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Theater in the education of children and teenagers participating in a clinical trial

ABSTRACT

OBJECTIVE: To analyze the effects of a pedagogical intervention on the learning of children and teenagers participating in a clinical research.

METHODS: Quantitative, quasi-experimental and longitudinal study, part of a group of studies conducted to test a vaccine against ancylostomiasis. Convenience sample with 133 students aged 10-17 years, of both sexes, from the school *Escola Municipal de Maranhão* (Southeastern Brazil), 2009. A structured questionnaire was used, which was administered before and after the intervention. The pedagogical device was the "Theater of the Oppressed". The dependent variables were specific and global knowledge about clinical research and about parasitic worms; the independent variable was participation in the educational intervention.

RESULTS: There was an increase in knowledge about signals and symptoms, susceptibility to reinfection and way of contagion after the educational intervention. We observed an increase in the number of right answers concerning duration of clinical research, procedures, the possibility of quitting participation, and occurrence of adverse events. The notion that the research's primary purpose is therapeutic remained, but the percentage of participants who associated the research with medical treatment decreased. The "Theater of the Oppressed" enabled that the discussions about helminthiasis and clinical research were contextualized and materialized. The subjects could dispose of or reduce their previous representations.

CONCLUSIONS: Participation of children and adolescents in clinical trials must be preceded by an educational intervention, since individuals of that age group do not even recognize they have the right to decide for themselves.

DESCRIPTORS: Ancylostomiasis, prevention & control. Child. Adolescent. Personal Autonomy. Health Knowledge, Attitudes, Practice. Health Education.

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INTRODUCTION

Paediatric clinical research should take into account the issue of the subjects' autonomous decision to take part. Consent forms are usually used to demonstrate the subjects' agreement to participate, as in autonomy based bio-ethical principilism.[12]

The Conselho Nacional de Saúde/Ministério da Saúde (CNS/MS) 196 resolution of 10/10/1996, requires consent forms to be signed in any research involving children and adolescents (those aged under 12 are deemed children and adolescents are those aged 12 to 18[a]). This consent is given by the legal representatives of the minor, without suspension of the individual's right to information, within the limits of their capacity.[b]

There has been little progress made in resolving the difficulties of obtaining children and adolescents' consent. They are deemed to be vulnerable individuals, unfit to agree to participation in studies, which justifies the parents' and guardians' authorisations on their behalf.[4]

CNS' 196/96 resolution states that, even though they are not legally capable of deciding to participate in research, children and adolescents have the right to freedom, to respect, to dignity and to the inviolability of their physical, mental and moral wellbeing guaranteed in the Children and Adolescents statute, which covers preserving their autonomy.[a]

In spite of this right, studies on clinical trials on under 18s indicate that they themselves are not involved in the decision process,[18] which is aimed at their parents or guardians.[20,24]

Children are in the process of developing autonomy and maturity. Competence to agree to participate in research does not depend solely on age but also on cognitive development, allowing them to better understand the consequences of taking part in a study.[5]

Paediatric clinical studies are as important as the autonomy of the children and adolescents in the process of deciding about participation in this type of study. Faced with the necessity to conduct clinical research ethically and obtain quality, informed consent, seeking educational strategies which favour autonomous decision making in minors is indispensable.

This study aimed to analyse the effects of a pedagogical intervention in children and adolescents' learning of concepts involved in a piece of clinical research.

METHODS

This was a quantitative, quasi-experimental and longitudinal study. It consisted of developing an educational intervention and evaluating its effects based on a before and after comparison (time 0 and time 1, respectively).

The study was carried out in June 2009 in the district of Caraí, MG, Southeast Brazil. This region is between the Mucuri and Jequitinhonha valleys, located 40 km far from Caraí and 590 km from the state capital, Belo Horizonte, and is an area in which ancylostomiasis, or hookworm, is endemic.

The convenience sample was made up of 133 pupils from a municipal school in Caraí, living in this district and in nearby rural areas, aged 10 to 17. This school was chosen due to the ease of carrying out a longitudinal study with a pre and post intervention instrument.

Clinical trials testing an ancylostomiasis vaccine are being carried out in this region. They are carried out by the Human Hookworm Vaccine Initiative (HHVI), a consortium of researchers from the George Washington University (USA), Fundação Oswaldo Cruz (Brazil) and the Sabin Vaccine-Institute (USA).

Alongside the research testing the vaccine, a paediatric study evaluating the effects of anthelmintic chemotherapy treatment and the reinfection dynamic of this parasitic worm among under-10s. The volunteers who agreed to take part in this study needed to follow guidelines and requirements which would affect or modify their routines. This meant preparing the subjects, i.e., interventions with the aim of informing them about the study, as the consent form alone was not enough to guarantee comprehension.[13,15,16] This preparation took place in different contexts of clinical trials, above all when the subjects were in positions of social vulnerability.[20] Thus, it was necessary to carry out some preparatory activities in the municipality of Maranhão.

The option of extending the pedagogical interventions to the entire community took into account that, in developing countries, creating discussion forums on the project in the whole community is common practice used to inform participants about the research.[10]

Studies indicate diverse strategies to promote the understanding of the consent forms: making them less complex;[19] having the doctor responsible explain them;[21] pedagogical interventions;[9] and group meetings for volunteers.[23] In this case, we decided to prepare the subjects of the paediatric study using games and role play as the pedagogic strategy for children up to the age

[a] Lei nº 8.069, de 13 de Julho de 1990. Dispõe sobre o Estatuto da Criança e do Adolescente e dá outras providências. Diário Oficial da República Federativa do Brasil, 1990 Jul 16; Seção 1:13563-577.
[b] Ministério da Saúde (BR), Conselho Nacional de Saúde, Comissão Nacional de Ética em Pesquisa. Normas para pesquisa envolvendo seres humanos. Resoluções CNS. nº 196/96 e outras. 2.ed. ampl. Brasília (DF); 2003.

of ten. Drama was used as a pedagogical instrument for those above this age, with a play in a public square. This study deals with the intervention in the form of theatre.

The play built on the informative and technical character of conventional health education as it treated the individual as an active subject in constructing meaning, in interacting with the world and with others.

In order to create this show, a group of adolescents worked with a playwright. Using a set of theatrical techniques inspired by the Theatre of the Oppressed, developed by the Brazilian Augusto Boal.[3]

Theatre of the Oppressed (referencing Paulo Freire's Pedagogy of the Oppressed)[6] is a system of physical exercises, aesthetic games, imaging techniques and special improvisations aiming at rescuing and developing the human theatrical vocation. It is an effective tool in understanding and seeking solutions to interpersonal and social problems. Its methodology follows two basic principles: making the audience into actors and making all the scenes from the play into a rehearsal to then be turned into reality. This theatre component requires construction and the use of popular topics, as well as the active participation of the audience in the play.[3] It is based on the assumption that human beings are naturally theatrical, as they constantly use tone of voice, facial expression and body language to communicate and interpret these signs in others in turn. In other words, the theatre is a vocation of every human being. As it is a universal language it can be understood by everyone.

The play "Amarelão: não quero não" (I don't want hookworm, no way), created by adolescents, incorporated typical language and everyday situations of the region. The text and music dealt with issues which acted as epistemological obstacles to understanding scientific concepts. Information on the clinical study to be carried out, common sense ideas about hookworm and on the research and researchers were all included.

In the educational model proposed by Freire[7] and adopted here, the teacher and students are involved in a mutual process of reconstructing collective knowledge. This process involves reading the world and reality, as well as reading words, concepts and scientific theories. These are the theoretic components which dialectically give new meaning to practice, reinterpreted by a conscious reading of the world.[6-8]

The dependent variables were: overall knowledge of parasitic worms, overall knowledge of clinical research, specific knowledge of parasitic worms and about clinical research. The independent variable was the educational intervention.

We took a similar qualitative study[9] with a population in the same socio-economic context into consideration when drawing up the questionnaire. The structured questionnaire was made up of 23 open ended questions regarding socio-demographic data, knowledge of parasitic worms and of clinical research.

The instrument was tested beforehand on a sample of 20 people who were residents of the same region, aiming at evaluating its duration and how well the questions were understood, with subsequent adjustments to the final version.

The data were collected in the school itself (in the classroom), during 20 minutes on average, by trained graduate and post-graduate students. The questionnaires were completed at Time 0 and Time 1, this latter being one week after the educational intervention took place. The interviewee read the questions and completed their answers according to pre-defined options.

An independent double check of all the questionnaires was carried out before analysing the data. The data entry was duplicated and carried out independently, using the Statistical Package for Social Sciences (SPSS), version 15 software.[17]

Correctly answered questions received a value of 1, and incorrectly answered were allocated 0. The individual descriptive statistical analysis of the questions was carried out by calculating the percentage of correct answers before and after the educational intervention. We used the McNemar test to analyse the significance of statistical differences between the responses.

The specific questions on the parasitic worms were treated dichotomously: correct options = 1; incorrect = 0. The questions about the clinical research were treated dichotomously and were of multiple choice.

An index to analyse overall knowledge of parasitic worms and clinical research was set up. It consisted of the sum of correct answers to the dichotomous questions, divided by the total number of question on the topic. The result was shown as a percentage.

The data obtained were shown as mean and standard deviation. The paired t-test was used to statistically compare the data collected before and after the educational intervention. The level of rejection of the null hypothesis in all statistical tests was 5%.

Volunteers eligible to take part in the study agreed to participate, and permission was given by their parents/guardians who, after receiving information about the research and having any doubts resolved, signed the consent forms. The research was carried out according to the requirements of 196/96 Resolution, and was approved by the Committee of Ethical Research on Human Beings of the Centro de Pesquisa René Rachou/Fiocruz (4/2008) and of the National Committee for Ethics in Research (678/2008).

RESULTS

The study counted on the participation of 133 students of both sexes (54.9% female); the average age was 13.16 (standard deviation: 1.94); 75.2% were in elementary education and 24.8% in secondary education. There was no statistically significant difference between the participants' level of education and gender, nor in the proportion of each sex.

Mean overall knowledge about parasitic worms and about clinical research before the educational intervention was 60.9% and 44.7% respectively (Table 1). After the intervention, these values increased to 64.8% and 52.0%, respectively ($p \leq 0.05$).

There was an increase in the percentage of correct answers to questions about symptoms and signs of ancylostomiasis and about susceptibility to reinfection ($p \leq 0.05$) (Table 2).

The percentage of correct answers on contagion with helminths via contact with the ground increased. The number of correct answers to question on contagion with ancylostomiasis via unwashed fruit and vegetables and standing water, in which a statistically significant difference was observed, decreased. The number of correct answers was < 16% in these two latter questions (Table 2).

There was an increase in correct answers on: duration of the research in the region, possibility of dropping out at any time and possible procedures in the clinical trials, as well as possible adverse effects of the product being tested ($p \leq 0.05$) (Table 3).

Before the intervention, 48% of participants believed that the researcher treated people for health problems and did tests. This fell to 27.1% after the intervention. The percentage of participants who believed that the researcher's aim was to conduct research, study and investigate how the organism reacted to the parasitic worm went from 14.4% to 45.9% after the intervention. Those who before the intervention did not know what the researcher's objective in their community was made up 33.1%, dropping to 15.8% afterwards (Table 4).

There were no marked changes pre and post-intervention in the knowledge of the benefits of the clinical research for the community. Health was seen by 27% of the subjects to be the benefit before the intervention and 31.1% afterwards (Table 5).

DISCUSSION

Education through theatre was eagerly accepted on the part of the children and adolescents and favoured overall knowledge and learning specific concepts about

Table 1. Mean percentage and difference of correct answers to questions about helminths and clinical research in Time 0 and Time 1. City of Maranhão, Southeast Brazil, 2009.

Group	% Correct answers		Difference in % of correct answers	Confidence Interval
	Time 0	Time 1		
Helminths	60.9	64.8	3.9[a]	0.017;0.061
Clinical research	44.7	52.0	7.2[a]	0.041;0.102

[a] $p \leq 0,05$

Table 2. Percentage and comparing the differences in the percentage of correct answers a to specific questions about helminths in Time 0 and Time 1. City of Maranhão, Southeast Brazil, 2009.

Question	% de correct answers		Correct response
	Time 0	Time 1	
Possibility of being infected by hookworm without knowing[a]	84	96	Yes
Knowledge of hookworm[a]	22	38	Yes
Symptoms of hookworm[a]	29	43	Weakness/drowsiness/ stomach pains
Possibility of hookworm transmission from walking barefoot[a]	89	98	Yes
Possibility of hookworm transmission from eating unwashed fruit and vegetables	13	9	No
Possibility of hookworm transmission from contact with standing water[b]	16	7	No
Possibility of exclusively visual identification	94	94	No
Reinfection with hookworm after treatment[b]	77	89	Yes
Anaemia as a consequence of hookworm[b]	81	91	Yes

[a] McNemar Test
[b] $p \leq 0,05$

Table 3. Comparison of the differences in percentages of correct answers[a] to questions about clinical research in Time 0 and Time 1. City of Maranhão, Southeast Brazil, 2009.

Question	% correct answers		Correct answers
	Time 0	Time 1	
Length of study[b]	12	38	2 years
Exam carried out in the study[b]	54	66	Faecal exam
Age of participants	20	30	0-10 years
Vaccine given during the study	20	28	Yes
Aim of the faecal exam	87	84	Discover type of worm
Only sick people participated	100	94	No
Aim of the study	96	100	Produce a vaccine
Possibility of dropping out of the study[b]	20	57	Yes
Possibility of a reaction if given treatment[b]	50	67	Yes

[a] McNemar Test
[b] $p \leq 0,05$

Table 4. Absolute and percentage frequency of the types of answers on the aim of the researcher in the community involved in the clinical study. City of Maranhão, Southeast Brazil, 2009.

Answer	Time 0		Time 1	
	n = 133	%	n = 133	%
Study a vaccine	6	4.5	35	26.3
Study how the organism reacts to the worm	4	3.2	7	5.3
Treatment	35	26.2	25	18.8
Health care	20	15.1	10	7.5
Research	9	6.7	19	14.3
Tests	9	6.7	1	0.8
Don't know	44	33.1	21	15.8
Other	6	4.5	15	11.2

Table 5. Absolute and percentage frequency of the types of response about the benefits of the clinical research for the community involved. City of Maranhão, Southeast Brazil, 2009.

Answer	Time 0		Time 1	
	n = 100	%	n = 106	%
Health	27	27	33	31.1
Financial	2	2	0	0.0
Quality of life	3	3	2	1.88
Knowledge	14	14	14	13.2
None	3	3	0	0.0
Treatment	17	17	23	21.69
Don't know	23	23	16	15.09
Other	11	11	18	16.98

hookworm and clinical research. This study identified an increase in the percentage of correct answers the pupils gave to questions about the clinical trials, similar to the results of a previous study using video-documentaries in the same region.[9]

That study, carried out among school pupils in an area of China with endemic schistosomiasis showed that educational programmes with non-traditional pedagogical strategies were useful in conveying information on helminths.[25]

In this work, the increase in the participants' overall knowledge about the study was less than in a study carried out in Africa, in which participants were informed about the research through informed consent.[15] However,

due to methodological differences, it is not possible to make a specific comparison.

One of the problems, indicated in the literature, with conducting clinical trials in socio-economically disadvantaged communities is "therapeutic misconception",[20] a phenomenon in which the participants of the clinical trial interpret the main goal of the study as treatment and not for scientific purposes.[2] This misconception was observed in this study with reduction in the number of participants who associated the research to medical treatment after the intervention.

Joubert et al[14] states that, when an educational intervention is well planned, a considerable number of the respondents manage to see its scientific aim, even in a socio-economically vulnerable situation.

We observed the power of the Theatre of the Oppressed in promoting this understanding of the research aims and in lessening therapeutic misconception, identified in this study and in a previous study in the same region.[1] The discussions on parasitic worms and clinical research were contextualised through the Theatre of the Oppressed, making more sense to the subjects and allowing them to move away from their previous ideas and conceptions.

While watching the play and taking part in the story, notable for its colloquialisms, its common sense and the typical everyday situations represented, the subjects identified with the characters, scenes and images so closely connected with their reality. This happened because theatre has the power to articulate this reality and configure it in the subjects' imagination. The sensitive dimension is revived and it becomes possible to create new subjective arrangements, related to perceiving and experiencing reality.

What distinguishes dialogical education – as used in the Theatre of the Oppressed – from traditional education is that it concerns itself the affective and inventive dimensions of learning, which are not taken account of in traditional education, where the emphasis is on technical-scientific rationality. In the dialogic relationship, information is reconstructed from experiences which are concrete and reflected, not solely copied and replicated.

Although dialogical education enhanced the learning conditions, a significant number of participants still had the misconception that the aim of the study was therapeutic. The decision to participate in clinical trials is frequently influenced by being socio-economically disadvantaged and the concomitant difficulty in accessing health care services, a worrying situation all over the world.[11,22]

In countries with marked social inequality and extreme poverty, many participants take part in clinical trials seeing them as an opportunity to intervene in their social and/or biological ills. It is necessary to think about educational preparation for these people. The aim should be to help them understand they have the right to the benefits of treatment even without taking part in a study.

This understanding may contribute to the participant not seeing the clinical trial as their only means of accessing health care and achieve real understanding of the scientific objective of the research. The aim is to reduce therapeutic misconception, which may lead to overestimating benefits and ignoring risks. Reducing therapeutic misconception would be a way of favouring autonomy in deciding to participate in clinical trials.[11]

These findings may not be representative of adolescents in situations of vulnerability throughout the region, as not all are enrolled in school and/or receive formal education. The quality of teaching in this community probably differs from that provided in metropolitan areas of Brazil, which means we cannot extrapolate the results for adolescents in developing countries. However, the size of the sample and the longitudinal design may be useful in assessing the effectiveness of educational interventions for children and adolescents in socio-economically disadvantaged situations.

This work adds to the scarce literature that exists on quantitatively evaluating informed consent in developing countries. New studies which deal with the volunteers' motivation in taking part in clinical research and the individual and contextual factors involved in their understanding of the process would be a welcome addition.

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