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ORIGINAL ARTICLE

ETHICS IN RESEARCH ABOUT THE PERCEPTION OF PHYSIOTHERAPY STUDENTS

ÉTICA EM PESQUISA SOBRE A PERCEPÇÃO DOS DISCENTES DE FISIOTERAPIA ÉTICA EN LA INVESTIGACIÓN SOBRE LA PERCEPCIÓN DE LOS ESTUDIANTES DE FISIOTERAPIA

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ABSTRACT

Objective: to discuss the perception of students of the Physiotherapy course about ethics in research. **Method:** exploratory, descriptive study, with qualitative approach, with students from a private Higher Education Institution in Maceió/AL. It was used as a tool for data collecting the guide of semi-structured interview. The interviews were analyzed by the Bardin Content Analysis Technique in the Thematic mode. **Results:** one indicated a divergent understanding about the concept of ethics and more convergent about the ethical principles of human research and the work of regulatory agencies of ethics. **Conclusion:** the differences found in the speeches of the participants of this study expose the need for adjustments of the curriculum of the Physiotherapy course in relation to the focus of the contents involving ethics. **Descriptors:** Ethics; Human Experimentation; Human Resources in Health.

RESUMO

Objetivo: discutir a percepção dos discentes do curso de Fisioterapia sobre a ética em pesquisa. **Método:** estudo exploratório, descritivo, com abordagem qualitativa, com discentes de uma Instituição de Ensino Superior privada de Maceió/AL. Utilizou-se como instrumento para a coleta de dados o roteiro de entrevista semiestruturada. As entrevistas foram analisadas pela Técnica de Análise de Conteúdo de Bardin na modalidade Temática. **Resultados:** apontou-se para um conhecimento divergente sobre o conceito de ética e mais convergente sobre os preceitos éticos da pesquisa com seres humanos e a atuação de órgãos fiscalizadores de ética. **Conclusão:** as divergências encontradas nas falas dos participantes abordados na pesquisa expõem a necessidade de adequações na estrutura curricular do curso de Fisioterapia em relação à abordagem dos conteúdos que envolvem a ética. **Descritores:** Ética; Experimentação Humana; Recursos Humanos em Saúde.

RESUMEN

Objetivo: analizar la percepción de los estudiantes del curso de Fisioterapia sobre ética en la investigación. **Método:** estudio exploratorio, descriptivo, con enfoque cualitativo, con los estudiantes de una Institución de Educación Superior privada en Maceió/AL. Fue utilizado como herramienta para la colección de datos el guion de entrevistas semiestructurada. Las entrevistas fueron analizadas por la técnica de análisis de contenido de Bardin en la modalidad temática. **Resultados:** fue apuntado a una comprensión divergente del concepto de ética y más convergente en los principios éticos de la investigación con los seres humanos y el trabajo de las agencias reguladoras de la ética. **Conclusión:** las diferencias encontradas en los discursos de los participantes de este estudio exponen la necesidad de ajustes en el plan de estudios del curso de Fisioterapia en relación con el enfoque de los contenidos que envuelven la ética. **Descriptores:** Ética; La Experimentación Humana; Recursos Humanos en Salud.

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INTRODUCTION

The ethics must be the basis of researches in any area of knowledge, considering that even studies related to the environment, flora and fauna can produce impacts with severe consequences.¹ The health area, which attends human beings, makes even more necessary the knowledge and the application of ethical principles¹, with the need for the researcher to observe him/herself and his/her behavior in the activity, seeking an attitude of respect with the study participants and the society.²

For the observation and constant improvement of ethical parameters, the discussion related to ethics applied to research must be intense at universities, pursuing the training of professionals with critical sense and humane eye.³ The research is presented as an opportunity for students and professionals to develop an explanation to a problem generated by a phenomenon whose scientific knowledge is still insufficient.⁴ The explanation occurs through a process of approaches and reworking of the confrontation between the new information and the knowledge available.⁴

The researches have become an activity so representative and important in Brazilian society that the number of professionals devoted to this occupation increased significantly.⁵ According to the National Research Council (CNPq), there was an increase related to the total of research groups in Brazil from 11.760, in 2000, to 27.523, in 2010, a gain of nearly 150%.⁶ Given this vertiginous increase in research groups, there is the need for a more effective teaching of ethics applied to research, so that researchers acquire knowledge about their responsibility to science, community and research participants.⁷

There are several mechanisms to monitor and supervise the projects and their implementation, in order to maintain compliance in the research and publication of data. In Brazil, there are two important documents with the positioning of institutions fostering research: the Report of the Committee of Research Integrity of the National Research Council (CNPq), facing the problem of integrity in research, proposing, firstly, preventive and pedagogical actions that can create a culture of academic honesty; and Higher Education Personnel's Improvement Coordination (Capes), which, in 2011, published a document with guidelines to fight plagiarism¹, recommending that public and private Brazilian education institutions advise and aware about the intellectual

property, in order to curb the practice of plagiarism.⁸

To regulate the relationship between ethics in research and human beings, it was established, two decades ago, the Resolution 196/96 of the National Health Council (CNS).⁹ This resolution establishes the Brazilian system of Ethical review - the CEP-CONEP system, compound by the Research Ethics Committee (CEP) and the National Research Ethics Commission (CONEP).¹⁰ The Resolution 196/96, which set the rules and guidelines for researches with human beings, was analyzed by members of the Brazilian CEP in a participatory manner, being replaced, after reviewed, by CNS Resolution 466/2012.¹¹ This latter document intended to improve the regulation of researches involving human beings, ensuring the rights and obligations concerning the research participant and, therefore, the researcher.⁵

Given the ongoing increase of research activities and the basal importance of ensuring the research ethics, this study intends to evaluate the knowledge of Physiotherapy students about the theme. By collecting information, the Higher Education Institution (HEI) may adopt mechanisms to ensure the develop of ethical research.¹ Identifying the "good" behavior in academic daily life, such as honesty in data handling and dissemination of knowledge, dissemination of ethical criteria in both writing and publishing of the results, is related to both basal ethical values for knowledge production, as to the "good" functioning of scientific institutions.¹

This study's objective is:

- To discuss the perception of students of the Physiotherapy course about ethics in research.

METHOD

Exploratory, descriptive study, with qualitative approach. One used as an instrument of research, a semi-structured interview guide with students from a private HEI located in the city of Maceió, Alagoas. The curriculum of the Physiotherapy course includes the thematic with the discipline of Bioethics and Deontology, available in the second semester of the course, and addresses the issues of ethics, morality, bioethics, research ethics and deontology.

Students from the first and tenth semesters of the Physiotherapy course were invited to join the study and sign the Term of Free Consent and Informed (TFCI), excluding all students who were 18 years old or less and/or

who had a previous higher graduation. The theme was the knowledge about research ethics. The sample consisted of 120 students from the first semester and 14 students from the tenth semester, in 2015. This difference between the numbers of students from these semesters was due to the increase in the number of places in 2015 in the surveyed HEI.

Data collecting took place at the premises of IES during April 2015. The interviews were analyzed thoroughly by Bardin Content Analysis Technique, in the Thematic mode. In qualitative researches, the sample closure by saturation is operationally defined by the non-inclusion of participants, that is, when the researcher believes that the data are redundant and/or repetitive.¹²

The data were subject to a pre-analysis (organization phase), categorized and, then, the recording units were created. The speeches of the participants were identified using 1P for participants from the 1st semester, followed by the order of the application of questionnaires, from 1P1 to 1P10, and 2P for participants from the 10th semester, followed by the order of the application of questionnaires, from 2P1 to 2P10. Three recording units were created: UR1 "Ethics Concept"; UR2 "Ethical Precepts of Research with Human Beings" and UR3 "Research Ethics Committee."

RESULTS AND DISCUSSION

◆ UR1 Ethics Concept

In this study, the criterion of saturation was reached with 20 students: 10 from the 1st semester and 10 from the 10th semester. In this UR, the addressed theme was the ethic, which had different understandings by the participants, whose concepts were put together into the following categories: bioethical principles; deontology and moral.

◆ Bioethical Principles

The theoretical framework used as the basis for what, later, was called the principlism, was bioethics school based on the use of the principles as an explanatory model.¹³ The defended principles of bioethics are: autonomy; non-maleficence; beneficence; and justice, under a common parameter, which is the respect to human dignity; it is not only the accomplishment of recommendations or standards, but also the reflection of the researcher and his/her staff, about the ethical implications of the research project.¹⁴

The beneficence comprehends from the improvement of knowledge about the disease

until the discovery of cures and rehabilitation.¹⁴ Non-maleficence comprehends the guarantee for the participant not to suffer any damage during the research, ensuring that foreseen damages are avoided.¹⁴ The relationship of equality between these two principles must be maintained, and the risk of the research for the participants shall never be greater than the benefit.¹⁵ The participants related the concept of ethics with the bioethical principles of non-maleficence and beneficence. It is noticed in the following speech:

It is the way each one respects, prevents and deals with situations relevant to the neighbor, in order to maximize the benefits and minimize the detriments (2P1);
The way people relate in accordance to the principles of the non-maleficence, and promoting the beneficence to the neighbor, given their thoughts of the advantages taken of certain situations (2P8).

The relation made by the students from the 10th semester between the concept of ethics and bioethical principles comes, possibly, from the contact with the discipline of bioethics and deontology, and for they are developing the Course Conclusion Work (TCC), which, when done with human beings, must respect bioethical principles and provisions of Resolution CNS 466/12.

The Resolution CNS 466/12 refers to the guidelines and norms regulating researches involving human beings, in order to ensure the rights and obligations of participants, scientific community and the State.¹⁴

The participants from the 1st semester did not correlate the bioethical principles, which can be explained by the fact that the discipline of bioethics and deontology is available in the 2nd semester of the Physiotherapy course, according to the curriculum of the HEI.

Deontology

The deontology is a special ethics adapted to the activity conditions of certain profession, imposing duties, responsibilities and rights.¹⁶ The professional behavior must be based on the norms of the code of professional ethics. The teaching of ethics and deontology is directly related, due to the insertion of content involving the isolated ethics and professional ethics in the curricula.¹⁷ Such fact enables the changes in the ethical-moral education of the students.

One notes the relation made by the students between the concept of ethics and deontology in the following speeches:

To respect other's right and opinion, regardless what I believe is right or wrong (2P8);

Respect of the patient's will and choice (2P2);

It's the respect to the life of any living being. (2P7).

The relationship between the concepts of ethics and deontology is perceived when observing that the physiotherapist's obligations towards the profession and the responsibility for the patients are placed in the concepts of ethics of the participants. These Physiotherapist's obligations are issues pertaining to Resolution nº 424/13 of the Regional Council of Physiotherapy and Occupational Therapy (CREFITO), which established the Code of Ethics and Deontology of Physiotherapy.¹⁸ The Resolution 424/13, in its art. 1st, "attends the physiotherapist duties regarding the ethical control of the exercise of their profession, without loss of all rights and privileges provided by law", and enhances the physiotherapist's duties, in its art. 14, section I - "respect human life from conception to death, never acting voluntarily in any activity that ravishes it, or that endangers the physical, mental, moral, cultural and social integrity of the human being."¹⁸ The ethics code guides the actions during professional activity.¹⁹ One notices the relationship between the participants' speeches and the content of the ethics code.

To respect the individual, and not to compromise his/her health and integrity (1P6);

A behavior every professional must have (1P2).

The participants related ethics to the need for confidentiality of information that is inherent to the patient. Resolution No. 414/12 provides for the compulsory medical recording by the physiotherapist, its guard and disposal.²⁰ Art. 13 of Resolution 424/13 reiterates that the physiotherapist must ensure that the records of the client/patient/user remain out of the reach of strangers who don't belong to the health staff of the institution, unless other conduct is expressly recommended by the management of the institution and has legal support.¹⁸ This is explicit in the participants' speeches.

To keep in appropriate place the information of the patients (2P2);

Not putting in embarrassing situations the involved people/patients (2P7).

The exchange of concepts presented by the participants shows that the fact the contents of Bioethics and Deontology are given in the same discipline produces disagreement over

the definition and improvement of knowledge about these topics.

♦Moral

The moral proposes concrete actions, characterized as a set of rules governing social behavior in order to ensure order.²¹⁻²² The rules lead to behaviors of good conduct, morality, precepts and principles established by the society showing honesty and correct attitude.²³ The ethics is related to the moral, for it is a type of normative knowledge, which intends to guide the actions of human beings, encouraging them to think over the different ways to justify the moral life.²⁴

Moral and ethics share an almost identical etymological meaning: "everything that refers to the way of being or personality acquired as a result of acting in accordance with some customs or habits considered good."²¹ However, ethics acquired triple function: 1) to clarify what is moral, what are its specific characteristics; 2) to support morality, that is, it intends to explain what are the reasons to the efforts of humans to live morally; and 3) to apply, to different aspects of social life, the results obtained in the previous functions, so that people adopt, in these areas, a moral critical, rather than adopting a dogmatic moral code or lack of moral references.²¹

It was perceptible, in the participants' speeches, the confusion caused by the concepts of the referred terms, for their great inter-relationship.

It's not to infringe the professional moral (2P10);

It's a set of norms and moral values (1P4).

The word morality means choosing the best option among the possible ones, from the individual conscience that guides the way people act, conforming to the guidelines established by the society.^{14,25} Therefore, morality has prescriptive character; when the individual begins to be aware of his/her attitudes, imposed acceptable social behaviors must be respected under the alternative of punishment, from the awareness of what is good or bad for that social group, and the degree of freedom for the individual's decision.²⁶ As presented in the participants' statements:

It's everything that is linked to the moral, conduct, the social living together and the personality (1P9);

A set of moral norms to be followed (1P7).

Despite extensive discussions and definitions, ethics is considered the most difficult theme of philosophy, being an area of speculation, research and discussion, where there are not widespread agreements,

creating, thus, major difficulty in distinguishing and defining the terms ethics and moral.²⁷

◆UR 2 Ethical precepts of research with human beings

UR 2 analyzes the participants' knowledge about the ethical principles that must be adopted in researches with human beings, that is, ethical behavior that must be part of the *ethos* and the researcher's study's stages, since the development of the theme, definition of objectives, application of the study, results record, analysis of results and its presentation. This is essential because ethics must be part of all actions, from the composition of the research's project to the behavior that researchers must adopt.²

One enhances that, among 10 participants from the 1st semester, only two mentioned any information about this UR. This may be due to the absence of such discussion at this semester of the course, because this content is available in the 2nd semester of the course in the discipline of Bioethics and Deontology, according to the curriculum of the HEI. In this recording unit, the category Risks and Benefits of the Research was created.

◆Risks and Benefits of the Research

A close relationship between the researcher and his/her research and between the researcher and the participants is necessary, since it will be the basis of study, influencing its results.¹⁷ In this study, it was enhanced the importance of keeping the participants aware of all risks and benefits, an issue described in Resolution CNS 466/12, which sets the guidelines and norms for researches with human beings.¹⁴

The Resolution 466/12 enhances that the ethics of the research implicates the balance between risks and benefits potential, individual or collective, leading to the maximum benefits and minimal injuries and risks; ensuring that foreseen injuries will be prevented.¹⁴

To let the individuals aware of the risks/benefits, predisposing strategies that minimize the present risks(2P1);

To avoid physical and emotional injuries, bringing benefits with the study's results (2P6);

To clarify all the risks and benefits to the participants(2P10).

In addition to clarifying the risks and benefits, the participant must be free to decide on the participation, so it is essential the researcher clarifies, to the participants, the whole process, presenting them the possibility of giving up, if they want to,

regardless of the reason, without any pecuniary loss, lack of access to treatment or appointment, or even ensuring that they will not suffer any retaliation.²⁸

Participants 1P2 and 1P3 complement, exposing, in their speeches, the importance of clarifying the research:

The person must be aware and agree joining the research(1P2);

The participant agrees joining the research(1P3).

There are regulations for researches with human beings; however, during a long period, experiments were conducted with human beings, without the possibility to choose on joining and/or know the research, facts that occurred on a large scale during the Nazi period.²⁹ The Nuremberg Code, dated 1946, was the document by which the scientific community intended to reply to the barbarity of the Nazi experiments, within the medical research.²⁹ The code emphasizes that the participant must have the freedom to leave the study if not physically or mentally capable. If this happens, the researcher must suspend the proceedings, if there is possibility of injury, disability or death to the participant.³⁰ The document also enhances the importance of the participant's consent, currently obtained by signing the Term of Free Consent and Informed (TFCI), which clarifies everything about the study to the participant. This set of recommendations was noticed in the participants' speeches of this study:

The researcher must emit and the participant must sign the Term of Free Consent and Informed (2P1);

TFCI presents to the participant what will happen during the research, and this document must be signed by him(2P5).

The TFCI is a formal document that must be signed by the participant after receiving all the necessary explanations to fully understand the study.^{28,13} This document intends to protect the participant, demonstrating the reliability and responsibility of the researcher with the theme and the participants' well-being.²⁸ Resolution CNS 466/12 enhances the TFCI, II.23- "document that must contain all necessary information, in clear and objective language, easy to understand, for the fullest clarification of the research which the individual proposes to join".¹⁴ The risks of the research must be analyzed by the researcher during its development, considering various factors, such as age, lifestyle, health, gender, among others, in order to select the participants and leading to the maximum benefits and minimal injuries and risks. After presenting the risks, the research must be

questioned and re-evaluated, verifying its viability, and ensuring that foreseen injuries will be avoided. The research should be useful to solve and/or raise social issues, helping the scientific community and the overall community; however, it does not allow an individual risk over the benefit of communities.²⁸

The discussion about the benefits is not limited to the participants, but is related to the entire academic community and society. Thus, the purpose of the research is to benefit, with its results, the largest possible number of people.

◆UR3 Research Ethics Committee (REC)

The purpose of this UR was to identify the knowledge of students from the 1st and 10th semesters about the responsibilities/duties of the REC. One enhances that the students from the 10th semester were broader and reported not only the responsibilities, but also the importance of this Committee, which, in accordance to Resolution 196/96, II.4, "is an interdisciplinary and independent collegiate body, with "public duty", existing in HEIs, in Brazil, where researches involving human beings are conducted, created to defend the interests of the research subjects".⁹

The presented concepts were placed in the following class: Function of the Research Ethics Committee.

◆Function of the Research Ethics Committee

The Research Ethics Committees (REC) were created by Resolution National Health Council (NHC) 196/1996, which, after revision, was replaced by Resolution NHC466/2012.³¹ The REC is the local level that integrates the CEP-CONEP System, which, at federal level, is represented by the National Council of Ethics in Research (CONEP) itself.¹⁰ The system is linked to other CNS organs and manages the Research Ethics National System (SISNEP), in which the studies must be registered for prior evaluation and approval. Recently, the SISNEP was replaced by Brazil Platform.¹⁰

At HEIs, the committees whose functions are not merely notarial, since its role is consultative and educational, must have pluralistic composition: half of its members may be part of the same professional category; the other half may include jurists, philosophers, bioethicists, sociologists, theologians, etc., and, always, a representative of the user community.¹⁰

The diversified composition of REC favors a complete evaluation of all stages of the studies, since the project development until

the final report and publication¹⁰, following all ethical aspects of researches involving human beings.³²

The function of the REC was enhanced in the participants' speeches:

To supervise the studies involving human beings, protecting life (2P3);

To supervise and to favor the development of the research with human beings, avoiding injuries, both to the surveyed public, as the researchers (2P4);

To approve, or not, the research, verifying if it's in accordance to the ethical and scientific norms (2P6).

The research submission to the REC is essential for a detailed evaluation of the study's reasons, since the objectives, the purpose, until the ethical behavior of the researcher in relation to his/her research and the participants, approving it, or not. The statements show that the future physiotherapists understand this:

To authorize and supervise if the researches are in accordance to the ethical norms (1P7);

To verify if the research follows the established ethical norms (1P8).

It's important both prior authorization of studies as supervision of the research become increasingly intense and resolute to ensure the well-being of those involved. One cannot deny that, nowadays, the researches are of great importance for the social, scientific and economic development of a country, and may contribute to social, educational, health and people's living conditions improvement.³¹

Knowing the REC, its composition and activities in the research universe is essential for researchers to develop projects guided by the ethical principles of research. Besides, the REC's action must be effective against the research projects developed within the HEI.

FINAL REMARKS

The divergent knowledge of the concept of ethics was evidenced in both groups, correlating it to terms such as moral, deontology and bioethical principles. Knowing the concept is necessary for an effective adoption of ethical practices, both in the professional context as scientific productions. The researcher must have good ethical basis, for he/she will handle ethical determinants during the project's development, and the participants, assuming direct responsibility for the proceeds of the study.

It was observed that both groups were more convergent about the ethical principles of research with human beings as the bioethical principles, especially the risks and

benefits of the research, and functionality of the REC as a supervisory agent.

In the HEI where the study was conducted, there is an important incentive policy for scientific production, since the 1st semester of the Physiotherapy course, allowing the students to become active agents in their education process, developing and improving the theoretical knowledge acquired in classroom. For the students to get involved with the research, one must previously teach them to know the stages and ethical principles of the research. However, it was noticed that, among the participants from the 1st semester, few mentioned any information about the ethical principles of research with human beings, unlike the students from the 10th semester, who showed increased knowledge about the theme. It is believed that this fact is due to the absence of such discussion during the 1st semester, as the content is presented in the 2nd semester, in the discipline Bioethics and Deontology, according to the curriculum of the HEI.

The results should be thoroughly analyzed by the HEI, as the correlations made by the participants about the theme demonstrated they do not have extensive knowledge about research ethics, exposing the need for adjustments in the curriculum of the Physiotherapy course regarding the discussion of the contents involving ethics.

It is proposed that the training process, which in a larger perspective that must have transverse character and continued, in which the students will be in touch involved in ethical discussions and problematizations, it is not the responsibility of just one discipline, discuss professional and ethical determinants of the profession. Therefore, one suggests the current discipline Bioethics and Deontology to be taught along with other disciplines, transversely, so that the students are able to distinguish and understand the peculiarities around it.

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