collected (n = 3,414)				Years of study <sup>a</sup>
	Age (years) <sup>a</sup>	Gender (%)		Per capita income (BRL) <sup>b</sup>	
		Women	Men		
A1	56.1 ± 12.0	90.0	10.0	900.00 (500.00 – 1,350.00)	8.0 ± 4.6
A2	55.2 ± 10.9	88.2	11.8	533.33 (339.00 – 800.00)	6.9 ± 4.0
B1	53.7 ± 14.3	85.4	14.6	500.00 (335.60 – 700.00)	5.4 ± 4.0
B2	61.3 ± 9.9	90.3	9.7	902.00 (653.62 – 1,400.00)	8.2 ± 4.1
C1	58.9 ± 12.3	91.3	8.7	750.00 (500.00 – 1,166.67)	8.4 ± 3.9
C2	58.1 ± 11.9	85.1	14.9	800.00 (551.50 – 1,383.50)	8.3 ± 3.9
D1	52.1 ± 12.5	92.3	7.7	678.00 (400.00 – 912.50)	7.2 ± 3.8
D2	56.2 ± 10.8	90.8	9.2	733.33 (500.00 – 1,168.33)	7.9 ± 3.9
E1	53.0 ± 12.3	88.7	11.3	560.00 (350.00 – 833.33)	6.6 ± 3.9
E2	53.7 ± 11.4	81.5	18.5	625.00 (350.00 – 1,000.00)	6.4 ± 3.7
F1	52.7 ± 11.8	90.5	9.5	508.50 (339.00 – 800.00)	6.5 ± 3.8
F2	57.2 ± 10.5	94.5	5.5	678.00 (452.00 – 1,000.00)	6.6 ± 3.8
G1	57.6 ± 13.6	82.3	17.7	625.00 (430.00 – 900.00)	5.9 ± 4.3
G2	63.4 ± 12.0	86.0	14.0	1,305.67 (726.33 – 2,283.33)	10.6 ± 4.5
H1	59.1 ± 10.5	85.1	14.9	700.00 (438.30 – 1,000.00)	6.4 ± 3.8
H2	58.0 ± 9.6	93.5	6.5	724.00 (450.00 – 1,000.00)	7.6 ± 3.8
I1	57.1 ± 10.7	81.8	18.2	750.00 (500.00 – 1,000.00)	7.4 ± 3.9
I2	54.2 ± 12.4	87.7	12.3	543.00 (362.00 – 800.00)	5.7 ± 3.7
<b>Total</b>	<b>56.7 ± 11.8</b>	<b>88.1</b>	<b>11.9</b>	<b>678.00 (424.06 – 1,000.00)</b>	<b>7.2 ± 4.1</b>

<sup>a</sup>Mean and standard deviation; <sup>b</sup>Median and interquartile range. Note: PAS = Brazilian government Health Gym Program (PAS, in the Portuguese abbreviation)

## Design of the community educational actions

Community educational actions to encourage consumption of fruits and vegetables lasted seven months and was based on the transtheoretical model of behavior change (TTM) and (Brazilian educator and philosopher) Paulo Freire's dialogic methodology.<sup>18,19</sup> Four different educational strategies were used: workshops (n = 4), postcards with motivational phrases (n = 3), actions in the environment (n = 4) and handing an educational folder (n = 1).

Workshops constitute a group work around a central issue approaching individuals in an integral way. Throughout this intervention, different techniques were used in the workshops according to the topics covered, such as round-table discussions, image theater, self-portrait and cooking. Actions in the environment consisted of modifications in the services physical sites using different techniques, allowing to construct an atmosphere of dialogue and reflection among the participants on the consumption of FH (fruits and vegetables, in the Portuguese abbreviation).

All activities, except the actions in the environment and the folder, were planned and applied according to the transtheoretical model of behavior change (TTM) stages of change and distributed in three groups, pre-action (pre-contemplation and contemplation), decision and action (action and maintenance) in order to meet the individuals' needs according to the different levels of readiness for changes. In total, 540 workshops and 171 actions in the environment were carried out at different times, in addition to the distribution of 4,449 postcards and 1,483 folders. The actions developed for those in pre-action aimed to promote knowledge about healthy eating, aiming to provide to the participants tools to evaluate their diet, increase self-confidence in order to adopt a healthy diet and help identify obstacles to changes and outline strategies to overcome them. As for actions for the preparation stage, they focused on helping individuals in proposing feasible goals for changing behavior, to be achieved in the following 30 days. Finally, the activities for those in the stage of action sought to favor abilities to change the behavior in the long term and to face new difficulties, encouraging the maintenance of the gains obtained and avoiding relapses.

Educational actions were built by an interdisciplinary team, consisting of nutritionists, educators and psychologists with experience in the area of health care education. For its development, a single team (consisting of three nutritionists and three academic supporters) applied the actions in order to maintain uniformity, under the supervision of the general coordination and support from the center's physical educators.

The educational action was carried out from August 2013 to December 2014, lasting seven months at each center. Reevaluation of participants after this period was conducted between January 2014 and March 2015.

## Transfer to services, professionals and the community

Consolidating what is advocated by the translational research, information regarding the initial evaluation, development of educational actions and their effectiveness were presented to the Municipal Department of Health managers, professionals and users of the centers services.

PAS managers and professionals gathered to present and discuss the results. For the centers services users belonging to both the Intervention and Control Groups, a banner with information about their diet and health were developed, as well as guidelines for encouraging the consumption of fruits and vegetables, to be discussed by the service coordinator, aiming to achieve aspects that could be improved and valuing positive aspects identified.

From the development of the research, the educational activities were reviewed and adapted to be applicable to the services of the Primary Health Care (PHC) service in Brazil and made available to interested parties.

## Discussion

For the adequate development of this translational epidemiological research, were considered essential: the design according to the reality of the service and the community; the integration between teaching-service, including for the resolution of logistical (technical and structural) problems; the continuous evaluation of all processes to obtain valid and reliable data; as well as returning the data to the different actors.

According to Translational Epidemiology, interventions should be implemented in specific contexts that reflect the real world, making it possible to apply scientific evidence in practice scenarios that improve the population's health under real-life conditions, to the detriment of studies conducted under ideal conditions that are unfeasible in the human context.<sup>3</sup> This article, when proposing the Primary Health Care (PHC) service in Brazil as a scenario, advances in this sense and reinforces the necessity and the feasibility of this type of study.

The use of educational theories in developing intervention was paramount in promoting reflection, better guiding the conduct of actions and facilitating the understanding of interactions and meanings that make up human behavior.<sup>20</sup> The transtheoretical model of behavior change (TTM) has been pointed out as a useful method for elucidating and facilitating changes in a variety of behaviors, even in the consumption of fruits and vegetables.<sup>19</sup> Evidence shows its applicability and potentiality in health care services,<sup>15,21</sup> making it possible to carry out differentiated interventions according to individuals' specific characteristics, such as availability, perception, attitude and motivation to make changes in specific behaviors.<sup>19</sup> To enable progress to be made to

interventions based on the transtheoretical model of behavior change (TTM), associating it with other theories and methodological references is suggested.<sup>22</sup> In this study, Paulo Freire's dialogic and problematizing pedagogy was used.<sup>18</sup> In it, the relation between educator and students is horizontal, so that there is an exchange of knowledge to the detriment of the relation of domination of one over the other, being an intervention of education focused on forming values, pleasure, responsibility, criticality and freedom.<sup>18</sup>

Conducting health care service research is complex because of its norms and routines. These aspects require detailed planning that consider its dynamics and anticipate challenges. In this sense, the awareness of managers and professionals and the development of tools such as the field manual, periodic training and weekly reports can contribute to the data quality.

As important operational points used, non-restriction of training to the moment before the field and activities of quality control implemented are emphasized, such as consistency analysis of the questionnaires and a weekly control sheet of the collection. These strategies have allowed differentiated solutions to the problems experienced in each field, besides providing information on the teams' productivity. This methodological care has contributed to standardization and quality of the research, maintaining consistency in the different fields, another important challenge of conducting a representative research in large metropolises.

Translational research is critical for improving and strengthening health care services due to investigating issues involved in decision-making processes and offering care, allowing the production of knowledge about health care systems and services, contributing to construction and adaptation of public policies.<sup>1,23</sup> However, methodological limitations often hamper potentialities visibility of studies on health care services, resulting in the little scientific valorization of the knowledge produced.<sup>24</sup>

The challenge of translational research is to reconcile the real life conditions with the objectives and methods employed by scientific research.<sup>3</sup> In this way, the teaching-service integration is critical. If on one hand the service points out the needs, on the other the research uses evidence-based theories and technologies to develop actions and improve strategies.

The fact that few studies describe the process of planning and implementation research is also considered a difficulty for performing translational research, making it difficult to design new studies.<sup>25</sup> This question probably derives from the restricted space that scientific journals provide for the publication of methodological articles. However, this scenario needs to be revised in view of the growing need to investigate the consistency of the results obtained and more effective actions.

Difficulties and limitations in conducting such research in health care services are recognized. The PAS characteristic of being an "open door" service (users can leave and return to the service), possibly with a high turnover of participants, can affect adhesion of participants, generating high



rates of losses. It is believed, however, that the methodological care implemented, with emphasis on the relationship with the service and the community, has contributed to remedy this limitation.

The definition of the sampling process from secondary data can generate distortions, as verified. Studies have increasingly used secondary data, given the high availability of data from information systems, public databases and surveys. As an advantage of the use of secondary data, it is possible to highlight the possibility of using large samples and including a large number of variables, saving time and money, lack of repetition of research and the waste of resources from existing research data, ensuring that sensitive themes or hard-to-reach populations are not over-researched.

Among the challenges and cons of its use, there is some concern with confidentiality and security of participants' individual data. And the data does not always respond in the best way to the research questions, in which the researcher cannot modify the methods.<sup>26</sup> Considering that the main concern in this sample process is to ensure that the sample is representative, the challenge of the secondary data quality is considered as a central issue. And it is revealed in this study that the use of this type of data in the sampling process can generate divergences that affect human and financial resource planning, as the size of the target population is uncertain.

In discussing translational epidemiological research, it is also important to mention issues of funding.<sup>1</sup> For the advancement of science, financing compatible with the project methodology is required, in addition to the equitable distribution of resources among regions and researchers. However, in Brazil there is a concentration of resources in the southeastern region and among more experienced researchers, not necessarily adequately considering research with greater relevance for designing public policies.<sup>27</sup> In addition, the distribution of resources is often incompatible with projects needs. In addition, the delay in granting resources for this study, made available after more than 12 months, makes planning and actions in the field of research difficult.

However, analysis of international financial investment in research shows growing recognition and emphasis on translational science, with important initiatives such as by the *Translational Research Institute*, in Australia, the *Center for Translation Research and Implementation Science* of the *National Heart, Lung, and Blood Institute* and Canadian program *Integrated Knowledge Translation*. In the first study, the portion of the allocation of federal resources was measured to improve the research translation of public policies in the United States, identifying a significant increase in funding between 2007 and 2014.<sup>28</sup>

As seen, there are many methodological challenges for carrying out translational epidemiological studies. But for its advancement, the need for expansion of research and methodological publications on the subject that reproduce valid and reproducible methods and propose to rethink concepts, logistics and priorities is imminent in order to enhance the production of knowledge and the valuation of sites for practice in which the population be inserted.

## Conclusion

This study presents the entire methodological course of a community trial conducted on health care services, showing the organizational process, its challenges and transfer to the service and users. The aim is to provoke a reflection on the need to carry out translational epidemiological research in the scope of Brazilian public health care services, scenarios still under-explored by epidemiologists.

## Contributors

ACS Lopes participated in the study design, fund-raising and development of the manuscript. MC Menezes, BVL Costa, NL Ferreira, PP Freitas, RD Mendonça, LMF Guimarães, MS Lopes, ML Araújo and ACS Lopes participated in data collection, analysis and interpretation, writing the manuscript and approving its final version.

Conflict of interest: The authors declare having no conflict of interest.

## References

1. Oelke ND, Da Silva Lima MAD, Acosta AM. Knowledge translation: translating research into policy and practice. *Revista Gaúcha Enferm/EENFUFGRS*. 2015; 36(3):113.
2. Silva AB, Morel CM, Moraes Ilara HS. Proposta conceitual de telessaúde no modelo da pesquisa translacional. *Rev. Saúde Pública*. 2014; 48(2): 347-356.
3. Szklo M. Epidemiologia translacional: algumas considerações. *Epidemiol Serv Saúde*. 2015; 24(1):12.
4. Estape ES, Segarra B, Báez A, Guertas A, Díaz Cc, Frontera WR. Shaping a new generation of hispanic clinical and translational researchers addressing minority health and health disparities. *P R Health Sci J*. 2011; 30(4): 167-175.
5. Qiang Y, Lyu PH, Ma FC, Yao L, Zhang SJ. Global informetric perspective studies on translational medical research. *BMC Med Inform Decis Mak*. 2013; 13: 77.
6. Brasil. Portaria nº 2.681, de 7 de novembro de 2013. Redefine o Programa Academia da Saúde no âmbito do Sistema Único de Saúde (SUS). In: SaúdeMd, editor. 2013.
7. Balas E, Boren S. Managing clinical knowledge for health care improvement. *Yearbook of Medical Informatics 2000: Patient-Centered Systems*. Stuttgart, Germany: Schattauer Verlagsgesellschaft mbH; 2000. p. 6.
8. Brasil. SUS: A saúde do Brasil. Brasília: Ministério da Saúde; 2011.
9. Canella DS, Silva ACFD, Jaime PC. Produção científica sobre nutrição no âmbito da Atenção Primária à Saúde no Brasil: uma revisão de literatura. *Ciência & Saúde Coletiva*. 2013; 18(2): 297-308.

10. Belo Horizonte. Índice de Vulnerabilidade à Saúde 2003. Belo Horizonte: Secretaria Municipal de Saúde 2003.
11. Brasil. Vigitel Brasil 2011: Vigilância de Fatores de Risco e Proteção para Doenças Crônicas por Inquérito Telefônico. Brasília: Ministério da Saúde; 2012. p. 132.
12. IBGE. Pesquisa de orçamentos familiares 2008-2009: avaliação nutricional da disponibilidade domiciliar de alimentos no Brasil. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística; 2010.
13. Brasil. Inquérito domiciliar sobre comportamento de risco e morbidade referida de doenças e agravos não-transmissíveis. Brasil, quinze capitais e Distrito Federal, 2002-2003. Rio de Janeiro: Instituto Nacional do Câncer; 2004.
14. Ferreira NL, Mingoti SA, Jaime PC, Lopes ACS. Effectiveness of nutritional intervention in overweight women in Primary Health Care. *Rev. Nutr.* 2014;27(6):677-87.
15. Menezes MC, Mingoti SA, Cardoso CS, Mendonça RD, Lopes ACS. Intervention based on Transtheoretical Model promotes anthropometric and nutritional improvements – A randomized controlled trial. *Eating Behaviors.* 2015; 17:37-44.
16. Moreira RAdM, Santos LCd, Lopes ACS, Menezes MCd. Eating behavior toward oil and fat consumption versus dietary fat intake. *Revista de Nutricao.* 2014;27(4):447-57.
17. Thompson FE, Subar AF. Dietary assessment methodology. In: Coulston AM, Boushey CJ, Ferruzzi MG (Edit.). *Nutrition in the prevention and treatment of disease.* 3th ed. London: UK; 2013 cap.1.
18. Freire P. *Pedagogia da autonomia: saberes necessários à prática educativa.* 48 ed. São Paulo: Paz e Terra; 2014.
19. Prochaska J, Norcross J, Di Clemente C. Applying the stages of change. *Psychotherapy in Australia.* 2013; 19(2):6.
20. Brasil. Ministério do Desenvolvimento Social e Combate à Fome (Brasil), Secretaria Nacional de Segurança Alimentar e Nutricional. Marco de referência de educação alimentar e nutricional para as políticas públicas. Brasília: Ministério do Desenvolvimento Social e Combate à Fome, 2012.
21. Hoy MK, Winters BL, Chlebowski RT, Papoutsakis C, Shapiro A, Lubin MP, et al. Implementing a low-fat eating plan in the Women's Intervention Nutrition Study. *Journal of the American Dietetic Association,* 2009; 109(4):688-96.
22. Horwath CC, Schembre SM, Motl RW, Dishman RK, Nigg CR. Does the transtheoretical model of behavior change provide a useful basis for interventions to promote fruit and vegetable consumption? *Am J Health Promot.* 2013;27(6):351-7.
23. Kothari A, Boyko JA, Campbell-Davison A. An exploratory analysis of the nature of informal knowledge underlying theories of planned action used for public health oriented knowledge translation. *BMC Res Notes.* 2015; 8: 424.
24. Dash P, Gowman N, Traynor M. Increasing the impact of health services research. *British Medical Journal.* 2003; 327(7427): 1339-41.

25. Pereira AC, Bensenor IM, Fedeli LM, Castilhos C, Vidigal PG, Maniero V, et al. Delineamento e implementacao do biobanco do ELSA – Brasil: estudo prospectivo na populacao brasileira. *Revista de SaúdePública*. 2013;47(suppl 2):72-8.
26. Tripathy JP. Secondary Data Analysis: Ethical Issues and Challenges. *Iranian Journal of Public Health*. 2013;42(12):1478-1479.
27. Yamamoto OH. Financiamento da pesquisa no Brasil: distorções e desigualdades. *Estudos de Psicologia (Natal)*. 2000;5(2):279-87.
28. Purtle J, Peters R, Brownson RC. A review of policy dissemination and implementation research funded by the National Institutes of Health, 2007-2014. *Implementation science: IS*. 2016; 11:1.

Received: April 25, 2017

Reviewed: August 14, 2017

Accepted: September 30, 2017