Effects of educational intervention in the ethical quality of the free and informed consent

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Abstract

Educational interventions have been used in order to improve the quality of understanding with regards to The Free and Informed Consent. However, some of these interventions have become ineffective, indicating the need of ensuring the ethical quality of consent. The aim of this study was to analyze the effects of an educational intervention for improving the ethical quality of consent. The study involved 148 participants who signed the Free and Informed Consent Form (FICF) for participation in a clinical trial conducted in the Northeast of Minas Gerais - Brazil. From this total, 105 participated in an educational intervention through a board game, while only 43 signed the informed consent form regarding that clinical trial. In order to assess the effects of an educational intervention, the Questionnaire on Quality Assessment of The Free and Informed Consent (QAQIC) was applied. The participants of the educational intervention showed greater knowledge about the information in the clinical trial, less influenced by the decision to participate in it. The results suggest that an educational intervention favors the quality of the free and informed consent in a clinical research.
Key words: Bioethics. Informed consent. Clinical trial. Helminthiasis.

Resumo

Efeitos de intervenção educativa na qualidade ética do consentimento livre e esclarecido

Intervenções educativas têm sido utilizadas para melhorar a compreensão do Consentimento Livre e Esclarecido. Algumas delas têm se mostrado ineficazes, indicando a necessidade de assegurar a qualidade do consentimento. Este estudo analisa os efeitos de intervenção educativa no aprimoramento da qualidade ética do Consentimento, envolvendo 148 participantes que assinaram o Termo de Consentimento Livre e Esclarecido para participar de ensaio clínico realizado no Nordeste de Minas Gerais/Brasil. Desse total, 105 participaram de intervenção educativa instrumentalizada por jogo de tabuleiro, enquanto 43 apenas assinaram o TCLE daquele ensaio clínico. Para avaliar os efeitos da intervenção educativa foi aplicado o Questionário de Avaliação da Qualidade do Consentimento Livre e Esclarecido. Os participantes da intervenção demonstram maior conhecimento sobre as informações do ensaio clínico, sofrendo menor influência quanto à decisão de participar. Os resultados sugerem que a intervenção educativa favorece a qualidade do consentimento livre e esclarecido na participação em pesquisas clínicas.
Palavras-chave: Bioética. Consentimento livre e esclarecido. Ensaio clínico. Helmintíase.

Resumen

Efectos de una intervención educativa en la calidad del consentimiento libre e informado

Las intervenciones educativas se han utilizado con el fin de mejorar la comprensión del Consentimiento Libre e Informado. Algunas de ellas han demostrado ser ineficaces, lo que indica la necesidad de asegurar la calidad del Consentimiento. El objetivo de este estudio fue analizar los efectos de una intervención educativa en el perfeccionamiento de la calidad ética de Consentimiento. El estudio involucró a 148 participantes que firmaron el Término de Consentimiento Libre e informado para participar en un ensayo clínico realizado en el nordeste de Minas Gerais/Brasil. De este total, 105 participaron en una intervención educativa instrumentalizada por un juego de mesa, mientras que sólo 43 firmaron el TCLE de aquel ensayo clínico. Para evaluar los efectos de la intervención educativa fue aplicado el Cuestionario de Evaluación de la Calidad del Consentimiento Libre e Informado (CECC). Los participantes de la intervención demuestran un mayor conocimiento sobre las informaciones del ensayo clínico, sufriendo menor influencia en relación a la decisión de participar. Los resultados sugieren que la intervención educativa favorece la calidad de consentimiento libre e informado en la participación en investigaciones clínicas.
Palabras-clave: Bioética. Consentimiento informado. Ensayo clínico. Helmintiasis.

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Research article

The goal of a free and informed consent is to assure research subjects the necessary information to decide, voluntarily and autonomously, to participate or not in a research [1]. Providing participants with awareness on the proposal of the clinical investigation allows them to judge – with their own values and interests – and decide to participate or not in the study [2, 3]. In Brazil, the cornerstone of ethically appropriate researches involving human being, besides the ethic value, is the requirement of legality [4, 5].

So that the free and informed consent be considered valid, it is essential that the research subject be informed of the study and his/her rights, have competence to understand the information and make decisions – and the decision must be free of coercion, that is, without influences [6].

Among the criteria necessary for the free and informed consent validation, the understanding of the information regarding the study and their rights is emphasized. Its importance lies on the greater control of the research subject over their actions and in the authenticity of their decision [7], and is also associated to a smaller chance of regret over the decision and less anxiety over the decision making process [8, 9].

Although essential, the understanding of the information of the free and informed consent, even after signing such consent (FICF), is considered low and/or incomplete in several studies [10-13]. In cases of participation in clinical trials, it is also registered a low comprehension among possible volunteers on concepts of "placebo" and "randomization" [14, 15]. The low comprehension is also verified regarding risks [16], benefits [17], research goals [18], data confidentiality [19] and the right to withdraw from the study [20].

Such situation is more concerning when said researches are conducted in developing countries, where characteristics related to low comprehension of the free and informed consent are commonly observed, such as fewer formal studies and illiteracy [21]. A study conducted in South Africa [22] states that people with lower economical power have lower capacity and confidence to question – which favors the acceptance of participating in clinical investigations without sufficient enlightenment [23].

Such deficiencies, added to a growing number of clinical researches conducted in developing countries [24], alert researchers to the need of developing ways to improve research participant's comprehension. Multimedia interventions, lowering the textual complexity of the FICF and conducting group meetings show controversial results [25-27]. Unlike this situation, the person-person interaction (researchers – potential participant), especially in prolonged discussion interventions, is considered the most effective way to improve research participant's comprehension [28], being pointed out by some as the preferred technique to obtain the consent [29].

Despite the effectiveness, such studies have a limited sample size and the interventions often don't consider pedagogical devices in its elaboration, which may implicate in some restrictions. Added to this situation, there is little literature in studies dedicated to test pedagogical strategies that consider the person-person interaction, especially in Brazil.

This way, it is necessary to reflect on the strategies which allow room for questionings and clarifications in an interactional way between participants and researchers – that at the same time pleases the participants.

Research's goal

This present study aims to analyze the effects of an educational intervention as a way to contribute to the ethical quality of the free and informed consent. The main hypothesis of this study is that the participation in an educational intervention, instrumentalized by a game, associated to the signing of the FICF of the clinical trial ABS-00-02 favors:

- a greater understanding of FICF's information in a clinical trial;
- a smaller influence in the decision making process of participating in a clinical trial.

Method and casuistry

It is an applied, gathering, interventional research, with a transverse configuration and a quantitative approach.

The present study integrated a clinical investigation (ABS-00-02) which goal was to evaluate the tolerance of a functional food, with anthelminthic characteristic, in adults resident in endemic areas for helminthiasis. It was conducted in the northeast region of the state of Minas Gerais, specifically in Americaninhas and surroundings, a district of the city of Novo Oriente, Minas Gerais/Brazil, between October of 2010 and March of 2012. The potential participants, after reading the FICF and asking ques-

tions, registered their participation by signing the term, in case of consenting in participating.

Sample and place of the study

The sample of this study was constituted of participants in the clinical trial ABS-00-02, being this the inclusion criteria established. Being necessary the experience of participants signing the FICF for clinical trial ABS-00-02, the present study used the intentional sampling criteria. To represent the data in this study, all 148 participants in the clinical trial were sought, a completed goal which will be further detailed in this section. We stress that, inevitably, the inclusion criteria of the clinical trial ended up overlapping the inclusion criteria of the present research, such as intended age, from 18-45 years old.

Also inevitably, the place of the present study is the same as the one where the mentioned clinical trial occurred. The city of Americaninhas is 60 km off from Novo Oriente's dirt road and 640 km off from the capitol Belo Horizonte. The small district has approximately 4,000 inhabitants and the local economy revolves mostly on family and subsistence agriculture, and also breeding of small animals. Living and transportation in the area are, at best, precarious, as well as the water supply and the local sanitation. The area has a Family Health team, formed by a nursing technician, community health agents, a nurse and a doctor. This is a typical rural area, characterized by poor social and economical conditions, difficult access to basic services, low education levels and little professional perspective.

Measurement and data collection instrument

The present study used a structured survey called Questionnaire on Quality Assessment of the Free and Informed Consent (QAQIC), composed of two groups of questions: questions measuring the knowledge of participants on the information contained in the clinical trial ABS-00-02 FICF (Group 1 – 12 questions) and questions measuring the influence in the decision making process to participate or not in this clinical trial (Group 2 – 8 questions). The questions regarding FICF comprehension were open questions, since this type of question can measure with greater precision the real knowledge of participants in a clinical trial, without such knowledge being overestimated [30].

The creation of the QAQIC questions was based in questions used in other surveys used for the same goals [25, 31], also contemplating the international guidelines for research ethics [4] and national resolutions on the subject [5]. Its creation was based in theoretical references on the construction of instruments of the same kind, with emphasis on the structure and the disposition of the questions [32].

The QAQIC was applied through a structured interview. Group 1 questions were stated without answer options and only the interviewer knew the correct answer for each question. This way, the participant's answer was registered and, later, it was checked to see if it corresponded to the information contained in the FICF on the evaluated theme. The correspondence between the participant's answer and the information on the FICF was considered an indication of comprehension on the subject.

As for Group 2 questions, the participants were asked the level of influence they felt in their decision to participate or not in the clinical trial, with possible answers being "no influence", "little influence" and "great influence". Each option was given a value: 0, 1 and 2, respectively.

The survey was conducted, on average, one month after having signed the FICF for the participation on the clinical trial ABS-00-02, that is, also after the educational intervention. The survey lasted, on average, 10 minutes and was conducted at the interviewee's home, without third party intervention or noises that could compromise the information or deviate the participant's attention. Before starting the survey, it was explained to the participant the goal of the present study and reinforced that the participation was voluntary. All interviewers had a graduation or post-graduation degree and were previously trained to standardize the interviews.

Educational intervention

Initially all 148 potential volunteers to the clinical trial ABS-00-02 were invited to participate in the educational intervention. However, only 105 agreed to participate, naming a schedule unavailability or own will as justification for not participating. Thus, the 43 research subjects who didn't participate in this activity only signed the FICF for the clinical trial.

The two groups were named *intervention group* and *control group*. On the first, the subjects participated in an educational intervention associated to the signing of the document; on the second, they only signed the FICF for the clinical trial. The educational intervention was carried out approximately two weeks before signing the FICF for trial ABS-00-02, through a single group meeting, composed by 12 participants, lasting, on average, 2 hours.

The educational intervention constituted on the use of a game with potential volunteers for the

clinical trial ABS-00-02, using cards with questions related to the information present at the FICF for the trial and the answers, a 6-sided dice, pawns representing the players and a big board (3m²) with spaces to pass through divided in two cycles that approached: means of transmission, prevention and treatment for helminthiasis; and the information present at the FICF for the clinical trial ABS-00-02. Each cycle has 30 cards with questions related to the specific information and were randomly drawn as the pawns moved between spaces in the board. The goal of the game was to reach the end of the board, passing through all the mentioned cycles, naming one of the groups the winner.

The game was conducted by a professional non-member of the clinical trial team. That professional initially separated the participants into two equal groups. For the game to move forward the group had to answer the questions correctly in each board. In case they answered incorrectly, the question was asked to the other group and, if they answered correctly, they could move their pawn a space. Before confirming the answer of a group, the other participants were asked about the reliability of the answer, a procedure that acted as a reinforcement of the contents and as an educational strategy, which intends to keep all participants attentive and active. The game ended when one of the groups reached the finish line of the board.

The game was the chosen resource given the motivation intrinsic to the activity, for its playful and consistent form to present the reality and events that put the participant in the position of subject and not a bystander. In the game, the participant faces challenges, tests limits, solves problems and formulates hypothesis [33]. It is believed that the game gives the research subject production and expression of subjectivity, and also demands the mobilization of cognitive elements, relational and affective which, together, ease the comprehension process of the research and its implications [34].

Additionally, the game can be understood as an active methodology used to broaden the understanding of the subject on the research, being potentially capable of contribute to the development of their autonomy and encourage them to think in a creative, free and inventive way, making the decision truly their own [35].

Statistical analysis

To assure the trustworthiness, a double independent entry of the data was made. In case of disagreement, the correspondent case was checked and corrected. The results were tabulated and treated through the Social Package Social Sciences 14 software (SPSS) [36]. The continuous variables were expressed through an arithmetic mean and standard deviation; and the categorical variables by relative and absolute frequency. Initially, the social demographic and economical variables were treated through descriptive analysis.

The univariate analysis between the intervention and control groups was made by the chi-squared test and a calculation of the chance ratio when the variables were categorical [36]. For the comparison between continuous variables an independent t-test was used. In all tests, a 5% level of significance was established.

Ethical considerations

The present study was approved by the Research Ethics Committee at George Washington University and at Centro de Pesquisa René Rachou, as well as the clinical trial ABS-00-02, approved by the National Research Ethics Committee. This study has followed all ethical guidelines of the Helsinki Declaration (2008) and Resolution CNS 196/96.

Results

Most participants are women (67.6%), brown or black (77.7%), with complete elementary school, attending or illiterate (65.43%), married (79.7%), with individual monthly income over R$ 545 (50.7%). The average age of the participants was 34.2 years-old (DP: 7.14), with minimum and maximum ages of 18 and 45, respectively.

The vast majority has the habit of watching television (93.3%) and not listening to radio (69.5%), and few have participated of previous researches (21.6%) (Table 1). It is noted that 43 participants have only signed the FICF for the clinical trial ABS-00-02 (control group), as the other 105 participants have participated in the educational intervention associated with the signature of this document (intervention group).

Through the chi-squared test (Fisher), a statistically significant difference between the groups of this study is noted related to the variable "color" (Table 1). Through the independent t-test, a statistically significant difference was not noted related to the average age of the groups.

Table 1. Distribution through categories of socioeconomic and demographic variables, in relative and absolute frequency. Americaninhas, Minas Gerais, Brazil, 2011

Category	Total (%)	Intervention	Control	p-value*
Color				
White	33 (22,3)	32 (30,5%)	1 (2,3%)	0,001
Brown/black	115 (77,7)	73 (69,5%)	42 (97,7%)	
Gender				
Female	100 (67,6)	67 (63,8%)	33 (76,7%)	0,127
Male	48 (32,4)	38 (36,2%)	10 (23,3%)	
Marriage status				
Single	30 (20,3)	26 (24,8%)	4 (9,3%)	0,051
Married/living together	118 (79,7)	79 (75,2%)	39 (90,7%)	
Individual monthly income				
Over R$ 545,00	75 (50,7)	62 (59%)	11 (25,6)	0,112
Under R$ 545,00	73 (49,3)	43 (41%)	32 (74,7%)	
Schooling				
Elementary school/illiterate	97 (65,4)	59 (56,2%)	27 (62,8%)	0,231
High school/higher education	51 (34,6)	46 (43,8%)	16 (37,2%)	
Assiste televisão				
Sim	138 (93,3)	95 (90,5%)	35 (81,4%)	0,086
No	10 (6,7)	10 (9,5%)	8 (18,6%)	
Watches television?				
Yes	45 (31,1)	70 (65,7%)	33 (76,7%)	0,374
No	103 (69,5)	35 (33,3%)	10 (23,3%)	
Participated in other surveys?				
Yes	32 (21,6)	27 (27,7%)	5 (11,6%)	0,059
No	116 (88,4)	78 (74,3%)	38 (88,4%)	
Total	**148 (100)**	**105(70,9)**	**43 (29,1)**	

*Fisher's chi-squared test

In Table 2 a statistically significant difference in the correct answers percentage for many questions between intervention and control group is noted. Hence, it is observed that participants in the educational intervention had a greater percentage of correct answers on the adverse effects foreseen in the protocol of the clinical trial, the secrecy of individual data, the foreseen benefits of the clinical trial and its scientific goals. It is also observed in the table a greater percentage of correct answers related to the reason why they were invited to participate in clinical trial ABS-00-02, the company sponsoring the clinical trial, the right of withdraw from the study and the knowledge of alternative treatments, besides the ones offered when participating in the clinical trial ($p \leq 0.05$).

It was not observed a statistically significant difference between intervention and control group regarding the correct answers percentage on questions related to the knowledge of the exams conducted during the clinical trial, the lack of compensation for the participation in the clinical investigation, the duration of the research and the fact that withdrawing from the study does not require the discontinuity of the medical treatment offered by this clinical investigation ($p > 0.05$) (Table 2).

Table 2. Percentage of correct answers related do the clinical trial ABS-00-02 and the rights of the participant in the study groups compared to the chi-squared test. Americaninhas, Minas Gerais, Brazil, 2011

Question	Intervention	Control	p*	OR**	IC***
Exams	95%	86%	0,530	3,243	0,934 – 11,267
Lack of compensation	90%	85%	0,431	1,544	0,523 – 4,541
Reason for invitation to participate in clinical trial	38%	19%	0,021	2,692	1,136 – 6,389
Adverse effects	53%	23%	0,001	3,371	1,687 – 8,433
Sponsor	25%	2%	0,001	13,823	1,812 – 50,232
Goal	56%	25%	0,001	3,742	1,700 – 8,119
Secrecy	81%	47%	0,001	5,312	2,258 – 10,580
Duration period	18%	19%	0,944	0,954	0,387 – 2,415
Benefits	79%	60%	0,022	2,471	1.144 – 5.338
Right to withdraw from study	95%	79%	0,002	5,294	1,659 –13,895
Discontinuance of medical treatment	36%	20%	0,074	2,142	0,919 – 4,931
Alternative to medical treatment	86%	58%	0,001	4,320	1,910 – 9,769

*Chi-squared test** Odds Ratio ***Trustworthiness interval [95%]

In Table 3, it is observed that in practically all measured domains the average score of influence in the decision-making process is lower in the intervention group, except in the *will to help* and *family* scores. Despite that, it is observed a statistically significant difference exclusively in the influence of friends and the medical treatment in the decision-making process to participate in the clinical trial ABS-00-02.

Table 3. Average score of the domains interfering in the decision-making process to participate in the clinical trial ABS-00-02, distributed by groups. Americaninhas, Minas Gerais, Brazil, 2011

Question	Intervention	Control	p*
Medical treatment	2,69	2,77	0,460
Medical exams	2,69	2,81	0,612
Friend	1,73	2,21	0,003
Family	2,19	2,19	0,252
Fiocruz	2,54	2,81	0,037
Meetings	2,74	2,79	0,181
Will to help	2,82	2,79	0,201
Learn more	2,65	2,72	0,748

*Mann-Whitney test

Discussion

It is considered an improvement on the quality of the free and informed consent when the individual has a greater knowledge of the study's information, the rights on the participation on the research and smaller influence in the decision, reflecting directly in their willingness to decide.

The present study has evidenced that the association of an educational intervention with the reading of the FICF is capable of favor a greater understanding of the information present in the FICF of a clinical trial and a smaller influence in the decision-making process for the participation in the clinical trial.

The greater understanding of the information on the clinical trial provided by the educational intervention is corroborated by studies that used educational strategies characterized by the interviewer-interviewee interaction. In a revision study on strategies used to improve participant's comprehension of clinical trials it is observed that interventions based in the interviewer-interviewee interaction are constituted as the most effective to favor the global comprehension of the information on the clinical trial [28].

A research conducted in Haiti, with the goal of improving the quality of the free and informed consent of a study on HIV has evidenced that the participants who had more time on the intervention, given by local counselors, had a greater comprehension of the information than those who only participated in a meeting with the doctor/researcher [37].

A possible explanation for the success of the educational intervention in improving the knowledge on the study lies on the duration of the contact of the participants with the information on the trial, since the intervention was conducted a month prior to the FICF. In a revision study on the patients' understanding of the free and informed consent, it is noted that the comprehension on the study was positively associated with the time they were given to assess the information and the opportunity to clarify their doubts [38].

The high percentage of knowledge on the data secrecy, foreseen benefits on the trial protocol and

the adverse effects was higher than the one seen in investigations conducted in developing countries [15, 39], in which the FICF was the only source of information on the study.

The knowledge on the absence of compensation to participate in the clinical trial was not associated to the participation on the educational intervention, considering the results were similar in both groups investigated. The high percentage of correct answers was also seen in similar studies in other developing countries [29, 40].

The comprehension of the right to withdraw from the study and the existence of alternatives to the medical treatment obtained with the clinical trial was associated to the participation on the educational intervention. This result was greater than those found in other studies conducted in the same region and in African countries [25, 41]. Understanding this information is essential to the willingness in the decision to participate in clinical trials [42].

Even with the knowledge of the right to withdraw from the study, it is observed that even after the educational intervention, participants believed that withdrawing from the clinical trial would lead to the loss of the medical treatment offered. This finding is corroborated in other studies in which the educational interventions were also tested on their effects on the comprehension of the free and informed consent [27]. A similar situation was found in other developed countries where parents believed they couldn't withdraw their children from the trial due to the loss of the treatment [43]. The comprehension of this information is essential to reach the autonomy in the decision to participate in clinical trials, since these participants feel compelled to participate in researches because of the possibility of treatment [44].

Even if the effectiveness of the educational intervention is considered in the comprehension of the information present in the FICF of the clinical trial, it is observed that the participation in this activity was not capable of favoring a greater understanding of essential information for the willingness in the decision to participate in the research. From this information, the reason why subjects were asked to participate in the research and the goal of the research stands out. A similar situation was found in studies conducted in developing countries [27, 45].

The non-comprehension of this information can lead to the volunteer not considering him/herself as a participant in a scientific research [46], signaling, in this case, the "therapeutic mistake" – a situation in which the therapeutic intent is attributed mainly to the scientific investigation [47].

The educational intervention also had an important effect on the influence of the research participant in the decision to join the clinical trial ABS-00-02, for it shows that participants in the educational intervention were less influenced by friends and their expectations towards the medical treatment than those who only signed the FICF of the clinical trial. This finding is expressive considering that in a research conducted in Thailand, on the experimental treatment of HIV, it is verified that close friends are considered a source of pressure for the participation in the study [48]. The influence of friends was also found in the African study [29]. Nevertheless, the African study on the quality of the free and informed consent for the participation in clinical trial [49] has shown that the possibility of medical treatment was an influent factor in the decision-making process to participate in the study.

Even if those two aspects are not mutually exclusive, given that the influence of friends can happen from an observation of difficulty to obtain treatment, one should wonder about this aspect, especially because it indicates a situation of socioeconomic vulnerability. In a situation of structural scarcity, the medical treatment offered by the clinical trial can act as a coercive factor, interfering directly with the willingness to of the consent [50]. Such situation affects decision even more in circumstances where the access to the health system is limited by economic factors inherent to the participant. That is, the most vulnerable would be the poorer participants in the least developed countries.

Within the limitations of the present study is the difficulty to concept the knowledge and the use of valid measurements to measure it, for the other studies that proposed to do so were conducted in different cultural contexts. We stress that the characteristics of the health systems in each country and its accessibility conditioned the influence related to the decision of participation. However, it is also important to specify that the essential themes measured by this study are present in the national and international ethics guidelines that standardize the research ethics.

To validate the data obtained, it is stressed the previous experience of interviewers in researches conducted in this region and in the creation of educational strategies [25], the standardization of the interviews and the previous training of interviewers, as well as the rigor in the data transcription. The adequacy of the language on the QAQIC to the context

where the research was conducted can be considered a potential factor to the validity of the study. The date of the conduction of the questionnaires deserves to be highlighted, in order to avoid the memory tendencies among the participants, since some clinical trial themes can present a smaller comprehension through time [40].

Even though the "color" variable has a significant statistic difference among the study groups, this difference shouldn't interfere with the results of this study, since and empiric study has shown that this characteristic is not associated to the knowledge of FICF information [12]. Given the fitting of all participants of the clinical trial ABS-00-02, it is believed that these results can be generalized to other situations in a similar social demographic context.

The study shows the interesting strategy to rescue in the scientific community the ethical imperative through which researches involving human beings are based, considering the use of an educational intervention instrumentalized by a board game can enable the research subject to a greater understanding on it through a playful methodology.

Final considerations

The results of the present study allow confirming the initial hypothesis, that is, the conduction of an educational intervention, instrumentalized by a board game, was able to improve the understanding of several information presented in the FICF of a clinical trial and reduce, in some dimensions, the influence in the decision-making process to participate or not in the research. In this sense, it is concluded that the conduction of a educational intervention, associated with the signature of the FICF, is capable to favor the ethical quality in the conduction of clinical trials and, thus, must be tied to the process of the free and informed consent to ensure favorable conditions to participants' expression of autonomy in their decisions.

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Authors' participation in the article

Lucas Lobato performed the field work, design and project of the study, statistic analysis and data interpretation. Beatriz Caçador participated in data analysis and interpretation. Maria Gazzinelli conceived the design and project of the study and participated in data interpretation. Vania de Souza participated in data interpretation. Amanda Nathale Soares participated in the statistic analysis and data interpretation. Edna Lucia Campos Wingester participated in the statistic analysis – and all participated together in the writing, revision of the manuscript and consolidation for final approval of the version to be published.

Attachment

Questionnaire on Quality Assessment of the Free and Informed Consent

SOCIAL DEMOGRAPHIC DATA

1. Gender
Male____ (1)
Female____(0)

2. Color (CFI*)
White____ (1)
Brown____ (2)
Black____ (3)

3. How old are you? _____ years old

4. Place of residency (CFI*)
Batatal __(1)
Peniche___ (2)
Americaninhas__(3)
Others (4). Where?_____

5. Are you married/living together?
Yes ___ (1) No __(0) (IF YES, SKIP TO 5.1)

6. Do you work?
Yes ___ (1) No __(0)

7. Do you watch TV?
Yes ___ (1) No __(0) (IF YES, SKIP TO 7.1)

7.1. How many times a week?

Once____ (1)
Twice to 4 times ____ (2)
> 5 times____ (3)

8. Do you listen to radio?
Yes ___ (1) No ___(0) (IF YES, SKIP TO 8.1)

8.1. How many times a week?
Once____ (1)
Twice to 4 times ____ (2)
> 5 times____ (3)

** CFI = Chosen for interviewer*

10. Could you answer until which grade you studied?
(CLASSIFY GRADE ACCORDING TO OPTIONS):

Incomplete elementary school (1st to 8th grade) ____ (1)
Complete elementary school (9th grade) ____ (2)
Incomplete high school (1 to 2 years) ____ (3)
Complete high school (3rd year complete) ____ (4)
Incomplete higher education
(incomplete graduation) ____ (5)
Complete higher education (complete graduation) ____ (6)
Illiterate (0 years of study) ____ (7)

11. What is your monthly income? _____
12. Have you participated in other surveys?_____

DECISION MAKING

13. Let's talk of you participation in this study, could you tell us if any of these people/situations may have influenced you to participate in the study? Do you feel it had No Influence, Little Influence or Great Influence in your decision to participate in this study? (READ OPTIONS)

	No Influence	Little Influence	Great Influence
Possibility of medical treatment	0	1	2
Possibility of medical exams	0	1	2
Your friends	0	1	2
Your family	0	1	2
Fiocruz personnel	0	1	2
Participating in meetings	0	1	2
Possibility of learning more about the disease	0	1	2
Will to help others	0	1	2

COMPREHENSION OF STUDY

(Answer "1" if the interviewee answer the option between brackets and "0" if not):

When you entered in the research, which exams must be done? (blood and feces)
Will you receive money to participate in the study? (no)
Do you know why you were invited to participate in this study? (lives in an endemic region for helminthiasis/lives in area with high incidence of worms)
Do you know the possible negative effects of participating in this study? (ONLY ONE) (death, redness, itch, headaches, diarrhea)
Do you know who is sponsoring this study? (Kraft Foods)
Do you know why this study is being conducted? (to test food against worms)

Is there another way to treat worms besides participating in this study? (yes)
Can you leave the research at any time? (yes)
If you leave, will you lose the worm treatment offered? (no)
Will your information be kept safe and in secrecy? (yes)
How long will this research last? (4-5 months)
What are the benefits of participating in this study? (learn more/medical treatment/medical exams)