

Learning from the past: Old and new ethical responsibilities in health research



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Abstract

Purpose/Background: This article critically examines the ethical issues in a longitudinal experimental study on the impact of nutrition and stimulation on early childhood development in Jamaica, originally conducted in 1991 and revisited in several cases, the last in 2022. It argues that the research involved ethically questionable practices from the outset including children in extreme poverty without guaranteeing minimal interventions and applying a double ethical standard.

Methodology/Approach: Using international bioethical standards, the authors assess the study's design and ethical shortcomings from the vantage point of the Declaration of Helsinki and CIOMS guidelines.

Results/Findings: They identified several ethically questionable practices including, the non-provision of food or stimulation, or both, children in the control groups, lack of documented ethical review, double ethical standards and new risks in the 2022 follow-up, such as, participant re-identification, the potential of stigmatization and undue inducement caused by financial compensation.

Discussion/Conclusions/Contributions: The authors urge for ethical accountability when current research builds on ethically compromised studies. They emphasize that researchers, ethics committees, and journal editors must critically assess the ethical background and challenges of cited studies, assuming shared responsibilities upholding universal ethical principles in research involving vulnerable populations.

Key words: Child development, CIOMS, Ethics committees, Exploitation, Double standards, Helsinki declaration, Poverty, Research ethics, Stunted growth, Vulnerability.



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Resumen

Aprender del pasado: viejas y nuevas responsabilidades en la investigación en salud

Propósito/Contexto. Este artículo revisa críticamente los aspectos éticos de un estudio longitudinal experimental sobre el impacto de la nutrición y estimulación en el desarrollo infantil, realizado en Jamaica, iniciado en 1991 y actualizado en varias ocasiones, la última, en 2022. Señala que, desde su origen, el estudio involucró prácticas éticamente cuestionables al incluir niños en pobreza extrema sin garantizar intervenciones mínimas y aplicando un doble estándar ético.

Metodología/Enfoque. A través de un análisis documental desde la bioética internacional, los autores contrastan el diseño y la ejecución del estudio con principios consagrados en la Declaración de Helsinki y las directrices CIOMS.

Resultados/Hallazgos. Se identifican múltiples prácticas éticamente cuestionables que incluyeron la no provisión de alimentos o estimulación, o ambos, a los niños en los grupos control, ausencia de revisión ética documentada, doble estándar ético y riesgos añadidos en el seguimiento de 2022, incluyendo re-identificación de participantes, potencial estigmatización y posible inducción indebida mediante compensaciones económicas.

Discusión/Conclusiones/Contribuciones. El artículo hace un llamado a no ignorar las faltas éticas del pasado, especialmente cuando investigaciones actuales se construyen sobre ellas. Sostiene que investigadores, comités de ética y editores deben asumir responsabilidades compartidas y promover una revisión crítica sobre los desafíos éticos de los estudios utilizados como base en nuevas publicaciones.

Palabras clave: desarrollo infantil, CIOMS, comités de ética, Declaración de Helsinki, desnutrición, ética en investigación, explotación, doble estándar, maldesarrollo, pobreza, vulnerabilidad.

Aprendendo com o passado: velhas e novas responsabilidades na pesquisa em saúde

Objetivo/Contexto. Este artigo analisa criticamente os aspectos éticos de um estudo longitudinal experimental sobre o impacto da nutrição e da estimulação no desenvolvimento infantil, realizado na Jamaica, iniciado em 1991 e atualizado várias vezes, a última delas em 2022. Ele aponta que, desde sua origem, o estudo envolveu práticas eticamente questionáveis ao incluir crianças em extrema pobreza sem garantir intervenções mínimas e aplicando um duplo padrão ético.

Metodologia/Abordagem. Por meio de uma análise documental a partir da bioética internacional, os autores contrastam o desenho e a execução do estudo com os princípios consagrados na Declaração de Helsinque e nas diretrizes do CIOMS.

Resultados/Conclusões. Foram identificadas várias práticas eticamente questionáveis, incluindo a não provisão de alimentos ou estímulos, ou ambos, às crianças dos grupos de controle, a ausência de revisão ética documentada, o duplo padrão ético e os riscos adicionais no acompanhamento de 2022, incluindo a reidentificação dos participantes, a potencial estigmatização e a possível indução indevida por meio de compensações econômicas.

Discussão/Conclusões/Contribuições. O artigo apela para que não se ignorem as falhas éticas do passado, especialmente quando pesquisas atuais se baseiam nelas. Ele sustenta que pesquisadores, comitês de ética e editores devem assumir responsabilidades compartilhadas e promover uma revisão crítica sobre os desafios éticos dos estudos usados como base em novas publicações.

Palavras-chave: desenvolvimento infantil, CIOMS, comitês de ética, Declaração de Helsinque, desnutrição, ética na pesquisa, exploração, duplo padrão, mau desenvolvimento, pobreza, vulnerabilidade.

Introduction

This report relates to the paper “Cognitive, psychosocial, and behavior gains at age 31 years from the Jamaica early childhood stimulation trial” by Walker *et al.* (2022), which was published in the *Journal of Child Psychology and Psychiatry*. We believe that this publication raises several serious ethical challenges that have not been addressed by the authors, the institutional review board (IRB) that reviewed the research, or the editorial board of the journal. The paper investigates the “evidence on adults of benefits from early childhood interventions in low and middle-income countries”, based on a previous study that was conducted with the same population in 1991, when they were children.

Approach

First, we argue that the original study published in 1991, *The Jamaican supplementation and stimulation study* (Grantham-McGregor *et al.* 1991), raises fundamental ethical challenges that, since the 1960s, have been addressed in numerous publications (Becher 1966) and acknowledged as ethically questionable in international normative documents, most notably in the Declaration of Helsinki (WMA 1964, 1975, 1983 & 1989) and in CIOMS International ethical guidelines for biomedical research (Council for International Organizations of Medical Sciences 1982). These publications and research ethics guidelines paid particular attention even at that time, to research with poor and vulnerable communities in the Global South.

The first point we want to highlight is the design of the initial trial, which served as the basis for several subsequent publications, including the paper published in the *Journal of Child Psychology and Psychiatry* in 2022. Inclusion required infants (aged 9 months to two years) to exhibit signs of “stunted growth”. This is a condition caused by malnutrition, undernutrition, or fetal undernutrition (due to mother malnutrition), something that has been well documented since the 1930s (League of Nations 1935; Food and Agriculture Organization 1950, 1957).

Furthermore, since 1975, FAO, WHO, and other organizations have conducted multiple studies in Jamaica and other Latin American and Caribbean countries, documenting how food deprivation and lack of stimulation affect both the physical and psychological development of children (Périssé 1981; Food and Agriculture Organization, and World Health Organization 1973; Food and Agriculture Organization *et al.* 1985; Bengoa 1970 & 1979). This indicates that all the children included in the original study were living under such conditions –not only in extreme poverty, but also suffering from malnutrition as a direct consequence of that poverty. Nevertheless, the researchers provided nutritional support to only two of the study’s four groups, and stimulation to only two groups as well, leaving one group without any intervention. Over a period of two years, the researchers observed how malnutrition and deprivation of various forms of stimulation affected the children.

Participants who did not receive nutritional supplementation or stimulation derived no benefit –and more seriously, the study was arguably harmful for them. After just one year, the researchers found clear differences between the groups, which should have raised the ethical obligation to suspend the study. In intervention studies, the concept of *clinical equipoise* no longer exists when the researchers became aware of the marked difference between groups (Cook & Sheets 2011). Yet the study continued, with researchers continuing to observe disparities in physical and mental development and, notably –remarkably, without providing food to the deprived groups in second year.

In their 1991 study, the authors stated that “there is little unequivocal evidence that nutritional supplementation of undernourished children has a beneficial effect on their mental development”. Given the substantial body of research already available at the time, clearly demonstrating such benefits, the justification for the study is questionable from the outset. Furthermore, although the authors state that “the main interest, therefore, centered on the possible interaction of stimulation with supplementation”, they simultaneously acknowledge that the positive effect of stimulation were already expected, since “we have shown several times that deprived Jamaican children benefit from stimulation” (Grantham-McGregor *et al.* 1991).

Finally, it is worth remembering that in the second half of the 1980s, nutritional support policies, albeit insufficient, were implemented in Jamaica for children under 5 years old (Altink 2020).

To summarize this assessment of the original study: First, the researchers deliberately withheld an intervention essential for life and health from one group of participants—children—and observed how this deprivation affected their development. This approach evokes comparison to the Tuskegee Syphilis Study (Brandt 1978), an infamous case that led to the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the creation of the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979).

Second, they applied a double ethical standard on the three groups that did not receive food, stimulation, or either—standards that would not have been permissible in the United States or any other high-income country (HIC).

Third, the researchers violated the principle of non-maleficence by exposing participants to harm with no direct benefit.

Fourth, there was no ethical justification for maintaining the group without food or stimulation under the argument that these were the “local standard” (status quo). As Alex London (London 2005) and many other ethicists since the 1990s have argued, to pretend to establish the local conditions of vulnerability as a *local ethical standard* instead of using a universal one, like the human rights approach and the best interest of children, constitutes the basis of exploitation (Angell 1997; Lurie & Wolfe 1997; Solbakk 2004; Solbakk & Vidal 2014; Vidal 2014).

Finally, we found no indication that the study was reviewed or approved by an independent research ethics committee, and no information about the way in which informed consent was obtained.

As established in international ethical standards, years before the study was conducted, in the CIOMS guidelines says (Council for International Organizations of Medical Sciences 1982): “*The ethical implications of research involving human subjects are identical in principle wherever the work is undertaken: they relate to respect for human dignity, and protection of the rights and welfare of human subjects*” and “*no intervention can be countenanced that involves any predictable risk to health or prospect of unreasonable psychological disturbance, physical discomfort or pain*”. And also, the Declaration of Helsinki in its various versions, before this study was conducted (WMA 1964, 1975, 1983 y 1989), emphasized that “*the interest of the subjects must prevail over the interest of science and society*”.

Since the Nuremberg Code, international medical journals have placed particular attention on avoiding the publication of unethical or questionable research, as well as on discouraging the use of data derived from such research in subsequent publications. For

these reasons, we believe that an editorial comment about the 2022 study published in the journal would have been appropriate, since it builds upon a study that was ethically compromised from the outset.

Moreover, the IRB should have pointed out some of the ethical problems of all the studies carried out, particularly in the most recent study, which continues to follow the same four participant groups, raising additional ethical challenges.

First, despite having obtained informed consent, participants were offered financial compensation, which could constitute a form of undue inducement.

Second, the purpose of the 2022 paper introduces a new risk, as participants were re-identified and re-contacted in order to assess various forms of socially reprehensible behavior, exposing them to potential reputational harm.

Finally, the groups have been merged in ways that make it difficult to establish a clear causal relationship between early deprivation (of nutrition or stimulation) and behavioral outcomes 30 years later.

These are some ethical concerns identified related to this research, which from the first study in 1991 to the last publication in 2022, have not been publicly acknowledged or addressed by the different entities responsible for ethical evaluation, of this research and its different publications.

Conclusions

It is essential to remember and learn from past mistakes to avoid repeating them.

Consequently, we should keep in mind all the ethical failures that have given inspiration for new and better international regulations. Even when we review studies that have been conducted in the past, ethical assessment should be a part the review process, particularly when those studies are cited to support current arguments or interpretations. Researchers, IRBs, and editorial boards must all participate in this critical and ongoing ethical reflection.

Authors' contributions

Susana M. Vidal: Conceptualization, Writing – original draft, Writing – review & editing; Sergio E. Gonorazky: Conceptualization, Writing – original draft; Shereen Cox: Conceptualization, Writing – original draft; Jan Helge Solbakk: Conceptualization, Writing – original draft.

Conflict of interests

The authors are responsible for the content of this report, and this should not involve their Institutions in any sense. The authors declare they do not have conflicts of interest.

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Ethical implications

The authors have no ethical implications to declare in the writing or publication of this article.

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