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Major causes of high attrition rate in clinical trials: Critical review and latest developments

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Abstract
The biggest obstacle in clinical trials is still participant attrition or dropout, which has an impact on study reliability and results. The main causes of participant withdrawal were covered in this review, including poor communication, convoluted procedures, time or money constraints, and a lack of drive. New, contemporary strategies have been employed to address these issues, including patient engagement initiatives, digital and community-based recruitment, and the application of wearable technology and artificial intelligence. Patients can now participate in trials more easily thanks to mobile health apps and remote participation, and their trust and understanding have grown as a result of patient advisory boards and educational initiatives. The goal of all these efforts is to reduce attrition, improve participant experience, and make trial outputs more reliable.

Keywords: Clinical trials, participant attrition, patient engagement, digital health, artificial intelligence

1. Introduction

1.1 Background on Clinical Trials

A clinical trial is a carefully planned study that evaluates the safety and effectiveness of new medical treatments, drugs, devices, or procedures [1, 2]. In such studies, the outcomes of an investigational therapy are compared with those of a control group involving human participants [3]. The term clinical trial generally describes any form of research in which people volunteer to test how an intervention works under controlled conditions. These trials progress through a series of phases (0, I, II, III, IV, and V), each phase determines treatment safety and benefit [2]. They generate reliable evidence on safety and efficacy [4]. The results help researchers refine study procedures during testing and give clinicians and patients dependable information that narrows the gap between efficacy—how a therapy performs in ideal settings—and effectiveness—how it performs in real-world use [3]. Over the past decade, the way trials are conducted has changed substantially. In order to handle complicated datasets, run biosimulations, and facilitate early disease detection [5], researchers are increasingly depending on data-driven approaches and artificial intelligence (AI) [5]. Furthermore, studies are now more effective and better adapted to the healthcare systems of today thanks to the use of flexible and adaptive trial designs [6, 7].

1.2 The Problem of High Attrition Rates

The number of participants who leave the trial before it is finished is explained by the attrition rate [8, 9]. This is crucial because if too many participants withdraw, the study may lose its validity and the findings may not accurately represent the situation. Additionally, attrition rates differ based on the participants and trial type. For instance, about 30% of participants in psychosis trials involving teenagers and young adults discontinue their participation overall [10]. The percentage increases to roughly 34% at follow-up, and about 26% of participants drop out of the trial for the primary endpoint. By the end of supportive care and palliative oncology trials, nearly 44% of participants depart [11]. Depending on the study design, dropout rates vary even in antipsychotic medication trials: roughly 48% of participants leave in placebo-controlled trials, whereas 28% do so in active-control trials [12].

Trials involving patients with substance use disorders are particularly prone to early dropouts [13]. Attempting to keep participants engaged is therefore crucial, and strategies like adjusting care, reducing delays, and keeping in touch with study participants on a regular basis can help.

1.3 Objectives of the Review

This review provides an in-depth examination of the causes and solutions to high attrition rates. Firstly, we'll analyze and identify the major reasons for attrition, including participant-level factors, patient demographic details (age, gender, background), and health-related characteristics, as well as study-level factors such as trial design, duration, and management style [8, 15]. In recent years, there have been some new approaches developed to reduce attrition, such as participant-centered strategies focusing on the comfort and motivation of participants, enhancement of trial design to reduce dropouts, use of retention materials, and national study coordinators, which make the participants feel connected and engaged [14]. This review is important for researchers and clinical trial managers as it explains what factors are responsible for attrition, and what the latest methods have proven effective in reducing attrition [16].

2. Major causes of high attrition rates

2.1 Study Design and Protocol Issues

This paragraph discusses the key factors of participants' dropouts in clinical trials. Complex protocols may overburden participants, causing withdrawal [9, 14]. Balanced protocols reduce dropouts. The second reason is unrealistic inclusion and exclusion criteria. When the rules are strict and irrelevant, then participants think that they do not fit the study's requirements, and as a result, dropout rates increase [14]. The third reason is patient burden and time commitment-sometimes trials fail to consider participants' time, effort, and financial costs, especially in long-term studies, which results in a greater likelihood of attrition [9]. The final factor is poor choice of endpoints or outcome measures-if the study goals are misaligned with participants' expectations or they think their participation lacks purpose, then they lose motivation to continue [8]. If the endpoint is meaningful and relevant to participants, this can help reduce dropouts. Figure 1 illustrates the major causes of high attrition in clinical trials and their interrelated effects on study outcomes.

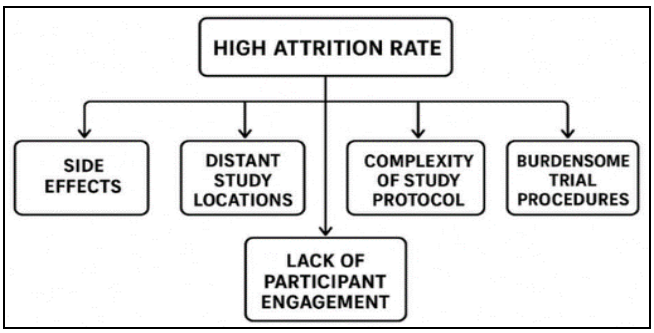

Fig 1: Flowchart showing the main reasons and ways to reduce high clinical trial attrition rates.

2.2 Recruitment and Enrolment Challenges

Recruitment challenges contribute to attrition; only 5% of eligible individuals participate due to ineffective strategies [17, 18]. Moreover, geographical distance, distrust, misinterpretation, and discrimination barriers could be reasons for the deterioration of participation [19]. To address those demanding situations, researchers should build agree with and credibility with individuals, explain the objectives of the trial, and provide financial or material incentives whilst needed [20]. Reaching various patient populations is likewise a mission, in particular due to the digital divide and constrained inclusion of centralized trial procedures [16]. Enrollment can occasionally be challenging due to competition for the same patient pool across several trials [21]. Additionally, participants may feel their participation is useless if they do not fully comprehend the requirements and benefits of the trial, which can result in a higher number of withdrawals [17]. To keep participants motivated and able to finish the study, effective retention strategies are essential. These include fostering strong, supportive relationships between staff and participants and clearly communicating the objectives and advantages of the trial [20, 22].

2.3 Patient-Related Factors

Along with different aspects, attrition rates in clinical trials and patient-related factors are the most important amongst them. Many studies have shown that participants often withdraw from trials when they feel that their participation does not yield direct or immediate benefits, leading to a loss of motivation [14, 15]. Another reason is being assigned to the placebo group or fear of side effects; many participants drop out of trials because they feel they are not getting actual treatment, or that they may get side effects [23]. Another major factor is personal and logistical barriers, such as transportation problems, time management issues, and the burden of frequent clinic visits, due to which participants find it difficult to complete the trials throughout the study [14, 24]. Additionally, for a diverse population, language and cultural barriers could be a major challenge for attrition rates [19]. If there is a language or cultural misunderstanding, participants may not understand the purpose and benefit of the trial clearly, and they may feel disconnected. Researchers must carefully consider trial design and participant engagement tactics, such as reducing participant stress, offering culturally sensitive support, and clearly outlining the objectives and advantages of the trial, in order to overcome these obstacles [7, 17]. Participants' motivation and trust will rise as a result of such actions, and attrition will ultimately decline.

2.4 Investigator and Site-Related Factors

Staffing/resource delays can reduce retention [25]. In order to ensure participant engagement and protocol adherence, larger, more seasoned sites with more seasoned coordinators typically have faster contract execution and IRB approval [9]. Furthermore, communique between researchers and participants is critical; retention will grow if members receive individualized care and help or if they get along well with the staff. An additional important element is the researcher's passion and involvement; without it, participants may lose motivation, with a purpose to sooner or later result in lower retention [15]. Finally, insufficient training may additionally hinder have a look at body of workers's capacity to control trial logistics and correctly interact members, which negatively influences protocol adherence and retention [14]. Sites with skilled, full-time coordinators have drastically better retention prices.

2.5 Sponsor and Regulatory Issues

Sponsor priority/funding changes affect trial progress. If a sponsor reduces funding or changes priorities in the middle of a take a look at, it is able to slow down or even forestall. When sponsors have consistent investment and clear priorities, trials can pass forward with fewer setbacks. However, regulatory limitations pose an additional assignment. Complex approval approaches and usa-particular rules frequently bring about lengthy delays, higher prices, and higher dropout quotes for trials [27, 28]. Enhancing local uniformity and streamlining those approval tactics ought to have a big impact. Careful planning is necessary for multinational trials. Every united states has its personal legal guidelines, traditions, and real-world difficulties [27]. When no longer properly coordinated, these components commonly cause misunderstandings and inefficiency. However, implementing decentralized methods, using standardized procedures, and having early discussions with regulatory bodies can all help things go more smoothly [29, 30]. Lastly, it is critical that sponsors, regulators, and CROs coordinate. Even a well-designed trial may encounter problems if there is a breakdown in communication or if roles are not clearly defined. Involving all parties early in the planning process, maintaining open lines of communication, and clearly defining roles typically help to keep everything on track and in alignment [28]. A summary of the major factors contributing to high attrition in clinical trials, along with modern strategies to mitigate them, is presented in Table 1.

Table 1: Major Factors Contributing to High Attrition in Clinical Trials and Modern Strategies to Reduce It

S. No.	Factor Contributing to High Attrition	Modern Strategies to Reduce Attrition
1.	Complex study protocols	Simplify trial procedures; adaptive designs; patient-centric protocol development [1-5].
2.	Strict or unrealistic inclusion/exclusion criteria	Broaden eligibility; involve patients in trial design [1-4, 6, 7].
3.	Patient burden (time, travel, costs)	Decentralized/virtual trials; mobile health apps; flexible visit schedules [8-13].
4.	Placebo assignment/fear of side effects	Clear informed consent; patient education; peer support programs [2, 7-10].
5.	Recruitment challenges (trust, geography, cultural barriers)	Community-based recruitment; digital/social media outreach; patient advocacy [5, 8-11].
6.	Investigator/site-related issues (communication, training, staff)	Staff training; personalized engagement; experienced coordinators [7, 12-14].
7.	Sponsor/regulatory delays	Early regulatory engagement; streamlined approvals; clear sponsor priorities [3, 15-17].

3. Latest Developments in Addressing Attrition

3.1 Innovative Study Designs

These days, a number of cutting-edge strategies are being employed to improve the effectiveness and participant experience of clinical trials. Trials are made flexible by adaptive trial designs, which allow for modifications to be made during the trial according to predetermined guidelines. For instance, changing the sample size and treatment arms can lower attrition and save money and time. Involving patients in the trial design process to make the trial relevant to their experience is known as patient-centric protocol development [7]. Particularly in specialties like nephrology, where patient involvement is more crucial, this strategy enhances both recruitment and retention. Results from pragmatic trials are more applicable and helpful for policy decisions because they are carried out in regular clinical settings and involve a variety of patient populations, which sets them apart from explanatory trials and reflects real-world circumstances [31]. Last but not least, decentralized or virtual trial components—which have grown significantly since COVID-19—let participants take part from home using digital tools like digital biomarkers, eConsent, and remote monitoring [29, 30, 32]. Although this strategy lowers participant burden and dropout rates, issues like data security, disparities in regulations, and the inclusion of underrepresented groups still need to be resolved [16, 27].

3.2 Enhanced Recruitment and Retention Strategies

These days, community-based and digital strategies are becoming more and more common to increase clinical trial participant recruitment and retention [18]. Because social media and digital platforms make it easier to reach a larger and more varied audience, they are thought to be more effective than traditional methods. Decentralization is facilitated by digital methods, which raises community involvement [22]. The recruitment process is made more efficient by social media campaigns, community feedback, and digital crowdsourcing, particularly when targeting teenagers and young adults, for whom online outreach is more successful [21]. Programs for patient engagement are also essential for trial retention; when participants' expectations are met and trust is established, they are more likely to remain interested in and participate in the trial [17]. Additionally, stakeholder engagement and personalized reminders enhance recruitment and retention [20]. Participants are kept motivated by retention incentives and support services, such as monetary or non-monetary rewards. Participants are more likely to finish the trial if their schedules are accommodated and obstacles like time, travel, or financial limitations are lessened [33]. Finally, community outreach and patient advocacy groups are important because they establish trust with participants, exchange information, and match research goals with community health goals [19]. Recruitment and retention can be enhanced through these connections, particularly for underrepresented groups.

3.3 Technological Advancements

Interventions can greatly improve patient engagement by applying behavioral science concepts [36]. Furthermore, artificial intelligence (AI) is being used in trials more and more. Using tools like machine learning and natural language processing, which can analyze large amounts of data to predict when participants might leave, researchers can make timely adjustments to keep more participants in the study [25]. Furthermore, patient outcomes are being modelled using digital twins powered by AI, which can be very beneficial for planning [37]. Technologies such as electronic consent (eConsent) and remote participation enable trial participation from home, improving accessibility

and reducing dropout rates [32]. Last but not least, wearable technology and sensors allow researchers to continuously monitor health and collect data in real time, increasing the reliability and accuracy of the results [38]. For example, to better understand suicide risk, the "Smart Crises" study uses wearables and artificial intelligence to track changes in appetite and sleep [39].

3.4 Improved Communication and Education

Nowadays, there are lots of innovative approaches to make scientific trials greater patient-pleasant and keep participant engagement. Examples of how AI is notably helping with patient training materials include digital fact simulations, language translation software, and digital consultations. By assisting sufferers in knowledge the significance and intention of the trial, those greatly improve affected person engagement. Peer training programs like Lupus Therapeutics Patient Advocates for Lupus Studies (LT-PALS) also are making a massive difference [41]. Especially for underrepresented corporations, they promote involvement, enlarge expertise, and raise self-esteem. Procedures for knowledgeable consent are also improving. Trial teams use affected person advisory boards to make sure consent paperwork are clean and clean to understand. To make sure that the bureaucracy for trials of uncommon neuromuscular problems virtually applicable the needs of the individuals, for instance, advisory committees assisted of their design. It's additionally essential to preserve members involved and get ordinary feedback. Trials like RDCTs use patient enter to beautify recruitment substances and preserve participant engagement, which notably reduces dropout rates [43]. To keep participants updated on study traits, the Recruitment Innovation Centre (RIC) additionally creates substances and runs social media campaigns. Lastly, patient advisory boards are actually involved within the making plans and control of trials. Case research from the Medical Research Council Clinical Trials Unit show that early affected person involvement complements trial protocols, sanatorium visit schedules, and support packages. This suggests that the trial is in the long run a whole lot greater appropriate for the parties. When all is said and done, incorporating affected person voices, adaptive communique, training, and engagement strategies without a doubt works—it keeps participants interested and improves the outcomes.

4. Conclusions

High attrition quotes in medical trials are a major hassle that influences take a look at results and reliability. This evaluation makes it clear that a range of factors make a contribution to participant withdrawal, which include complex tactics, challenges with enrollment and recruitment, logistical and private barriers, troubles with the site and the investigator, and sponsor/regulatory factors. Initiatives like virtual gear, AI, decentralized trials, adaptive trial designs, and affected person engagement packages have all contributed to a recent decline in dropout rates. The simple goals of those techniques are to preserve participants involved, advantage their accept as true with, increase their know-how of the trial, and generate extra reliable effects. Future research must put participants first, use generation wisely, and talk in reality at every flip. Trials can proceed extra smoothly and yield outcomes that make sense in the real international if this is done.

5. Declaration of Generative AI and AI-Assisted Technologies in the Writing Process

During the preparation of this manuscript, the author(s) used AI-assisted tools such as QuillBot and Grammarly to improve grammar, readability, and linguistic clarity. The author or authors critically reviewed and edited every output produced by these tools. The author(s) alone is in charge of the final content, which includes concepts, interpretations, and conclusions.

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Author contribution

Mansi Shukla: Conceptualization, supervision, critical review, editing of the manuscript, and correspondence with the journal.
Aditi Sharma: Literature collection, data analysis, writing—original draft preparation, and overall manuscript design.
Both authors contributed to the discussion, interpretation of literature, and approved the final version of the manuscript.

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