UNDERGRADUATE RESEARCH IN NATURAL AND CLINICAL SCIENCE AND TECHNOLOGY (URNCST) JOURNAL
Read more URNCST Journal articles and submit your own today at: https://www.urncst.com

ENCYCLOPEDIA ENTRY OPEN ACCESS

The Role of Truth in Double-Blind Clinical Trials

Adithi Chellappan, BSc Student [1]*

[1] Department of Biology, Union College, Schenectady, New York, United States 08540

*Corresponding Author: achellappan2005@gmail.com

Abstract

Double-blind clinical trials are crucial in the fields of medicine and clinical research for producing reliable and unbiased scientific evidence. Historically, double-blind trials have been instrumental in establishing a rigorous standard for evaluating treatment efficacy by eliminating researcher and participant biases. By concealing treatment allocation, these trials aim to produce objective and replicable data that drive contemporary medical practice.

However, the ethical dimensions of double-blind trials raise substantial concerns. Key issues include the potential harm from administering placebos instead of effective treatments and the ethical dilemma of withholding care. This paper seeks to address and highlight these concerns by discussing the relationship between double-blind clinical trials and the scientific community as well as the advantages and disadvantages of double-blind clinical trials within the scientific community and society at large. The analysis emphasizes the necessity of adapting double-blind trials to incorporate ethical considerations without compromising the integrity of the research. By refining trial designs to include usual-care controls, the medical community can uphold both ethical standards and methodological rigor. This balanced approach ensures that double-blind trials continue to contribute valuable insights into treatment efficacy while safeguarding participant welfare.

Keywords: double-blind clinical trials; healthcare; trial design; truthfulness; ethical dilemmas

Introduction

Double-blind clinical trials in contemporary medicine are considered the gold standard for scientific evidence for their ability to eliminate various confounding variables associated with studies [1]. In a double-blind trial, the "truth" becomes a central concept, as participants and researchers alike are unaware of who receives treatment or placebo. In the context of clinical research, "truth" may refer to both factual accuracy and sincerity in approach. Patients receive either a placebo or the treatment being researched, but which patients receive which treatment is not disclosed to either party involved in the study. This unique setting allows for investigating the role of truth concealment in medicine and the ethical and procedural criticisms of this format of scientific study.

To establish a common language for the complex meanings of "truth," it is defined as "the body of real things, events, and facts" and/or "sincerity in action, character, and utterance"[2]. In double-blind clinical trials, neither researchers nor participants know which treatment is the drug being studied and which is the placebo. This concealment occurs to determine if the treatment works. The concealment of the first definition of truth refers to the treatments themselves, and the concealment of the seconddefinition of truth refers to researchers giving the impression they know what treatment the patient is receiving.

The first double-blind clinical trial was conducted by the UK Medical Research Council (MRC) in 1943 to study patulin's effect on the common cold [3]. Although the treatment had no significant effects, the data collection method gained traction, leading to the first randomized control trial in 1946. Since then, this method has evolved and is now synonymous with rigorous standards of objectivity in clinical science, leading to the current scientific landscape where double-blind clinical trials are the gold standard for scientific evidence [4].

Body

Double-Blind Trials and the Scientific Community

Double-blind clinical trials have become the hallmark of scientific evidence, especially in healthcare and pharmaceuticals. This consensus is partly due to the philosophy of science itself, which focuses on empirical observation of objective reality [5]. As the empirical foundation of scientific observation strives to remain unbiased, the objective approach drives home the trustworthiness of science, although skepticism can arise due to ethical complexities.

Double-blind clinical trials are thus favored precisely because they aim to circumvent biases and generate evidence that can be confidently relied upon, eliminating various confounding variables that could skew results.

The trustworthiness of science has been questioned due to the significant implications of scientific progress on society [6]. Scientific progress dictates the direction of society's progress, like the wave of Artificial Intelligence (AI) and AI-dependent products in recent years making an impact in all spheres of society. Thus, when issues are sensitive, it becomes harder to trust the scientific community due to the malleability of truth in science, which is associated with empirical evidence [6]. Since finding truth in the science world is reliant on empirical evidence, the methods of evidence acquisition become crucial to science's trustworthiness. The primary argument for double-blind clinical trials is that if one method consistently produces evidence close to objective realities, it becomes difficult to stray from, lending double-blind clinical trials further credibility. Thus, a widely accepted method like the double-blind clinical trial becomes favored due to the consensus in society, including the scientific community.

Although consensus is considered one of the lower forms of scientific evidence as it relies on the majority's opinion rather than empirical evidence, it was the consensus of the scientific community that led to the implementation and standardization of double-blind clinical trials [7]. This paradoxical relationship between consensus and double-blind clinical trials is an interesting caveat when analyzing their credibility.

The Advantages of Double-Blind Clinical Trials

Double-blind clinical trials mitigate the effects of confounding variables on a study, making it easier to establish causality between a treatment and its efficacy [8]. Confounding variables can affect the relationship between cause and effect, muddying the results. Double-blind clinical trials minimize bias as researchers are also unaware of which patients receive the placebo or treatment, leading to greater objectivity in scientific evidence and higher-quality data.

The efficiency of double-blind clinical trials in finding evidence has been thoroughly investigated. One study focused on hypertensive patients and their willingness to participate in placebo-controlled trials [9]. Participation can be affected due to the possibility of receiving a placebo. For individuals desperate for treatment, the idea of possibly receiving a placebo could act as a deterrent due to its inability to truly address and treat the disease. As a result, the placebo in double-blind clinical trials has gained criticism due to ethical concerns and procedural concerns of a lack of participation, decreasing the sample size.

This study only investigated placebo-controlled trials, which can be single-blind or double-blind. Double-blind clinical trials don't always have to include an inactive placebo; some researchers use the current treatment courses instead. This usual-care control can mitigate some concerns associated with placebos. The study concluded that 24% of participants cited the possibility of receiving a placebo as a deterrent to participation [9]. Although 24% is not negligible, it does not negate the various advantages of double-blind clinical trials, making it evident that the merits outweigh the negatives.

The Disadvantages of Double-Blind Clinical Trials: Ethical Concerns

From an ethical standpoint, double-blind trials present a moral conflict between two ethical principles: utilitarianism, which prioritizes the greatest good for the most number of people, and deontology, which prioritizes absolutist moral duty and patient rights. Double-blind clinical trials aim to reduce researcher and participant bias, but may withhold potentially effective treatments from patients. On one hand, utilitarianism thinking supports these trials as they generate knowledge that benefits society broadly. On the other hand, deontology argues against placing participants at risk for scientific progress. Thus, a well-rounded ethical analysis must consider both viewpoints to strike the balance between collective knowledge and individual rights.

One major ethical concern with double-blind clinical trials is the withholding of treatment from patients. Physicians have the responsibility to do no harm, but participating in double-blind clinical trials can harm patients as they do not receive the treatment they need. Thus, there are ethical concerns with recruiting patients for double-blind clinical trials, as it denies patients treatment for the greater good.

Usual-care controls instead of inactive placebos can improve recruitment and subvert ethical concerns. However, current practice favors placebo controls over usual-care controls when a credible placebo is available [10]. This practice encourages scientists to deny patient treatment for research integrity, favoring data over patient well-being. It was found that usual-care controls should become more widespread to address ethical concerns, allowing physicians to provide quality care while performing double-blind clinical trials.

Another ethical concern is the "tunnel-vision" phenomenon, where researchers focus on the disease instead of treating the patient holistically. Double-blind clinical trials can blind those involved to how the treatment affects the patient's body. By studying a disease and its treatment in the vacuum created by a double-blind trial, researchers and physicians involved in the patient's care can be blinded to the various external factors that can also influence a patient's recovery. Additionally, advances in clinical and epidemiological research have shifted focus from populations to individuals [11]. Studying disease and treatment in isolation in double-blind clinical trials can lead to treating the patient as a subject for research, ignoring external factors affecting the disease and treatment.

The focus on isolation in double-blind clinical trials can hinder the best course of treatment, as the controlled

environment is not true to patients' daily lives. The standardization of double-blind clinical trials can lead to ignoring factors affecting disease and treatment, inhibiting patients from receiving the best care possible.

The Disadvantages of Double-Blind Clinical Trials: Procedural Concerns

Double-blind clinical trials are favored for limiting bias and confounding variables, but there are procedural criticisms. The primary argument against double-blind clinical trials is the placebo effect, where subjects receiving a placebo demonstrate results similar to those receiving treatment. This effect undermines the statistical integrity of results. The placebo effect rate has risen at approximately 7% per decade over the last 30 years [12]. Although double-blind clinical trials aim for impartiality, the prevalence of the placebo effect raises concerns over their integrity. One solution is administering usual-care controls to minimize psychosomatic effects, as physical intervention can mitigate the placebo effect [12]. However, in certain studies, placebos remain vital to isolating the effect of new treatments by eliminating all variables associates with current care protocols. Therefore, the decision to use placebos or usual-care controls ought to be informed by ethical and procedural considerations alike.

Double-blind clinical trials are the most common type of trial design in healthcare, but it is significant to consider the effect of experimental design on patient results. One study focused on randomized-controlled trials of antidepressants and found that patient response and remission rates were significantly affected by study type [13]. This highlights the need to carefully consider the merits and flaws of double-blind clinical trials, ensuring they do not compromise patient care and outcomes in favor of data. Possible solutions include utilizing usual-care controls in the place of placebos in order to strike a balance between retrieving optimal data and providing treatment to patients as well as further study into honing the nature of double-blind clinical trials.

Conclusion

Double-blind clinical trials have quickly dominated the scientific landscape since their inception in 1943, becoming the preferred research model for their ability to limit bias and create controlled environments. These characteristics produce objective empirical evidence, informing well-studied scientific inferences.

However, ethical and procedural concerns exist, as study design significantly affects results and patient outcomes. Future trial designs could incorporate usual-care controls, develop stronger consent frameworks, and specify conditions under which placebos are ethically viable. The design of double-blind clinical trials can inhibit the best course of treatment due to the preferred administration of inactive placebos, which is harmful and hinders results. It is crucial to be aware of the possible negative effects of double-blind clinical trials and use them carefully to achieve scientific evidence as close to the truth as possible.

Conflicts of Interest

The author declares that they have no conflicts of interest.

Authors' Contributions

A.C. made substantial contributions to the design of the study, the collection of data as well as interpretation and analysis of the data, revised the manuscript critically, and gave final approval of the version to be published. (GHI)

Acknowledgements

I would like to thank Professor Patrick Singy for assisting me and advising me throughout the process of writing this manuscript. Additionally, ChatGPT-3.5 was used to assist in the writing process.

Funding

This development of this encyclopedia entry was not funded.

References

[1] Pocock SJ. Clinical trials: A Practical Approach. John Wiley & Sons; 1983.
[2] Merriam-Webster Dictionary [Internet]. Springfield (MA): Merriam-Webster Incorporated; c2017. Truth; [cited 2024 Aug 8]; Available from: https://www.merriam-webster.com/dictionarry/truth.
[3] Bhatt A. Evolution of clinical research: A history before and beyond james lind. Perspectives in Clinical Research. 2010 Jan 1;1(1):6. https://doi.org/10.4103/2229-3485.71839
[4] Hariton E, Locascio JJ. Randomised controlled trials–" the gold standard for effectiveness research. BJOG an International Journal of Obstetrics & Gynaecology. 2018 Jun 19;125(13):1716. https://doi.org/10.1111/1471-0528.15199
[5] Okasha S. Philosophy of Science: A Very Short Introduction. Oxford University Press; 2016.
[6] Oreskes N. Why trust science? Princeton University Press; 2021.
[7] Solomon M. Making medical knowledge. 2015. https://doi.org/10.1093/acprof:oso/9780198732617.001.0001
[8] Gore SM. Assessing clinical trials- double-blind trials. 1981 Jul 11;283(6284):122–4. https://doi.org/10.1136/bmj.283.6284.122
[9] Halpern SD, Karlawish JHT, Casarett D, Berlin JA, Townsend RR, Asch DA. Hypertensive patients' willingness to participate in placebo-controlled trials: implications for recruitment efficiency. American Heart Journal. 2003 Dec 1;146(6):985–92. https://doi.org/10.1016/s0002-8703(03)00507-6

[10] Avins AL, Cherkin DC, Sherman KJ, Goldberg H, Pressman A. Should we reconsider the routine use of placebo controls in clinical research? Trials. 2012 Apr 27;13(1). https://doi.org/10.1186/1745-6215-13-44
[11] Pearce N. Traditional epidemiology, modern epidemiology, and public health. American Journal of Public Health. 1996 May 1;86(5):678–83. https://doi.org/10.2105/ajph.86.5.678
[12] Nayak D, Chowdhury N. Lessons from Placebo Arm Wrestle in Clinical Research. Psychiatric Annals. 2014 Feb 1;44(2):84–8. https://doi.org/10.3928/00485713-20140205-06
[13] Rutherford BR, Sneed JR, Roose SP. Does study design influence outcome? Psychotherapy and Psychosomatics. 2009 Jan 1;78(3):172–81. https://doi.org/10.1159/000209348

Article Information
Managing Editor: Jeremy Y. Ng
Peer Reviewers: Neha Dhanvanthry, Jeremy Ng
Article Dates: Received Aug 28 24; Accepted Nov 18 24; Published Feb 19 25

Citation
Please cite this article as follows:
Chellappan A. The role of truth in double-blind clinical trials. URNCST Journal. 2025 Feb 19: 9(2).
https://urncst.com/index.php/urncst/article/view/698
DOI Link: https://doi.org/10.26685/urncst.698