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Medical research in humans, non-maleficence and homeopathic self-experimentation

Italo Márcio Batista Astoni Junior¹, Giovano de Castro Iannott²

Abstract

Medical research in humans, non-maleficence and homeopathic self-experimentation

This conceptual article aims to establish connection between medical research in humans, non-maleficence and homeopathic self-experimentation. Medical research in humans, usually performed in the other, has been permeated by expressive abusive practices in relation to participant subjects. It is in this context, therefore, that non-maleficence, the basic ethical principle limiting these violations, emerges. Non-maleficence is an assumption that must guide the decisions on the field of medical research, representing its harmlessness or moderation. In regards to the subject who experiences it, the investigation in humans can also be conducted as self-experimentation, that is, performed in one self. Self-experimentation, which is of great value in different areas of the medical science, is called in homeopathy as homeopathic self-experimentation. Homeopathic self-experimentation has important non-maleficent characteristics, which makes it an ethical, safe, viable, reproducible alternative, consistent for the therapeutic medical research in humans.

Key words: Ethics. Medical research. Non-maleficence. Homeopathic self-experimentation.

Resumo

Este artigo, de natureza conceitual, objetiva estabelecer conexão entre a pesquisa médica em seres humanos, a não maleficência e a auto-experimentação homeopática. A pesquisa médica em seres humanos, geralmente realizada no outro, tem sido permeada de expressivos abusos em relação aos sujeitos participantes. E neste contexto que emerge a não maleficência, princípio ético básico limitante dessas violações. A não maleficência é o pressuposto que deve nortear as decisões no campo da pesquisa médica, representando sua inocuidade ou moderação. No que tange ao sujeito que experimenta, a investigação no ser humano pode ser conduzida, também, como Auto-experimentação, ou seja, como experimentação realizada em si mesmo. A auto-experimentação, de grande valor em diferentes áreas da medicina, é denominada, na homeopatia, como auto-experimentação homeopática. A auto-experimentação homeopática é dotada de importantes características não maledicentes, o que a torna prática ética segura, viável, reproduzível e consistente da pesquisa médica terapêutica em seres humanos.

Palavras-chave: Ética. Pesquisa médica. Não maleficência. Autoexperimentação homeopática.

Resumen

Investigación médica en seres humanos, no-maleficencia y auto-experimentación homeopática

El presente artículo, de naturaleza conceptual, tiene como objetivo presentar conexiones entre la investigación médica en seres humanos, el principio de la no-maleficencia y la auto-experimentación homeopática. La investigación médica en seres humanos, generalmente realizada en el otro, se ha caracterizado a lo largo del tiempo por expresivos abusos en relación a los sujetos participantes. En ese contexto emerge la no-maleficencia, principio ético básico que trata de inhibir esas violaciones. La no-maleficencia es un presupuesto que debe orientar las decisiones en el campo de la investigación médica, representando su inocuidad o su moderación. En cuanto al sujeto que experimenta, la investigación en el ser humano puede ser realizada, asimismo, como auto-experimentación, es decir, como experimentación realizada en si mismo. La auto-experimentación, de gran valor en diferentes ramos de la medicina, es denominada, en la homeopatía, auto-experimentación homeopática. La auto-experimentación homeopática presenta importantes características de no-maleficencia. Ese hecho hace con que la auto-experimentación homeopática sea una elección ética segura, viable, reproducible y consistente para la investigación médica terapéutica en seres humanos.

Palabras-clave: Ética. Investigación médica. No-maleficencia. Auto-experimentación homeopática.

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Human Research in Brazil is known as a research that directly or indirectly involves human beings, fully or partially, including the administration of information or materials¹. Research subject in Brazil is the voluntary participant of it, individually or collectively, with no form of remuneration allowed¹.

Since past times and not much recent, medical research in human beings, usually performed in the other one, has been covered of significant abuses regarding its participants². Often painful and destructive, such abuses are almost always originated by disrespect and relativity to man values by the man himself, even constituting crimes against human kind. As an example, the events occurred in the Nazi Germany³.

The overreactions commanded by Hitler originating the Nuremberg Code, the first guiding mark for biomedical research, have been deeply shocking³. According to Annas⁴, healthy people were infected by malaria at Dachau concentration camp, in order to test the therapeutic efficacy of several drugs. Many others have died due to the surplus of these substances. Freezing experiments were conducted, in which citizens were forced to remain naked and exposed to cold or in cold water tanks for several hours. Humans (creatures) were placed in chambers in which pressure was modified so that atmospheric conditions at higher altitudes could be pretended. However, due to the high risk of physical and mental damage, as well as associated death risks, those potential victims might have firstly had their health compromised. In studies meant to make sea water drinkable, some human guinea pigs were expected to die after such horrible suffering and that others would at least be affected by delirium and convulsions.

As a reaction to these violations, appearance, rescue and the application of several conceptions that could upgrade the human being have become indispensable for the world and the experimental science, from which we highlight:

a) The Kantian view of the person as a goal in himself, promoting respect for oneself and among the others, instead of an instrument⁵;

b) The concept of ontological or intrinsic dignity, the base for development and preservation of human rights³;

c) The need of protecting the individual integrity and the participant in the scientific investigation³, including those considered vulnerable;

d) The regulation of such protection as a limiter of the investigator autonomy, through international agreed documents specific in each country¹;

e) The requirement of ethical reflection regarding achievement and utilization of results from medical trials¹;

f) The search for basic ethical principles that might be the basis for such trials and reflections⁶.

By aiming and embracing the performance of all these formulations, it is in this context, therefore, that the basic ethical principle of non-maleficence emerges and is inserted.

The Non-maleficence Principle

The non-maleficence principle is a global duty equally required of all people in their relationships⁷. It is an assumption that ethically guides the decision-making process and conflict resolutions in the fields of health, medicine and medical research in human beings, notably representing its safety or moderation. It is associated to the Latin maxim *primum non nocere*, which means "First, do no harm", present in the Hippocratic Oath⁸.

Its most common approach is usually done with the beneficence principle, because they are similar to each other⁸ and mutually related⁹. Some philosophers combine them in the same concept, by hierarchically structuring them and giving primacy to non-maleficence⁸. Others, in turn, such as Beauchamp and Childress⁸ separated them believing that if they are united in the same idea, significant differences will be obscured, therefore leveling them in the same hierarchic plan. Beauchamp and Childress⁸, the creators of principlism classify them as:

a) *Non-maleficence*: We shall not inflict harm or damage;

b) *Beneficence*: we shall prevent harms or damages to be caused, solve them and promote goodness.

According to these authors⁸, at a first moment, non-maleficence is independently formed as a negative imperative, expressing the obligation of not causing intentional harm or damage. In relation to other basic ethical precepts, such as beneficence, its previous leveling determines that its choice as the basis for solving moral conflicts will depend very much on the context.

Damage is described by Ferreira¹⁰ as: *harm, moral or material loss, effective, concrete, proven loss; possible, imminent loss*. By Constantino¹¹ as: *harm that can be extended to the physical dimension; result of one's action or omission, or done by others that might bring negative consequences to physical integrity, health or well-being*.

In a second moment, non-maleficence also consists of the non-intentional kind, predicted or unpredicted involuntary damage, that is, it refers to risk or possibility of damage, as well as its magnitude, prevention and repairing. The non-intentional and unpredicted loss has slippery slope or inclined plane as a plausible cause that occurs when an action, apparently innocent and regarded as isolated, leads to a status of increasing harms, often unacceptable¹². It is similar to a slippery slope in which lots of exceptions may create a permissiveness picture, with progressive erosion and subtle deletion of important morality limits⁸.

Perhaps the damage risk on human medical investigation might never be eliminated, being therefore unavoidable to protect people that participate of it. The amount ministered of this protection is risk-benefit ratio, in which risks must be reduced to those essential for achieving the pursued goals while benefits are targets of maximization⁶. In order to be justified, great risks require significant targets in the same proportion⁸. Risks, being reasonable and therefore acceptable, need to be less than the sum of all benefits⁶.

According to Constantino¹¹, risk chances suppose responsibility over the occurrence of damage and their anticipation is, at least, considered negligence⁸.

The Non-maleficence Principle and Its Regulation

The non-maleficence principle will be shown as follows in several points of the main national and international documents regarding medical research in human beings, as well as its presence in other important ethical regulations:

*Nuremberg Code*¹³

The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury;

The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment;

Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death;

The researcher must be prepared to terminate the experiment at any stage, if he has probably cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject

*Helsinki Declaration VI*¹⁴

Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others;

Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits (...);

Clinical research involving humans should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject;

The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to (...) minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

International Ethical Guidelines for Biomedical Research Involving Human Subjects¹⁵

- Guideline 2 - Essential information for prospective research subjects:

Any foreseeable risks, pain or discomfort, or inconvenience to the individual associated with participation in the research;

The subject or the subject's family or dependants will be compensated for disability or death resulting from such injury.

- Guideline 10 - Equitable distribution of burdens and benefits:

Groups or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed.

- Guideline 13 - Right of injured subjects:

Research subjects who suffer injury as a result of their participation are entitled to financial assistance or other to compensate them equitably for any resultant impairment, disability or handicap. In the case of death, their dependants are entitled to compensation. Subjects must not be asked to waive the right to compensation.

Brazilian Regulatory Guidelines and Standards for Research Involving Humans²

- Terms and definitions:

Leading researcher – person in charge of (...) integrity and well-being of the research subject;

Research risk – possibility of damages to the

physical, psychic, moral, intellectual, social, cultural or spiritual dimensions of the human being, at any stage of the research or as a result of it;

Damage associated or resulting from the research – immediate or late exacerbation to the individual or the community, with proven direct or indirect causal nexus, as a result of scientific study.

- Ethical Aspects

The ethical nature of the research implies consideration between risks and benefits, either real, potential, individual or collective, committing with the maximum of benefits and minimum of damages and risks, as well the assurance that predictable damages will be avoided.

- Risks and benefits:

It is assumed that all research involving human beings embraces risks;

The leading researcher is obliged to immediately cease research when perceiving any risk or damage to the subject's health that may result from it, which is not in the consent form;

The research ethics committee of the institution shall be informed regarding all side effects or significant facts that may change the normal course of the trial;

The research subjects that might suffer any kind of injury resulting from their participation, whether provided or not in the consent form, besides the right of integral assistance, shall be granted with indemnity.

Universal Declaration on Bioethics and Human Rights¹⁶

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

International Code of Medical Ethics¹⁷

A physician shall always bear in mind the obligation of preserving human life.

Code of Medical Ethics¹⁸

The physician shall maintain the utmost respect for the human being and always act for his benefit. Never use his knowledge for causing physical or moral injuries, for the human being extermination or for allowing and covering any attempts against his dignity and integrity;

To the physician it is forbidden to cause any injuries to the patient, by direct action or omission, classified as lack of skill, imprudence or negligence.

In spite of achieving the regulation of the non-maleficence principle, abuses in human medical trials still keep happening over time¹⁹, allowing the re-emergence of self-experimentation, especially homeopathy, that essentially consists of several non-malevolent properties.

The Principle of Non-Maleficence and Homeopathic Self-Experimentation

Relying on the concept of research subject, research in humans may be also conducted as self-experimentation, that is, as an experiment done in oneself.

Self-experimentation is the procedure in which the experimenter seeks knowing through one's senses. Clarifying facts and guiding behavior, in various situations it has been of great value for different fields of medicine, presenting a long and well-documented history. In a pioneer way, the Nuremberg Code refers to it on item 5: *No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also act as subjects*¹³. It is guided by the Golden Rule that recommends that one should treat others as one would like others to treat oneself, or by an ethical conscience that opposes this other one being experimented or exposed.

In turn, homeopathic self-experimentation is the prove of medicines, aiming direct knowledge and the medical use of its healing properties,

which the medical researcher is voluntarily subject to, making his own feelings and psyche available²⁰. It is the method that reveals the way how medical substances act, by interrogating the source itself and the experimental model in which all developments of homeopathic medicine is based onto.

Homeopathic self-experimentation, not only in relation to the other one but also to the subject that experiences it, consists of non-malevolent features, having a proper risk-benefit ratio.

Regarding the other one, by excluding its mediation and shifting the focus of the experimentation for the testing physician, it protects and prevents harms to be intentionally or involuntarily to him, since he is not the one who tests it anymore. It does not use sick subject regarded as vulnerable or sufferers, once it respects them and protects their integrity, but rather medical researches assessed as healthy. In clinical practice and through the knowledge from the healing virtues of the tested drug, as well as its resulting memorization, the testing physician is allowed to recognize his own similarity in the patient history. It is therefore an essential criterion that guides prescriptions and therapeutics success. By resembling his patient, his own feelings and psyche, the Homeopath testing makes Homeopathy a similarity medicine of dialogue, consent and then of communion, nearness and inclusion.

Regarding the subject that experiences it, it produces symptoms or slight and temporary effects. It happens due to the way the tested substance is prepared (called *dynamics*), as well as the minimization of the used dose, usually unique, ultra-diluted and managed through different ways. Besides, according to Hahnemann²¹, it enables pure, precise and faithful knowledge regarding the symptoms triggered by the tested drug, resulting from the sensibility of the testing physician. It reduces the chance of errors, even in an involuntary way, through the experience of the other in case this one is experiencing it. It also provides greater capability of observation,

self-knowledge and conscience enlargement to the homeopath subject, favorably reverberating and optimizing his medical ability, as well as promoting his own health²¹.

Final considerations

Abuses in medical experimentation, that is, treating the human being as a *guinea pig* and its inherent risk to the species survival must be cautiously avoided, guiding the behavior of every medical research. The human being is not interested in becoming a mere object of the scientific research that he created and developed on his own.

By considering its non-maleficence potential and the risk-benefit ratio, the homeopathic self-experimentation is a safe, viable, reproducible and consistent practice of therapeutic medical

research in human beings. According to Hahnemann²¹, it is, therefore, an experimental process of excellence in order to know the medical inputs destined to treat natural diseases. To experimentally provide several substances in slight doses is a safe and natural path for faithfully verifying the peculiar effects of drugs regarding the health status of man.

Homeopathic self-experimentation, when medically performing similarity as an expression of non-maleficence, is classified as an act of love for others and it may be extended over the whole human kind²².

Finally, it is necessary that more studies about ethics and self-experimentation be developed in the field of homeopathy, aiming to disseminate it and taking better advantage of it.

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Authors' participation in this Article

- Italo Márcio has fully written the article and Giovano Iannotti has contributed with guidance, review and important suggestions.

