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The use of control group in research design: the ethical challenge in the population with intellectual and developmental disabilities

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ABSTRACT

Ethics studies moral values and defines good and bad conduct in research and researchers. In research with human beings, it plays a crucial role in imposing limits, reducing abuses, and providing fair lines of research. The use of control groups in this type of research has been addressed and seems to be an effective method to assess the effects of an intervention, but it has raised doubts about the ethical challenges it involves. Therefore, this narrative review aims to address the ethical challenges in the use of control groups in research projects. In the analysed studies on populations with intellectual and developmental disabilities (IDD), it was found that most researchers favoured the use of control groups, which, during the research period, did not engage in any activity other than the usual activities in their daily lives. However, they should ensure that the control group has the opportunity to perform an intervention equal to the one performed by the experimental group after the end of the research. In addition, it was possible to verify that, for the most part, the authors ensure the follow-up of ethical standards in studies with human subjects.
KEYWORDS: control group; experimental group; ethical challenges; intellectual and developmental disabilities; research design.

INTRODUCTION

Over the years, much has been studied regarding ethical issues. The term ethics, which comes from the Greek Plato and Aristotle, refers to the habitual way of behaviour and defines good or bad conduct (Shephard, 2002). It studies moral values, morality being the right motives and actions of a person (Lumpkin, 2016). In the area of research involving human beings, this is an extremely important topic that assists researchers in pursuing lines of research and intervention that are appropriate and equitable among all. However, this type of research raises ethical issues related to how the people participating in the studies should be treated by researchers (Oliver, 2010).

In this sense, any research involving the participation of human beings should be submitted to an institutional ethical board in order to achieve the ideal balance between the rights and needs of potential participants, society and researchers (Kent, 1997). It is essential that ethics committees ensure compliance with formal codes of ethics, such as the Declaration of Helsinki, but also do not neglect to review the proposed research against general ethical principles (Shephard, 2002).

The Declaration of Helsinki, created by the World Medical Assembly in 1964, is considered the most important international document addressing ethical procedures in human research (World Medical Association, 1996). This document argues that the purpose of human research should always be to improve the knowledge about the disease and its treatment (World Medical Association, 1996). In order to guarantee good practices in human research, the Declaration of Helsinki includes standards which aim to guide researchers in the preparation and application of their studies (World Medical Association, 1996). Thus, although all the rules are essential to ensure the ethical compliance of research, it is important to emphasise the need for a

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careful and meticulous assessment of the possible risks in comparison to the probable benefits, taking into account that the interests of the subject should always prevail over the interests of science and society. Also noteworthy is the rule that addresses the privacy and impact of the study on the physical and mental health of those involved, as well as the rules concerning informed consent, the possibility of abandoning the study at any time, and the recognition of the equality of all human beings (World Medical Association, 1996).

Regarding research with humans (with or without disabilities), three fundamental ethical principles should apply: 1. respect for persons, including their autonomy and right to self-determination; 2. beneficence for participants and the community by maximising benefits and minimising risks; and 3. justice, both legally and morally, in the treatment of those involved in research and in the treatment of the communities to which the participants belong (Council for International Organizations of Medical Sciences, 2002).

In research involving the participation of human beings, control and experimental groups are often used. The control group allows researchers to investigate and analyse the influence of a variable, which is an essential part of scientific research (Pithon, 2013). However, the use of control groups is not consensual, although this type of methodology proves to be useful in many investigations, since using an exquisite control group, the possible significant improvements acquired during or after the intervention, by the experimental group, are more likely to be attributed to the intervention, strengthening the credibility of the results obtained (Kinser & Robins, 2013). In this way, the use of the control group helps researchers differentiate the results obtained in the applied intervention from the results related to variables unrelated to the research (Kinser & Robins, 2013).

However, it is necessary to understand that in research with human beings, the well-being of the participants takes priority over any other interests and, therefore, essential ethical issues must be taken into account in the planning and application of the research. Participants in research involving the use of control groups should have access to all the necessary care that they already enjoy since an untreated control group is unethical when conducting research in clinical populations (Kinser & Robins, 2013). Furthermore, all participants should be fully informed about the objectives, methodological processes and purposes of the studies (Annoni, 2018; Sarker, 2014). The studies must not be harmful to the participants, and the groups should be randomised as everyone has the right to benefit from a presumably better service (Annoni, 2018; Conner, 1980).

Thus, the aim of this narrative review is to analyse what has been established on the topic and address the ethical challenges related to it.

MAIN FINDINGS

Control group

Regarding the control groups, it should be taken into account that they must necessarily be composed of individuals with the same characteristics as the individuals belonging to the experimental group. The control group allows researchers to investigate and analyse the influence of a variable, which is an essential part of scientific research (Pithon, 2013).

According to Street and Luoma (2002), there are fundamental reasons for including a control group in a study involving intervention. Studies comprising control and experimental groups have the possibility of analysing in a detailed way the effects of one or more variables on the participants. In addition, the use of these groups allows researchers to understand if the results obtained are not caused by the patient's expectations or beliefs. If the main variables unrelated to the research are discarded, the result will be more reliable (Street & Luoma, 2002). Also, Kinser and Robins (2013) believe that control groups are necessary to understand, in a clear way, if the results are exclusively or largely due to the applied variable or if they are related to external factors. If an individual belonging to the experimental group shows significant improvements during or after the end of an intervention and a control group maintains the same results as the baseline, it is possible that the improvements are attributed to the intervention, thus reinforcing the results obtained by the researcher. In this way, it is essential that the design of a control group is as exact as that of an experimental group (Kinser & Robins, 2013).

In non-pharmacological research, where "placebo" control groups are not used, the most common types of control groups are the ones in which usual care is maintained, that is, only the care that the individual is used to and/or needs is maintained; the control group which will benefit from the intervention, that is, the one which continues to receive the usual care which was used until then and, after the end of the research, will have the opportunity to receive the same intervention as the experimental group. Finally, the active control group, in which individuals receive some type of intervention during the study, allows for keeping their expectations and attention under control (Lindquist et al., 2007; Street & Luoma, 2002).

Ethical challenges associated with the use of control groups

Before the initiation of any experimental intervention involving the participation of human subjects, it is essential that all ethical issues are considered (Kent, 1997; Oliver, 2010; World Medical Association, 1996).

In any intervention, be it pharmacological, behavioural, motor or cognitive, the researcher should seek a favourable balance between the benefits and harm that may eventually arise from the outcome of the research (Shephard, 2002). That said, the researcher should conduct the research according to the appropriate risk management, by qualified researchers and technical support staff, having all the necessary care, in an appropriate environment in order to protect the privacy of those involved and safeguard any possible situation (Harriss & Atkinson, 2009; World Medical Association, 1996).

According to the Declaration of Helsinki (World Medical Association, 1996), all research participants should receive the best possible response to a problem, and it is only acceptable that this does not happen when there are no proven interventions and when patients receive a less effective treatment than the best proven one are not subject to avoidable risks for not receiving the best-proven treatment, and when the methodological reasons are scientifically consistent enough to prove that the use of an untreated control is necessary to determine the effectiveness of the variable under study (World Medical Association, 1996). Thus, a no-treatment control group is unethical when conducting research with clinical populations because, from the outset, there is a known effective therapy or minimum level of care expected, depending on the severity of the clinical condition (Kinser & Robins, 2013).

Millum and Grady (2013) state that a placebo control is necessary to demonstrate efficacy, but sometimes, the risks of forgoing treatment make it unethical to ask participants to accept them since the risks of forgoing or delaying treatment should not be negligible.

In the case of sport or exercise, given their proven health benefits, asking recipients belonging to the control group not to perform any exercise when they were already doing so or doing so to a lesser extent is a request contrary to that set out in the Declaration of Helsinki (Oliver, 2010).

Any research team should take into account several factors that call into question the ethics of using control groups in research. Thus, it is essential that the research has a valid scientific basis (Miller, 2008) and that the individuals belonging to the control group are not exposed to excessive risks, such as foregoing a medication/therapy that has proven to be effective (Annoni, 2018; Sarker, 2014), that there is no "therapeutic equivocation", that is, that all participants are well informed about the research objectives, methodologies and procedures (Annoni, 2018; Sarker, 2014), this implies that all participants should sign the informed consent but above all, understand what is intended by the research and be entitled to an equal opportunity (Sarker, 2014; World Medical Association, 1996). Informed consent should contain the research objectives, methodology, anticipated benefits and potential risks, right to refuse participation or withdraw from participation without any reprisal, conflicts of interest, funding sources and institutional affiliations (Harriss & Atkinson, 2009). In the case of research involving children or populations who cannot autonomously give informed consent, researchers should seek the consent of the responsible person and the assent of the participant. It should be noted that any research involving people with physical disabilities and/or IDD can only be conducted if the individual's disability, which does not allow him/her to sign informed consent, is a characteristic of the population being researched (Harriss & Atkinson, 2009).

When control and experimental groups are used in research, it becomes possible through the control group to reduce the various biasing factors that may influence the research findings (Lindquist et al., 2007; Sarker, 2014). Furthermore, when these are designed randomly, the possibility of bias by the researcher while selecting participants for different groups is minimised, and consequently, the effects of confounding variables are minimised.

However, control and experimental groups should only be designed when there is sufficient uncertainty about whether the new treatment is better than the existing one or not, since on the off chance that one group of study participants receives better treatment than the other, several ethical issues arise (Sarker, 2014).

DISCUSSION

The present study sought to analyse the established ethical challenges regarding the use of control groups in experimental studies with human beings, given their methodological relevance, with particular emphasis on studies carried out with people with IDD within the scope of physical activity and physical exercise.

As has been mentioned, in the case of non-pharmacological intervention, there are distinct control groups. However, those who do not receive any type of intervention during or after the study seem to be the least ethical since all individuals should be entitled to the same opportunities (Sarker, 2014). In this way, if the intervention programme is applied

after the end of the study or another type of beneficial intervention is promoted for the control group, provided that it is different from the one used for the experimental group, all participants in the study will benefit.

In this sense, it becomes relevant to understand how researchers have addressed this and other ethical issues in the development of their studies in different contexts. Concerning sports sciences, and particularly in studies with disabled people, this fact becomes particularly relevant, given the need for more studies (preferably RCT) with this population (Jacinto et al.,

2021). Specifically, regarding people with IDD, since this is a population subgroup that, due to their intellectual and adaptive limitations (American Psychiatric Association, 2013), cannot always make themselves heard, being necessary faithful compliance with ethical standards so that the rights of individuals are fulfilled, and their opinion and wishes are taken into consideration.

In a study conducted by Álvarez and collaborators (Gómez et al., 2018), in which the objective was to analyse the effect of a virtual reality-based intervention on the motor development and postural control of children with Down Syndrome, the authors conducted a quasi-experimental research. The participants were randomly divided into an experimental group and a control group. The authors informed the guardians and participants about the procedures, aims, objectives and methods of the study, and the informed consent was signed by them, as this is a group of children. The research project was approved by the bioethics committee of the Adventist University of Chile (Gómez et al., 2018). In this way, the authors ensured that all the procedures followed were in accordance with the ethical standards of the World Medical Association and the Declaration of Helsinki. Throughout the research, the control group did not perform the intervention, maintaining only the usual activities of daily living, including therapies. The results obtained by the authors after the intervention were positive. However, there is no record in the article about the possibility of the programme being applied to the control group after the end of the investigation. This raises some ethical questions: Once the positive effects of the intervention programme have been verified, should it not be ethically applied to the control group? With the methodology used in this study, the control group did not benefit from the research at any time.

In contrast, in the randomised controlled trial (RCT) conducted by Vreuls et al. (2022), with the aim of understanding the effects of indoor climbing on the employability and professional self-efficacy of people with IDD who have lower levels of social skills, the authors ensured that the control group would have the opportunity to enjoy indoor climbing sessions after the end of the intervention programme, for the same period of time and under the same conditions as the experimental group. In the present study, the participants were randomly distributed using a randomisation programme into three groups: an experimental group and two control groups. The experimental group had indoor climbing sessions, while the first control group had a sports programme, and the second control group had no additional programmes other than those which were already part of their daily activities. By providing the opportunity for control group participants to enjoy the indoor climbing sessions after the study had ended, Vreuls et al. (2022) considered that the waiting time for participants would not be excessive and the risk of dropout would be lower. Similarly to the study discussed above, Mitchell et al. (2013) also conducted an RCT with the aim of understanding the effectiveness of a walking-based intervention designed for adults with IDD, in which the control group did not take advantage of any activity other than the usual ones. However, as soon as the intervention programme with the experimental group was completed, the control group would be given the opportunity to enjoy the same intervention, thus ensuring that all participants were engaged in a programme that proved beneficial to the participants. Also, in the RCT conducted by Wang et al. (2022), where the authors aimed to assess the effects of a physical activity programme on obesity, physical fitness and blood pressure in adolescents with IDD, two groups were made. The experimental group benefited from physical activity sessions, while the control group did not benefit from any activity during the study, keeping only their usual tasks. Although it did not enjoy any activity other than the usual ones during the investigation, it received the opportunity to perform the same physical activity programme as the experimental group once the investigation ended (Wang et al., 2022). However, knowing that regular physical exercise decreases the risk of the onset of metabolic and cardiovascular diseases (Ruegsegger & Booth, 2018; Yum et al., 2020), is it ethical to have a control group in the protocol under study?

In the study conducted by Yum et al. (2020), with the purpose of understanding the effects of music therapy on social skills in children with Autism Spectrum Disorder (ASD) and DID, the authors conducted a RCT with two intervention groups. The experimental group, who received weekly music therapy sessions and the control group who received sessions without music, but focused on social skills. In this way, the authors ensured that all participants enjoyed a beneficial therapy, with none of the groups being left without intervention. In addition, all participants gave oral consent to participate,

and a signed consent form was obtained from their guardians. The authors mention that all procedures were reviewed and approved by the Human Research Ethics Committee of the Hong Kong University of Education in accordance with the Helsinki Declaration (Yum et al., 2020), thus ensuring the ethical and moral principles of research with humans.

In quasi-experimental studies and RCTs conducted with people with IDD, it was possible to verify that in most of the cases mentioned (Mitchell et al., 2013; Vreuls et al., 2022; Wang et al., 2022; Yum et al., 2020), the control groups have the opportunity to use the same intervention after the end of the study or use a different intervention from the one the experimental group is receiving during the study. Keeping a control group active or waiting for the end of the intervention to receive the same programme allows them to keep their expectations and attention under control (Lindquist et al., 2007; Street & Luoma, 2002). Despite the existence of numerous ethical issues regarding the use of these groups, in the analysed studies, most researchers favour good ethical conduct, trying to comply with their moral and ethical duties, favouring equal opportunities and transparency before, during and after the study.

As mentioned, the use of control groups in human research has proved to be useful to differentiate the results obtained and ensure, as far as possible, that they are due to the intervention programme applied and not to factors outside the research (Kinser & Robins, 2013; Street & Luoma, 2002). In the case of people with IDD, it was possible to verify that interventions within the scope of physical activity (Gómez et al., 2018; Mitchell et al., 2013; Wang et al., 2022), physical exercise (Vreuls et al., 2022) and promotion of social skills (Yum et al., 2020) are beneficial to promote the quality of life of this population. Thus, it seems pertinent to continue research in this area in order to promote more reliable information that benefits interventions in this area. To this end, the use of control groups seems to be a methodologically more robust procedure; however, it is essential that researchers take into account the guidelines of the Declaration of Helsinki (World Medical Association, 1996) and follow all the procedures required by the ethics committees so that the studies are valid and provide benefits to those involved.

With this study, it was possible to conclude that promoting activities to the control group during the research seems to be a viable option (Vreuls et al., 2022; Yum et al., 2020). Nevertheless, the chance to enjoy the same intervention programme as the experimental group should be offered to the control group if it is found to bring benefits to the health, well-being and quality of life of the study population, thus ensuring equal opportunities (Sarker, 2014; World Medical Association, 1996).

Particularly regarding people with IDD, international ethical guidelines (Dalton & McVilly, 2004) recommend (1) before initiating a research project, researchers should ensure that, wherever possible, benefits to participants as a result of their involvement in the project can later be made available to any participants who were involved in a control or alternative treatment group (principle of justice) and (2) the selection of a control or comparison group be such that any potential disadvantage to persons assigned to those groups is minimised, and that mechanisms are in place to ensure that these persons have access to any benefits later established as a result of the study.

As future recommendations, we alert researchers to the need to consider all ethical issues inherent to research. It is essential to know the population with whom they will work and, given the characteristics of people with IDD, if necessary, to have the ability to adapt the information on the methods, procedures and objectives to make sure that those involved understand all the steps of the research and that their consent is given based on their willingness to participate in the study and not by external influence. Another key issue that should be taken into consideration when conducting research studies with this population is the random allocation of volunteers. People with IDD have different characteristics, making them a very heterogeneous population group. Thus, it is essential that researchers take this into account when building the control and experimental groups since the control groups must necessarily be composed of individuals with the same characteristics as the individuals belonging to the experimental group (Pithon, 2013).

While selecting the study sample (both experimental and control group) in exercise science research (Navalta et al., 2020), researchers must guarantee that he/she does not discriminate against anyone based on any characteristic, including race, colour, religious creed, ancestry, national origin, physical or mental disability, medical condition, marital status, sex, age, gender identity, sexual orientation, veteran status, or citizenship status.

The elaboration of RCTs or quasi-experimental studies seems to be an added value for scientific research, as they allow assessing the effects of an intervention programme in a detailed way, reducing the main extraneous variables. When control groups are used, it is fundamental to establish a methodology that privileges all the individuals who voluntarily accept to participate in the investigation. In this way, using a control group that can benefit from a programme that enhances their skills during the investigation, but which is different from what is being investigated seems more appropriate than a control group that does not benefit from

any intervention during the investigation. Nevertheless, and understanding that there may not always be the means to do so, it is essential to guarantee the promotion of the intervention programme studied to the control group if it is found to bring benefits to the individuals.

CONCLUSIONS

When studies with control and experimental groups follow all the ethical indications and requirements, taking into consideration adequate risk management between benefits and harms, valid scientific basis, clarification about the study, signed informed consent and equal opportunities, they become an interesting answer in scientific research. However, taking into consideration the issue of equal opportunities, it seems essential that, before the research begins, researchers assess the possibilities of giving volunteers from the control group the opportunity to at least perform the same intervention as the experimental group after the research is finished. Indeed, everyone deserves to enjoy therapy that has been proven effective in promoting quality of life, well-being, and health.

In the case of studies involving people with IDD, there are aspects to be taken into account in order to ensure that all ethical procedures are effectively and validly ensured. In the case of informed consent, although it must be signed by the guardian and it is necessary to comply with this rule, there is an ethical obligation to ensure that the participants understand the procedures of the study in which they will participate, making it essential to adapt the language and use methodologies that facilitate their understanding. Furthermore, it is essential to have a thorough knowledge of the population belonging to the sample, and it is not considered ethical to hide details of the diagnosis in order to benefit the investigation. All information must be properly documented in the studies so that there are no doubts as to the veracity of the facts.

In summary, it seems that researchers have followed the main ethical standards, trying to mitigate any inequality that may arise. There are still some ethical challenges in the design and application of studies of this type, particularly in the population with IDD.

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