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AUTONOMOUS DECISION AND BEHAVIOR REQUIRED IN CLINICAL TRIALS: STUDY WITH A SOCIOECONOMICALLY VULNERABLE POPULATION

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ABSTRACT: Quasi-experimental study conducted to assess the effects of an educational intervention based on the Health Action Process Approach Model, in which autonomous decision-making and behaviors required for the participation in a clinical study were favored. This is an intervention study involving participants in a clinical trial conducted in the State of Minas Gerais, Brazil. The intervention was based on the social and cognitive variables of the Health Action Process Approach model and assessed by applying questionnaires before and after intervention. The results were compared using the McNemar test. The educational intervention favored knowledge on both the expectations about the results of the clinical trial and risk of infection by intestinal helminths, development of the ability to plan the behaviors required by the clinical trial and the necessary confidence to lead, keep, and retrieve them. Analysis of the results showed that the educational intervention favored both autonomous decision-making and the behavior required by clinical trials.

DESCRIPTORS: Personal autonomy. Trial. Social vulnerability. Cognitive sciences.

DECISÃO AUTÔNOMA E O COMPORTAMENTO REQUERIDO EM ENSAIOS CLÍNICOS: ESTUDO COM UMA POPULAÇÃO SOCIOECONOMICAMENTE VULNERÁVEL

RESUMO: Estudo quase-experimental realizado para avaliar os efeitos de uma intervenção educativa baseada no Modelo do *Health Action Process Approach*, no qual foram favorecidos a tomada de decisão autônoma e os comportamentos necessários para a participação em um ensaio clínico. Este é um estudo de intervenção envolvendo participantes de um ensaio realizado no Estado de Minas Gerais, Brasil. A intervenção foi baseada nas variáveis sociocognitivas do modelo de *Health Action Process Approach* e foi avaliada aplicando questionários antes e depois da intervenção. Os resultados foram comparados usando o teste de McNemar. A intervenção educativa favoreceu o conhecimento sobre a expectativa dos resultados do ensaio e sobre o risco de infecção por helmintos intestinais, bem como o desenvolvimento da capacidade de planejar e a necessária confiança para conduzir, manter e recuperar os comportamentos exigidos pelo ensaio. A análise dos resultados mostrou que a intervenção educativa favoreceu a tomada de decisões autônomas e os comportamentos necessários para a participação no ensaio clínico.

DESCRITORES: Autonomia pessoal. Ensaio clínico. Vulnerabilidade social. Ciências cognitivas.

DECISIÓN AUTÓNOMA Y COMPORTAMIENTO REQUERIDO EN UN ENSAYO CLÍNICO: ESTUDIO CON UNA POBLACIÓN SOCIOECONÓMICAMENTE VULNERABLE

RESUMEN: Estudio cuasi-experimental realizado para evaluar los efectos de una intervención educativa basada en el Modelo *Health Action Process Approach*, con el fin de proporcionar una decisión autónoma y adoptar comportamientos necesarios a la participación en un ensayo clínico. Se trata de una investigación de intervención realizada con participantes de un ensayo clínico desarrollado en Minas Gerais, Brasil. Hemos llevado a cabo la intervención basada en las variables socio cognitivas de *Health Action Process Approach* evaluadas por un cuestionario administrado antes y después de la misma. La comparación entre los resultados ha sido realizada con la Prueba de McNemar. La intervención educativa ha favorecido el conocimiento de las expectativas de los resultados del ensayo clínico, los riesgos de infección por helmintos intestinales, el desarrollo de la capacidad de planear los comportamientos requeridos por el ensayo y la confianza en hacerlos, mantenerlos y recuperarlos. La intervención educativa ha favorecido la decisión autónoma y la adopción de los comportamientos necesarios a la participación en el ensayo clínico.

DESCRIPTORS: Autonomía personal. Ensayo clínico. Vulnerabilidad social. Ciencias cognitivas.

INTRODUCTION

Randomized clinical trials (RCT) are considered a standard in the methods of research in Epidemiology, being the best source of scientific evidence available to determine the effectiveness of an intervention. In order that their results be reliable and valid, these trials should be conducted under controlled conditions avoiding possible bias. Thus, it is essential that these trials be conducted in accordance with the method established in their clinical protocols.[1]

Given that RCT have humans as their main object of study, they must be submitted not only to the scientific and methodological canons of experimental science but also to those of another instance, which should decide whether they are ethically sustainable,[2-3] and driven by universal ethical guidelines.[4-6] Therefore, the investigator should seek to achieve two objectives in scientific practice: producing reliable scientific knowledge, ensuring respect for the human dignity of the participants. [7]

One of the strategies to achieve this dual objective is the use of the informed consent, since the potential participants must be clarified about the goals and methodological procedures of the study as well as the risks and benefits and their rights as participants.[6] Thus, this procedure aims to offer a treatment to the participants within their dignity, ensure respect for their individual autonomy,[8] and inform about the procedures established in the study protocol.

However, the dual objective that leads to obtain the free and informed consent (FIC) has a risk of not being achieved. Usually, study volunteers do not understand the objectives of the study, procedures of clinical investigations, data confidentiality, risks and benefits, and their right to withdraw from the study.[9-17] This situation becomes more serious when we consider that participants' knowledge of trial procedures may decrease in monthly intervals,[18] and the free and informed consent form (FICF) may not be suitable to the education profile of the study population.[19]

A strategy to achieve the dual goal of FIC is to conduct educational interventions involving the potential volunteers.[20] However, interventions usually do not consider some aspects that interfere with behaviors required to participate in a clinical trial, [11,21-22] and do not employ methodologies able to overcome the informative character of education.[20]

Thus, an educational methodology that takes into account both the social cognitive and psychosocial aspects of behavior besides knowledge can minimize the frequent difficulty in participants' understanding. Furthermore, it may favor participants' autonomy to decide on their participation in the study and adherence to methodological procedures of the investigation. Our hypothesis is that explanatory and predictive models of health behavior, especially social cognitive models, address the need to act in this direction.

The Health Action Process Approach (HAPA)[23-24] provides an explanatory and predictive model, which is useful for various behaviors and intentions related to health, including diet,[25] food hygiene,[26] physical activity,[27] and smoking.[28] The HAPA is used to predict cognitive and behavioral outcomes, as well as to help understand the mechanisms of change in health behavior. In this model, motivational and volitional aspects are considered as intervening variables in adopting a behavior.

This study is pioneer in non-using the HAPA in both studies conducted in Brazil and evaluation of behavior in clinical trials. It is known that educational interventions able to favor an increase in the variables of this model, thus favoring a behavior linked to participation in a clinical trial, can be implemented by analogy to others.[29]

Therefore, the present study had two objectives: to analyze the effects of a HAPA-based educational intervention in (I) favoring an autonomous decision of volunteers to participate in a clinical trial and (II) achieving the required behavior in this clinical investigation.

METHOD

This is a quasi-experimental study with longitudinal configuration and quantitative approach. It is a part of the ABS-00-01 study (Preparation of the community to participate in clinical studies on a food product with anthelminthic qualities), whose goal was to recruit potential volunteers for the ABS-00-02 clinical trial (Double-blind, randomized, and controlled

study on the tolerability to regular consumption of a mixture of oils by adults living in a helminth-endemic area). The objective of this clinical trial was to assess the tolerability of a functional food with anthelminthic qualities in adults living in a helminth-endemic community, in the Northeast region of State of Minas Gerais, Brazil. Volunteers should exhibit a new daily behavior, consume a functional food (Tang® juice) for 42 consecutive days, to participate in this clinical trial. Thus, participants should establish a plan during this period, in which the Tang® juice should be consumed always at the same time and in consecutive days, despite their daily routines.

These studies were conducted in Mucuri Valley, Northeast region of the State of Minas Gerais, Brazil, in the period April 2010 - March 2012.

Sample and place of study

As established in the inclusion criteria of this study (ABS-00-02), the sample was composed of participants included in the ABS-00-01 study. The sampling criterion was intentional because of the expectation that all participants signed the FICT of the ABS-00-01 study. The authors of this study sought to recruit all participants of the ABS-00-01 study because their purpose was that all volunteers could participate in educational activities before signing the FICT of the ABS-00-02 clinical trial.

This study was conducted in four rural communities in the municipalities of Novo Oriente and Caraí, in the Mucuri valley, Northeast region of the State of Minas Gerais, Brazil, in the period July-August 2010.

Measuring instrument and data collection

A structured questionnaire (social cognitive questionnaire SCQ), was prepared to assess the effects of educational intervention on the social and cognitive variables. Formulation of this instrument was based on the "Risk behaviors and health" document, as suggested by the author of the HAPA model,[30-31] to guide the creation of psychometric scales and to measure the social and cognitive and health-behavior variables. The SCQ was prepared to assess adoption of behaviors required in the ABS-00-02 clinical trial, since the expected behaviors specifically address changes in behavior related to the themes of diet,[25] food hygiene,[26] physical activity,[27] and smoking.[28]

Experts in psychometric scales participated in the instrument formulation. The questionnaire was administered as a pilot test in subjects of the same region and age range of the study participants. After this step, the required adjustments and changes were performed.

The SCQ had two groups of questions, which measured socio-demographic (Group 1) and social and cognitive (Group 2) characteristics, including: risk perception, expectation about results, action, maintenance, and recovery self-efficacy, and planning. The variables in Group 1 were collected through closed questions and those in Group 2 were measured through the 3-point Likert Scale: disagree (D), neither agree nor disagree (NAD), and agree (A).

In order to facilitate participants' understanding of questions posed in the SCQ, scientific terms such as "helminth infection" were replaced by expressions familiar to them such as "get worms".

The SCQ was applied in July 2010, at two different times, before (time 0) and after (time 1) the educational intervention. Time 0 was a week after signing the FICT of the ABS-00-01 study, and Time 1 was a week after the educational intervention.

The SCQ was applied by means of a structured interview (duration: about 20 min), which was held at the participants' homes without third-party interference or noise that could divert their attention. Participants were informed about the purpose of the study and the voluntary nature of their participation.

Educational intervention

The educational intervention was developed in two meetings held in July 2010 in one of the municipal schools for students living in the municipalities of Caraí and Novo Oriente de Minas. These meetings were conducted by professionals not related to the ABS-00-02 clinical trial team and instrumentalized with two educational resources, the Board Game and Lego®, which were used in different days.

At the first meeting, the Board Game was played. This game consisted of a large board (3 m^2) and colored pins 30 cm (similar to those used in bowl games), which represented three different groups of players. In addition, cards containing questions or problem situations were used. In this board, the players should go through a sequence of places, which were distributed in three cycles: (1) information on intestinal helminthiasis (modes of transmission, prevention, and symptoms), (2) objectives of the ABS 00-02 clinical trial, and (3) role of researchers in this clinical trial in the communities of Caraí and Novo Oriente de Minas. In each cycle, 15 cards were randomly selected whenever a pin progressed on the board. These cards asked for specific information about the cycles. They also included problem situations in which the participant was the protagonist of a fictitious situation in which he exercised the power to decide, recognizing himself as being able of acting to change a reality. These situations were characterized by both presenting a set of scenario, characters, circumstances, and problems close to the participant reality and requiring a decision to be taken.

At the second meeting, the participants used a Lego® composed of several volumetric and dockable pieces, which allow building many structures. The goal was to assemble a house similar to those found in Caraí and Novo Oriente de Minas, participating in five consecutive steps: motivation, first attempt, planning, second attempt, and completion. When participants received a model home, they were invited to freely build their replicas. Then they received disordered photos of the assembly of the house model to organize them in a logical sequence. Finally, they exercised the planning process by both restarting the assembly of their replicas and following the steps they have planned.

Statistical analysis

To ensure reliability, data were typed twice and independently. When a discordance was observed, the specific case was conferred in the original questionnaire and corrected. The results were entered and processed using the Statistical Package for the Social Sciences software (SPSS, v.14).

In the descriptive analysis, continuous variables were expressed by arithmetic mean and standard deviation and the ordinal ones by relative and absolute frequencies. Univariate analysis was performed using the McNemar test. The level of 5% was set for statistical significance.

Ethical considerations

This study was approved by both the Institutional Ethics Committee, George Washington University (Washington, DC, USA), and the René Rachou Research Center (MG, Brazil). The ABS-00-01 study and the ABS 00-02 clinical trial were approved by the Brazilian Council for Ethics in Research (CONEP). The study was approved by the Research Ethics Committee (UFMG; protocol: 0342020300010), and all ethical guidelines of the Helsinki Declaration (2008) and Legal Resolution n. 466/12 (Brazilian Health Council, CNS) were followed.

RESULTS

A total of 116 subjects participated in the study. Most of them were female (70.7%), had elementary school (62.9%), and lived in rural communities in the municipality of Caraí (73.3%). These participants had a mean age of 31.4 years, with minimum and maximum of 18 and 45 years, respectively.

Risk perception

A statistically significant increase was observed in the number of participants who agreed on absence of symptoms of intestinal helminthiasis, need to change habits to avoid contamination by helminths, and a higher probability of infection with helminthes (Table 1) in people living in rural areas compared to urban areas ($p \leq 0.05$).

Table 1 - Answers on the knowledge of risk of contamination by nematode parasites in Novo Oriente and Caraí at Times 0 and 1. Minas Gerais, Brazil, 2010

Items	Answers						*p**
	Time 0			Time 1			
	A	NAD	D	A	NAD	D	
Is infected by worms	94.8	0.9	4.3	99.1	0.0	0.9	0.22
Feels weak with worms	97.5	2.5	0.0	99.1	0.0	0.9	0.99
Contamination is in the urban area	69.8	11.2	19.0	91.4	3.4	5.2	0.001
Worsens if sick and untreated	98.2	0.9	0.9	99.1	0.0	0.9	0.99
Worms cause anemia	80.2	11.2	8.6	97.5	0.0	2.5	0.06
Infection with worms increases willingness to work	4.3	5.2	85.5	5.2	0.0	93.8	0.99
Changing habits decreases the chance of having worms	81.9	6.9	11.2	91.4	6.0	2.6	0.02
Verminosis is asymptomatic	42.3	4.3	53.5	81.9	0.0	18.1	<0.001

* McNemar Test; A: agree; NAD: neither agree nor disagree; D: disagree.

Expectations regarding the results of the ABS-00-02 clinical trial

A statistically significant increase was observed in the number of volunteers who disagreed that their participation in the ABS 00-02 clinical trial could both provide medical treatment against other diseases and protect them from future infection with intestinal helminthiasis ($p \leq 0.05$). At Time 0, almost all participants disagreed that consumption of Tang® could cause an adverse effect, a situation similar to that observed at Time 1 (Table 2).

Table 2 - Answers about expectations regarding results of the ABS-00-02 clinical trial at Times 0 and 1. Minas Gerais, Brazil, 2010

Items	Answers (%)						*p**
	Time 0			Time 1			
	A	NAD	D	A	NAD	D	
Derive personal benefit from the trial	73.3	15.5	11.2	88.0	0.0	12.0	0.51
Not get worms	39.7	6.0	54.3	26.7	3.4	69.9	0.04
Can help the community	92.2	4.3	3.4	95.7	1.7	2.6	0.62
Have treatment against other diseases	72.5	15.5	12.0	54.3	3.4	42.2	<0.001
Waste time with the trial	10.3	4.3	85.4	9.4	3.4	87.1	0.82
Risk of having an adverse effect by consuming Tang®	6.0	2.6	91.4	5.2	3.4	91.4	0.75

* McNemar Test; A: agree; NAD: neither agree nor disagree; D: disagree.

Self-efficacy of action, maintenance, and retrieval of information in the ABS-00-02 clinical trial

After educational intervention, a statistically significant increase was detected in the number of participants who agreed that they were ready to participate in all meetings with the team of the clinical trial ($p \leq 0.05$). Regarding self-efficacy of maintenance, comparison before and after intervention revealed a statistically significant increase in the number of participants who agreed to remain in the trial although its procedures interfered with their routine work. In terms of self-efficacy recovery, a statistically significant increase was observed in the number of participants who agreed to remain in the clinical trial, although they have forgotten to apply the procedures established in this study protocol ($p \leq 0.05$). They alleged that they could solve any problem to remain in clinical trial (Table 3).

Table 3 - Answers on adhesion, maintenance, and recovery self-efficacy at Times 0 and 1 of the ABS-00-02 clinical trial. Minas Gerais, Brazil, 2010

Items	Answers (%)						*p**
	Time 0			Time 1			
	A	NAD	D	A	NAD	D	
Action self-efficacy							
Readiness to participate in group meetings	62.9	20.7	16.4	81.9	7.8	10.3	0.007
Conduct trials activities without their families	90.5	4.3	5.2	98.3	0.0	1.7	0.12
Need to strive to participate in the trial	88.8	3.4	7.8	94.0	2.6	3.4	0.99
Can participate in the study if it starts in a week	94.8	4.3	0.9	97.4	1.7	0.9	0.99
Need to be better prepared to participate in the trial	66.3	7.8	25.9	61.2	1.7	37.0	0.06
Maintenance self-efficacy							
Remain in the trial even without noticing any improvement in health status	84.5	7.8	7.7	90.6	2.6	6.9	0.55
Remain in the trial even if it takes their time	84.5	8.6	6.9	91.4	4.3	4.3	0.55
Remain in the trial even if it affects their work routine	61.2	18.1	20.6	76.7	7.8	15.5	0.04
Remain in the trial until the end	80.2	14.6	5.2	89.7	6.9	3.4	0.51
Recovery self-efficacy							
Remain in the trial even forgetting to take the Tang® juice	88.7	5.2	6.0	97.4	2.6	-	0.02
Remain in the trial even failing to consume the Tang® juice daily	87.1	9.5	3.4	96.5	1.7	1.7	0.69
Solve problems to remain in the trial	88.0	6.0	5.2	100.0	-	-	0.02

* McNemar Test; A: agree; NAD: neither agree nor disagree; D: disagree.

Planning the activities proposed in the ABS 00-02 clinical trial

A statistically significant increase ($p \leq 0.05$) was noted in the number of participants who said they already know planning when and how to take Tang® juice daily and have a plan on how to change their daily routine to consume this functional food (Table 4).

Table 4 - Answers about planning the activities proposed in the ABS-00-02 clinical trial as observed in Times 0 and 1. Minas Gerais, Brazil, 2010

Items	Answers (%)						*p**
	Time 0			Time 1			
	A	NAD	D	A	NAD	D	
When taking the Tang® juice	29.3	7.8	62.9	53.4	11.2	43.3	<0.001
How to take the Tang® juice daily	22.4	9.5	68.1	52.6	11.2	36.2	<0.001
Change plans to achieve taking the Tang® juice daily	42.2	7.8	50.0	69.8	6.0	24.1	<0.001
Participate in meetings on the weekend	97.5	0.9	1.7	96.6	1.7	1.7	0.99

* McNemar Test; A: agree; NAD: neither agree nor disagree; D: disagree.

DISCUSSION

The HAPA model educational intervention favored both the autonomous decision of potential volunteers to participate in a clinical trial and the validity and reliability of data obtained in this investigation. An effective favoring was observed since the intervention favored the participants' understanding of the real proposals of this clinical trial and their risk of infection by intestinal helminths in the region where they live. In addition, the intervention developed the ability to plan the steps that should be taken in this clinical trial, the confidence to perform, keep, and restore them in case of oblivion .

Increasing the perception by the volunteers of their risk of infection by intestinal helminths in the rural areas of Novo Oriente de Minas and Caraí can promote autonomous decision so that they can participate in the ABS-00-02 clinical trial. Effectiveness of an intervention in increasing risk

perception was also observed in the same region in interventional studies in which interventions based on mediatic and recreational strategies were tested.[21-22] Increased perception of susceptibility to infection by intestinal helminthes in endemic regions is important to recognize the magnitude of these diseases, as helminthes is often seen as a common and normal condition in this region.[32]

When potential volunteers recognize the extent of the disease, they can be altruistic volunteers in the ABS-00-02 clinical trial, reinforcing the autonomous character of their decisions. In a situation of socioeconomic vulnerability, participants tend to be motivated by scarcity in the access to health services.[33-34]

Development of planning initiative also favored the autonomous decision of the participants in the clinical trial. Potential clinical trial participants who have this initiative can base their decisions on the feasibility of inserting the proposed activities in their daily routines.[35]

Development of this initiative also has positive effects to the validity of data obtained in the clinical trial. When clinical trial participants acquire the planning initiative, they become able to anticipate potentially harmful barriers to their adherence to the procedures in the clinical trial protocol. As evidenced in a longitudinal study for adherence to physical activity, planning of these activities was considered an important predictor for adoption of this behavior.[36] The finding of this study is significant if we consider that non-adherence to the protocol as established in the clinical trial may lead to a bias in the results.[1]

Increase in the confidence of clinical trial participants in the action, maintenance, and recovery of behaviors established by the clinical trial also has a positive implication for validity of data obtained in this investigation, since it can promote the behavior of consuming juice daily. Some studies suggest that action and maintenance self-efficacy are positively associated with intention to establish and maintain behavior.[36-38] Regarding recovery self-efficacy, its importance lies in the fact that participants resumed their habit of drinking the juice even after they forgot practicing the activity for a day. This finding is also an expressive for its strong positive association with the desired behavior.[36]

Expansion of understanding about the actual benefits offered by the ABS-00-02 clinical trial can favor autonomous decision of research participants. Educational intervention is significantly relevant to autonomous decision of potential research volunteers because it contributed to reduce unfounded expectation that their participation in the ABS-00-02 clinical trial could immunize them against future infection by helminths. This mistaken belief could affect even more autonomous decision of these participants, since the municipalities where this clinical trial was conducted are known for their endemic with these verminoses.[39]

Weakening of the belief that participation in the ABS-00-02 clinical trial would ensure treatment for all diseases was also important in favoring autonomy for the decision of potential volunteers of this clinical trial. Clinical trials conducted in African countries show that volunteers agreed to participate in these investigations due to either the possibility of having medical treatment for their diseases or the poorness of health service in their area.[33]

However, the educational intervention had little effect on the notion of most participants that adverse effect as a result of ingesting functional food is possible. Insertion of volunteers in a clinical trial without a proper understanding of their risks may violate their rights as volunteers as they can be subject to risks that were not previously shown. In developed and developing countries, understanding of risk was low as described in a review on quality of free and informed consent.[16] In a study on drugs against malaria conducted in Thailand, only 6.6% of participants remembered what they were told about the risks of their participation.[13] Similarly, only 18% of participants understood the risks of the trial in an oncology clinical trial conducted in Sweden.[40]

Almost all participants responded positively, even before they know the present study, when they were asked if they wished to participate in the ABS-00-02 clinical trial if it was started next week. In addition, participants also did not know the possible adverse effects of functional food. Such readiness to accept participation was also found in a study on a vaccine against ancylostomiasis conducted with volunteers in the same region. The authors observed that these felt ready to participate immediately in the study without thinking about implications.[32] In a clinical trial on the researcher-participant relationship in which a pharmaceutical company was involved, participants also showed to be ready to sign the consent form before reading it.[41]

Such readiness can be interpreted considering that some populations tend to believe undoubtedly in both the lack of interest of medical action and competence of the researcher, besides the fact that they have difficulty in distinguishing between the roles of the physician and researcher. In this case, it seems that such beliefs have more influence on their decision to participate in a clinical trial that their understanding of the study.

In this study, the authors show that the unconditional desire of volunteers to participate in a study may also be influenced by their beliefs. Consequently, such beliefs can cause an appreciation of potential benefits at the expense of possible risks involved in the study thus compromising the exercise of autonomous choice.

Thus, potential volunteers can either be abdicate their responsibility of choice during the decision making process. Thus, we refer herein to the Kant's concept of self-imposed immaturity. This status of immaturity of volunteers refers to their inability to use their own understanding to think and act independently without being guided by another.[42]

Humans may experience the immaturity status at some point of their social formation. In this case, the immaturity status can be considered natural since it is not different from immaturity for lack of knowledge. Kant also states that social institutions tend to keep human beings in this condition. For this purpose, fear and embarrassment are mostly used as tools to keep individuals in a immaturity status, although they may have a higher condition.

Therefore, everyone could leave his immaturity status and seek clarification, provided they are able to think. However, not everyone can leave this condition. The philosopher says emphatically how comfortable such condition can be, as always another person will decide, think, and know what to do.[42]

When volunteers in their immaturity condition unconditionally say yes to participate in the study, it is as if they transfered to the researcher the act of deciding what is best for their health. In this case, volunteers leave their autonomy giving preference to their desire to participate in the study . Emancipatory education is a way to facilitate the exercise of autonomy, indicating a gateway to adulthood. In this conception of education, autonomy is a condition of decision and humanization built with decisions taken previously.[43]

When we combine exercise of autonomy to the traditional predictors (risk perception, expectations regarding outcomes, self-efficacy, and planning), we assume that untying participants' decision from any obscure belief is possible. This corresponds to leaving convenience towards own thinking, which is not established externally, but internally.

This study has limitations, although it contributes to both show the appropriateness of using the HAPA model in clinical trials and ensure the dual purpose of the FIC (including generation of reliable and generalizable scientific knowledge, and guarantee of respect to human dignity of participants). Limitations are due to the fact that it was conducted in two different municipalities, although their socioeconomic characteristics are similar. Regarding the interval between Times 0 and 1, other variables modifying the effect of social and cognitive variables must also be considered.

This study shows that association between educational intervention and the FIC process is important, and health professionals conducting clinical trials, mainly physicians and nurses, should keep in mind that FIC is not limited to signing the form. Given the increasing number of clinical trials in Brazil and Latin America, educational intervention with volunteers in such studies is a possible field of activity for nurses since they are linked to both educational activities and holistic care of the human being. Moreover, nurses can use the educational strategies employed in this study as a reference for developing health education interventions, as they go beyond the merely informative practices in health education.

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