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Barriers to Patient Recruitment and Patient Participation Concerns in Clinical Trials

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Abstract

Difficulties with clinical trial recruitment severely hamper research advancement and the generalizability of study results. The research site may take a lot of time and effort to enroll participants in clinical studies. Every research is unique in several ways, including stages, study indications, eligibility requirements, etc. When determining the enrollment deadline, the potential duration of the trial is usually based on the study's indication and the accessibility of the patient population in the research site's geographic region. Every clinical trial's success depends on its ability to recruit and retain patients, yet these efforts are under extreme strain globally. Patients also have concerns and face significant challenges when participating in clinical trials, such as lack of trust, communication, family support, fear of side effects, etc. This manuscript explores the differences between barriers to recruitment and concerns about participation It consists of a survey intended to collect information on these matters. The collected data is then analyzed and presented using graphs and charts to illustrate the results.

Keywords: *Clinical Trial Recruitment, Participation concerns, Barriers to recruitment, Clinical trials, Awareness of clinical trials, Strategies.*

Introduction

The advancement of medical knowledge and the creation of novel therapeutics depend on clinical trials. However, one of the biggest challenges facing researchers continues to be patient recruitment. A strong study design is necessary for a clinical trial to be effective, but so is the capacity to attract and include a wide range of patients. Various logistical, social, and psychological variables that discourage potential participants from participating or staying in research might be substantial barriers to patient recruitment. [1] Understanding these barriers is imperative to enhance recruiting tactics and guarantee that clinical trials encompass diverse groups who will eventually utilize the evaluated therapies. Enrollment and retention rates are also significantly impacted by patient participation concerns, such as distrust of medical research, fear of adverse effects, and misunderstanding of trial protocols. It is essential to address these issues to create an environment of hospitality that promotes involvement and improves the wider integrity and appropriateness of clinical research.[1][2]

This study attempts to investigate the numerous barriers to patient involvement in clinical trials, look at patient participation concerns, and suggest ways to improve involvement. By identifying and addressing these challenges, we can pave the way for more effective and inclusive clinical research, ultimately benefiting both patients and the broader healthcare system.

What is a Clinical Trial?

Clinical trials are research studies that assess the safety and efficacy of novel medical interventions, such as medications, equipment, or treatment plans. They normally follow a defined procedure and are carried out in phases.

1. **Phase I**: Prioritizes safety, defining the proper dose, and detecting adverse effects in a limited number of volunteers.
2. **Phase II:** Analyses the intervention's efficacy and safety in a wider cohort.
3. **Phase III:** In large populations, the novel intervention is compared to traditional therapies to confirm efficacy, monitor adverse effects, and collect information about safe usage.
4. **Phase IV:** Conducted after the intervention has been authorized to assess long-term effects and overall efficacy in the general population.

Clinical trials are vital for furthering medical knowledge, expanding treatment options, and ensuring that novel medications are both safe and beneficial for patients.

Patient recruitment

Patient recruitment is the process of determining and enrolling people to participate in clinical studies. Effective recruiting is critical to the success of a study because it guarantees there are enough participants to obtain accurate data.
Important elements of patient recruiting include:

1. Awareness: Informing potential participants of the trial's purpose and objectives.
2. Eligibility Screening: Determines if participants meet the study's particular inclusion and exclusion criteria.
3. Engagement: Enhancing trust and resolving concerns about involvement to raise enrolment.
4. Diversity: Ensuring that the participant pool represents a diverse population to increase the study's relevance and applicability.

Patient recruiting challenges may include a lack of information, misunderstandings about clinical trials, logistical hurdles, and worries about safety or commitment. Effective measures are required to overcome these barriers and increase enrollment rates.

Patient Enrolment

Patient enrolment is the official procedure of registering patients in a clinical study once they have been recruited and given their consent to participate.

This stage consists of several vital activities:

1. Informed Consent: Participants are given comprehensive information about the study's objective, methods, risks, and benefits. They must willingly agree to participate by signing a permission form.

2. Baseline Assessments: Before participation, individuals may undergo evaluations to collect baseline data, which is necessary for comparing results later.

3. Assignment to Study Groups: After enrolment, participants are assigned to various research arms (e.g., treatment or control groups) based on the trial design.

4. Documentation: Proper documents are kept to capture participant information, consent, and pertinent medical history.

Successful patient enrolment is critical to the integrity and validity of clinical trials, as it ensures that enough participants are available to fulfill the study's objectives and timeframe.

Patient Participation

Clinical trials require patient participation to advance medical research and improve treatment options. The following are some of the key components of this:

- Informed consent: patients must be fully informed about the trial's purpose, procedures, potential risks, and benefits before enrollment for them to make an informed decision about their involvement.
- Eligibility Criteria: Trials are characterized by a set of eligibility requirements that specify who is eligible to participate. These requirements may include age, gender, medical history, or stage of a disease.
- Diverse Representation: Trials must include a diverse range of participants to guarantee that the results apply to a range of populations, including different age groups, genders, ethnicities, and health backgrounds.
- Patient-Centric Design: Patients' needs and preferences are a growing focus of trials. Involving patients in the design phase can increase recruitment and retention rates.
- Impact on Treatment: Patients may receive individualized care and access to novel treatments that are not yet generally available.
- Hazards and Benefits: Patients may gain from being a part of the process that leads to future medical improvements, even if there might be hazards involved with participation, such as adverse effects from experimental medicines.
- Support and Resources: Throughout the experiment, patients should have access to resources and assistance, such as details on what to anticipate and who to ask questions of.
- Post-Trial Access: It's critical to take into account the participants' circumstances following the trial's conclusion. Some might desire to keep receiving the therapy or participate in relevant research going forward.

Clinical trial patient involvement is essential to the validity and generalizability of study results. However, several concerns may prevent eligible volunteers from enrolling or continuing in research.

Common Barriers to Recruitment

Three primary categories may be used to classify recruitment barriers: factors connected to patients, factors related to the site, and factors relating to the system.[4][5]

1. **Patient-Related Factors**:
   These comprise personal circumstances, health literacy, and individual attitudes that influence participation willingness.

- ***Awareness and Knowledge***
  Many prospective participants have no understanding of current clinical studies or are unlikely to know why they are being conducted. According to McCarthy et al.'s study from 2021, just 20% of eligible patients were aware of relevant trials. [11]
- ***Perspectives and Attitudes***
  Lack of willingness to participate in clinical trials is influenced by negative assumptions about them, such as misunderstandings about randomization, distrust of medical research, and fear of adverse effects (Boulware et al., 2020). [6]
- **The Understanding of Health**
  Lower health literacy skills among patients may make it difficult for them to understand trial material, which may affect their desire to sign up. Interventions in education can improve understanding as well as engagement (Green et al., 2022). [7]

2. **Site-Related Factors**:
   These are the logistical problems at study locations, such as infrastructure, personnel availability, and patient demographics in the area.

- ***Recruiting Infrastructure***
  Recruiting attempts may be hampered by understaffed, underfunded, and poorly trained site workers. According to Albrecht et al. (2019), sites that have professional recruitment coordinators typically have greater enrollment rates. [8]
- ***Characteristics of the Patient Population***
  Research locations situated in areas with a lower patient eligibility rate provide various challenges. Potential for recruitment is strongly influenced by demographic and geographic characteristics (Peters et al., 2021). [6]

3. **Systemic Factors**:
   These comprise the general clinical trial environment, financing constraints, and regulatory hurdles.

- ***Regulatory hurdles***
  Complicated regulatory procedures have the potential to postpone the start of trials and inhibit study locations from continuing with certain projects. Recruitment might happen more quickly if regulatory procedures are streamlined (Friedman et al., 2020). [9]
- ***Finance Restrictions***
  Reductions in financing frequently lead to a decrease in resources for recruitment. Higher budget trials usually employ more effective recruiting techniques (Levine et al., 2023). [10]
  Age criteria can be a barrier to patient recruitment and enrollment in clinical trials.
- ***Exclusion of Older Adults:***
  Due to concerns about polypharmacy, comorbidities, and unpredictability in drug metabolism, many trials do not include older adults. This restricts the results' wider patient population applicability**.**
- ***Pediatric Restrictions:***
  Trials involving children frequently have strong age limitations, which might obstruct important information about the safety and efficacy of the intervention.
- ***Variability in Response:***
  Age limits can distort trial findings and limit our understanding of how interventions operate throughout the lifespan since various age groups respond to treatments differently.
- ***Selection Challenges****:*
  It may be challenging to identify eligible participants due to narrow age limits, which might cause delays and higher trial expenses.

Concerns Regarding Patient Participation

Clinical trial patient involvement is essential to the validity and generalizability of study results. However, several concerns may prevent eligible volunteers from enrolling or continuing in research. These concerns can be roughly divided into the following categories:

1. **Efficacy and Safety:**

- Fear of Adverse Effects: A lot of patients are concerned about possible hazards or adverse effects from the experimental treatment.
- Uncertainty about Efficacy: If a patient's prior therapies have failed, they may have doubts about the new treatment's efficacy.

2. **Informed Consent**
- Complexity: Patients may find it difficult to understand long consent papers and medical terminology, which might cause them to get confused about the goals and methods of the research.
- Comprehension: Patients may be hesitant to assent if they are unclear about the nature of the experimental treatment, its dangers, or its advantages.

3. **Trust and Mistrust**
- Historical Context: Research misconduct in the past has the potential to breed mistrust, especially among underrepresented groups.
- Relationship between the Provider and the Patient: Participants may be discouraged and mistrustful of healthcare professionals if they perceive a lack of communication or transparency.

4. **Logistical Challenges**
- Time Commitment: Patients, particularly those managing job or family commitments, may find the demands of routine tests, visits, and follow-ups to be too much to handle.
- Geographic Barriers: Patients who live distant from trial locations may find it difficult to travel, which makes participation more challenging.

5. **Psychological and Social Factors**
- Anxiety and Fear: Serious anxiety might be brought on by worries about possible adverse effects and the unpredictability of experimental therapies.
- Social Support: Since emotional and practical support is frequently essential, a patient's choice to participate may be impacted by the absence of support from friends or family.

6. **Cultural and Demographic Factors**
- Cultural Beliefs: Patients from various origins may have opinions on clinical trials that are influenced by cultural customs or beliefs.
- Demographic Disparities: Underrepresentation in trials is frequently the result of differences in age, gender, socioeconomic level, and ethnicity, all of which might have an impact on the desire to participate.

7. **Communication Barriers**
- Health Literacy: Individuals with inadequate health literacy may find it difficult to comprehend trial material, which might impede their capacity to decide wisely.
- Language Barriers: If documents in the non-native speaker's native language are unavailable, or if interpreters are not offered, non-native speakers may find it difficult to figure out the specifics of the trial.

Improving recruitment and retention rates in clinical trials requires addressing these issues. Researchers may guarantee that clinical trials are representative of the general population and promote higher patient engagement by improving communication, building trust, and making participation easier to understand. [12]

Methods

Survey Design

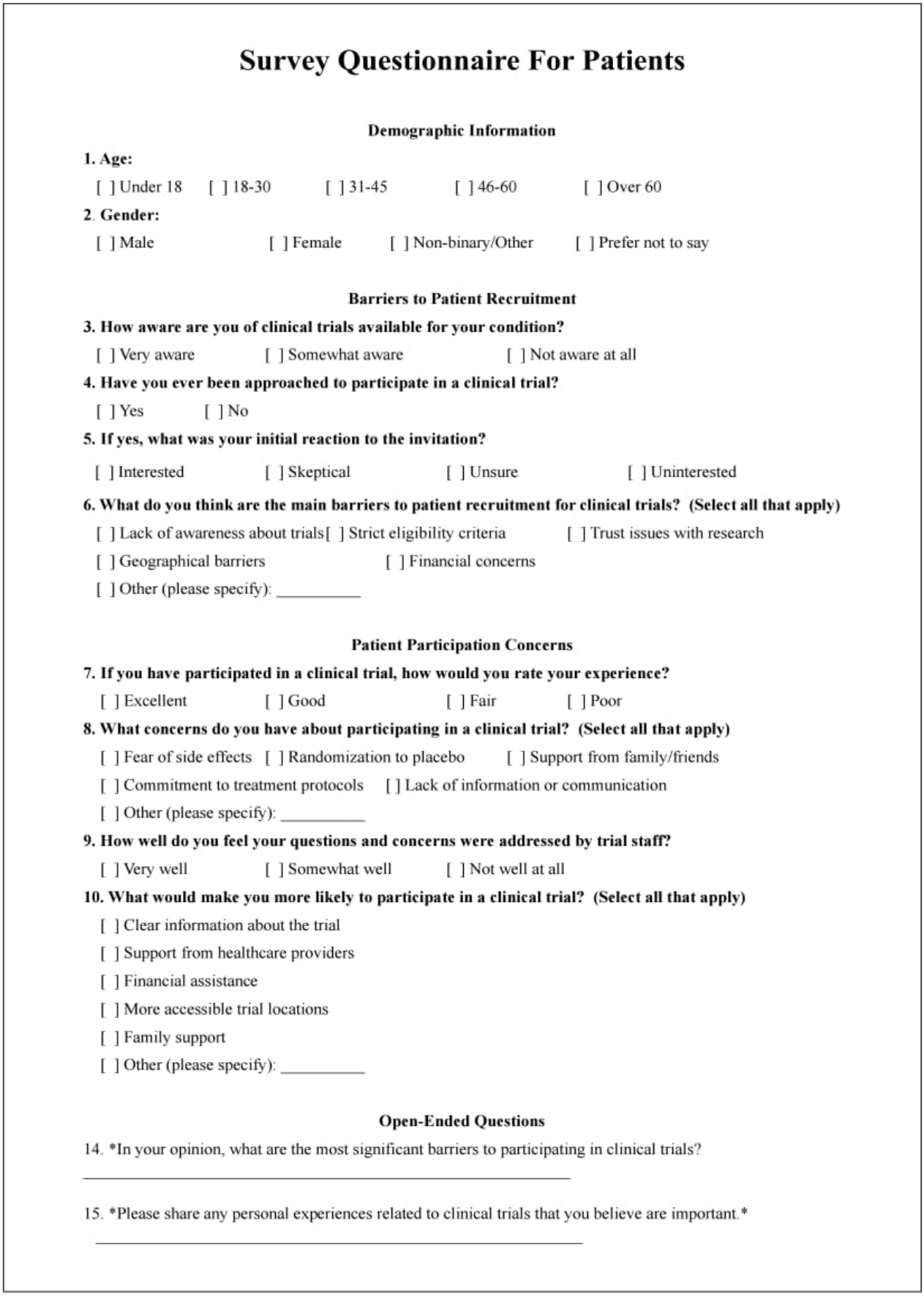
A thorough questionnaire was created to evaluate:

1. Survey Questionnaire for patients.
2. Survey Questionnaire for the patient recruitment team.

The survey was distributed to patients across various healthcare settings, targeting individuals.

1. Demographic Information: Age, and gender,
2. Barriers to Recruitment: Awareness of clinical trials, past invitations, and perceived barriers.
3. Participation Concerns**:** Experiences in trials, concerns about participation, and factors influencing willingness to participate.

Survey questionnaire sample paper.



Survey Questionnaire For Patients

Demographic Information

1. Age:

[ ] Under 18 [ ] 18-30 [ ] 31-45 [ ] 46-60 [ ] Over 60

2. Gender:

[ ] Male [ ] Female [ ] Non-binary/Other [ ] Prefer not to say

Barriers to Patient Recruitment

3. How aware are you of clinical trials available for your condition?

[ ] Very aware [ ] Somewhat aware [ ] Not aware at all

4. Have you ever been approached to participate in a clinical trial?

[ ] Yes [ ] No

5. If yes, what was your initial reaction to the invitation?

[ ] Interested [ ] Skeptical [ ] Unsure [ ] Uninterested

6. What do you think are the main barriers to patient recruitment for clinical trials? (Select all that apply)

[ ] Lack of awareness about trials [ ] Strict eligibility criteria [ ] Trust issues with research

[ ] Geographical barriers [ ] Financial concerns

[ ] Other (please specify): _____

Patient Participation Concerns

7. If you have participated in a clinical trial, how would you rate your experience?

[ ] Excellent [ ] Good [ ] Fair [ ] Poor

8. What concerns do you have about participating in a clinical trial? (Select all that apply)

[ ] Fear of side effects [ ] Randomization to placebo [ ] Support from family/friends

[ ] Commitment to treatment protocols [ ] Lack of information or communication

[ ] Other (please specify): _____

9. How well do you feel your questions and concerns were addressed by trial staff?

[ ] Very well [ ] Somewhat well [ ] Not well at all

10. What would make you more likely to participate in a clinical trial? (Select all that apply)

[ ] Clear information about the trial

[ ] Support from healthcare providers

[ ] Financial assistance

[ ] More accessible trial locations

[ ] Family support

[ ] Other (please specify): _____

Open-Ended Questions

14. *In your opinion, what are the most significant barriers to participating in clinical trials?

_____

15. *Please share any personal experiences related to clinical trials that you believe are important.*

_____

Figure 1 Survey questionnaire for patients (Sample Paper)

Patient Recruitment Survey Questionnaire

Demographics

1. Role in Clinical Trials:

[ ] Principal Investigator [ ] Research Coordinator [ ] Nurse

[ ] Other: _____

2. Years of Experience in Clinical Trials

[ ] 0-1 year [ ] 2-5 years [ ] 6-10 years [ ] 11+ years

Recruitment Process

3. What methods do you primarily use for recruitment? (Select all that apply)

[ ] Referrals [ ] Advertisements [ ] Social media [ ] Community outreach

[ ] Other: _____

4. On a scale of 1 to 5, how would you rate the effectiveness of your current recruitment methods?

[ ] 1 (Not effective) [ ] 2 [ ] 3 (Neutral) [ ] 4 [ ] 5 (Very effective)

Identifying Barriers

5. What do you perceive as the main barriers to patient recruitment? (Select all that apply)

[ ] Lack of awareness about the study [ ] Concerns about participation safety

[ ] Eligibility criteria too strict [ ] Language or cultural barriers

[ ] Time constraints for patients [ ] Trust issues with the research process

[ ] Other: _____

6. How often do you encounter these barriers?

[ ] Always [ ] Often [ ] Sometimes [ ] Rarely [ ] Never

7. Please rate the following potential barriers on a scale of 1 to 5:

Awareness of study

[ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5

Safety concerns

[ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5

Eligibility criteria

[ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5

Language barriers

[ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5

Solutions and Strategies

8. What strategies do you believe could help overcome these barriers? (Open-ended)

_____

9. Have you implemented any successful strategies in the past? If so, please describe. (Open-ended)

_____

10. Do you have any additional comments or insights regarding patient recruitment barriers? (Open-ended)

_____

Figure 2 Survey Questionnaire for Patient Recruitment Team (Sample Paper)

1 Data Analysis

Responses were analyzed quantitatively, using descriptive statistics. Graphs and charts were generated to illustrate the findings.

1.1 Survey Results

Demographic Information

1. Age Distribution

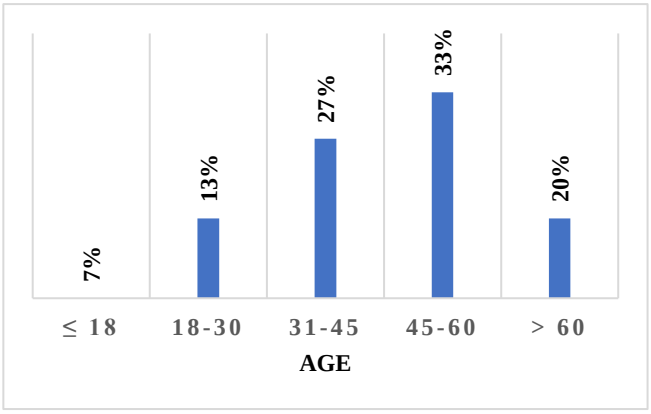


Figure 3 Age distribution of survey participants.

2. Gender Breakdown

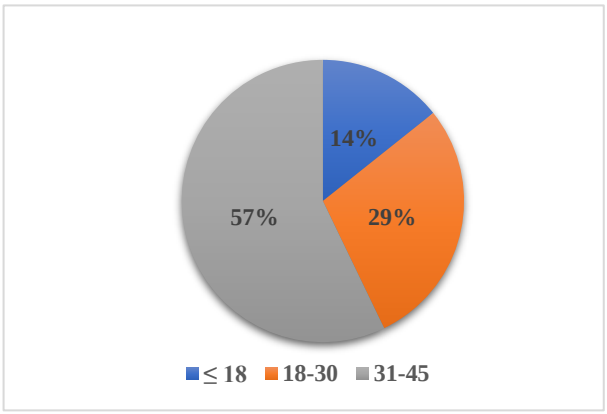


Figure 4 Gender distribution of survey participants.

Barriers to Patient Recruitment

3. Awareness of Clinical Trials

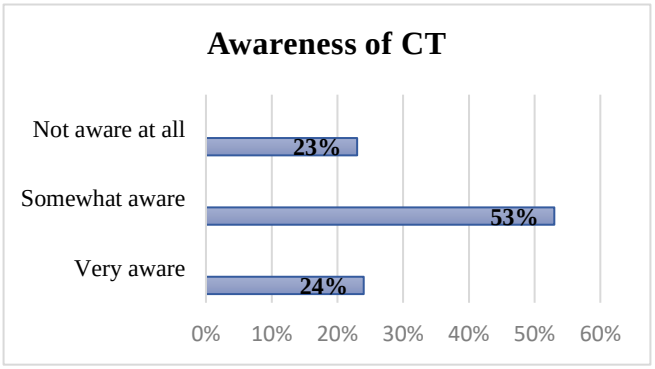


Figure 5 Gender distribution of survey participants.

4. Previous Invitations to Participate in Trials

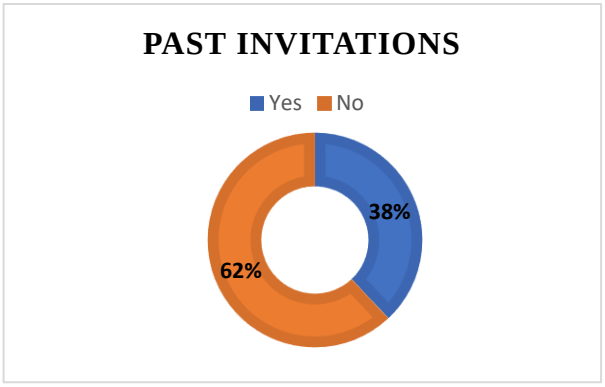


Figure 6 Past Invitations to Participants

Perceived Barriers to Recruitment.

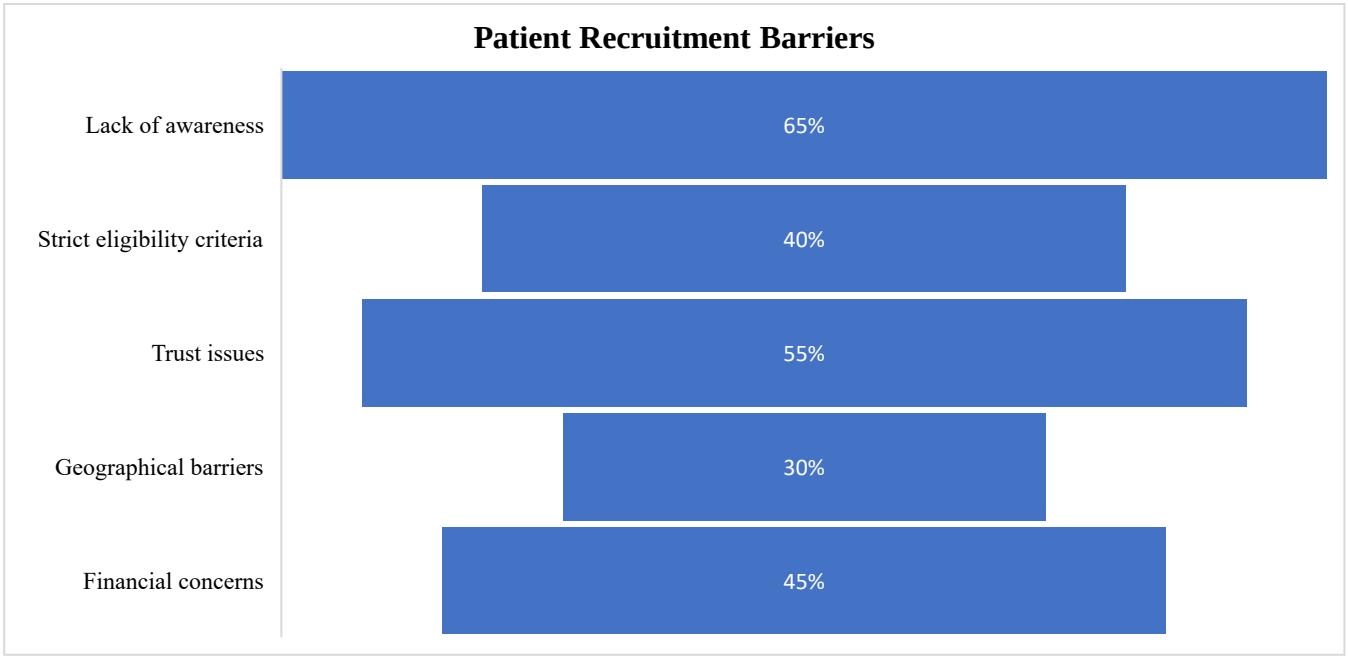


Figure 7 Perceived barriers to patient recruitment.

Patient Participation Concerns

Concerns About Participation

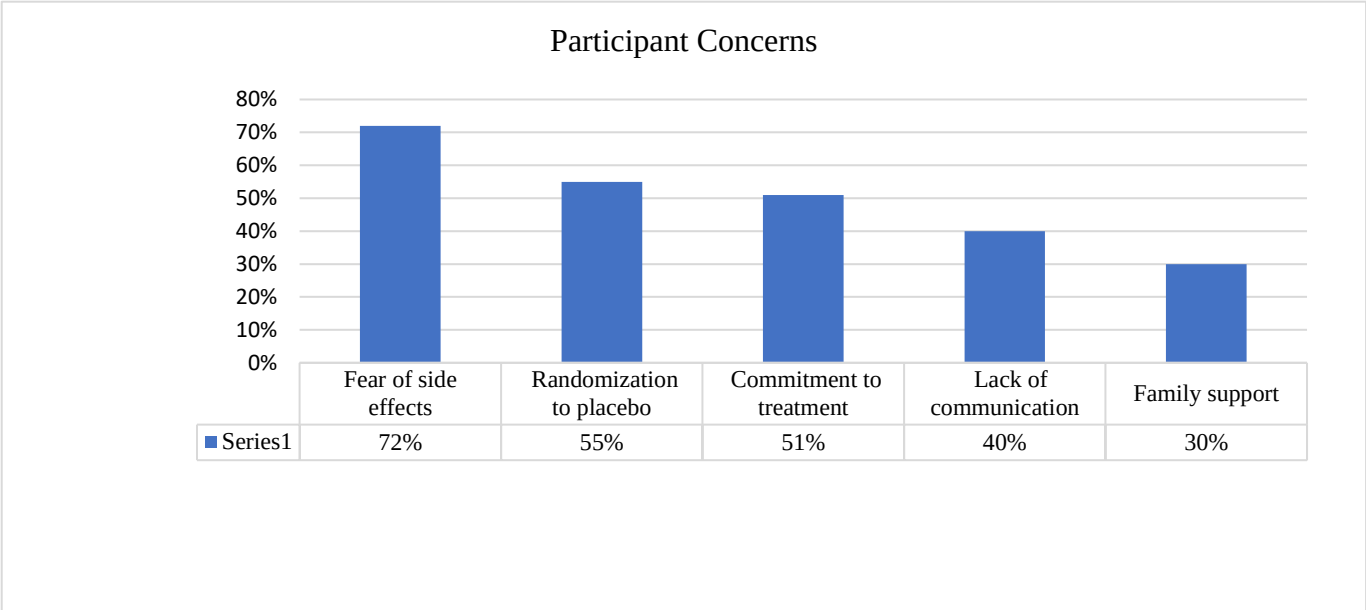


Figure 8 Main concerns regarding participation in trials.

Factors Influencing Willingness to Participate

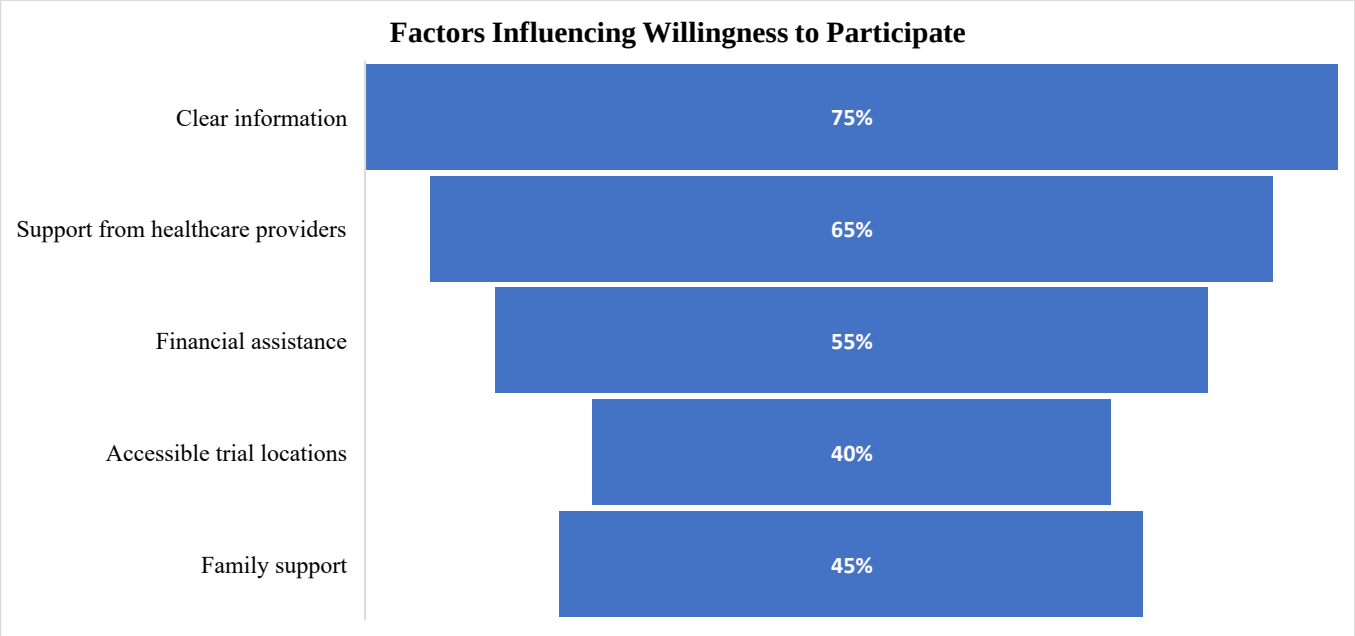


Figure 9 Factors that could enhance willingness to participate in trials.

Open-Ended Responses

1. Key Barriers Identified:
   "Limited understanding of what trials involve."
   "Previous negative experiences with healthcare."
2. Significant Participation Concerns:
   "Worries about the unknown side effects of new treatments."
   "Feeling unsupported during the trial process."

Discussion

Differentiating Participation Concerns from Recruitment Barriers

According to the study results, communication and psychological issues are frequently at the forefront of participation concerns, while awareness and trust are the primary barriers to recruitment. [32]

Addressing these various problems can result in more successful recruiting and retention tactics in clinical trials.

Strategies for Improvement

Enhancing clinical trial patient recruitment and participation is crucial for promoting medical research and ensuring diverse study representation. The following are specific tactics to overcome the barriers encountered in these domains:

Raising Awareness and Education

Lack of understanding and awareness of clinical trials is one of the biggest obstacles to patient recruitment. Many prospective volunteers may be unaware of the specifics of studies or have misconceptions about them. Establishing effective community engagement initiatives is essential to addressing this. It is possible to successfully enlighten the public about the goals and advantages of clinical trials by setting up informational sessions in community centers, schools, and places of worship. Making easily accessible teaching resources, such as pamphlets, films, and internet articles, might also aid in clarifying the procedure. These materials ought to provide a clear explanation of the trials' objectives, qualifying requirements, any hazards, and participants' rights. Getting local influencers to contribute testimonies or personal stories can help boost involvement and credibility. [11]

Developing Trust

For patient recruiting to be successful, communities must be trusted. Due to systemic suspicion of medical research or past experiences, many people may be hesitant to participate in clinical trials. Building trust and credibility can be facilitated by involving local organizations and community leaders. By publicizing the experiment and its advantages throughout their networks, these leaders can act as promoters. Transparent communication is also essential. The objectives of the experiment, the steps involved, and any possible risks or advantages should all be stated clearly by the researchers. Directly addressing widespread misunderstandings, such as the fear of being used as "guinea pigs," could ease worries and promote cooperation.

Improving accessibility

Accessibility is a key aspect of patient recruitment. Many people are discouraged from participating in trials due to logistical constraints. To promote accessibility, researchers should explore conducting trials in a variety of locations including rural and underprivileged regions. This method not only expands the possible participation pool but also promotes diversity. Furthermore, having flexible scheduling alternatives, such as weekend and evening hours, can fit a wide range of patient schedules, making participation more accessible. Additionally, making trial locations conveniently accessible via public transit or providing transportation assistance can help to reduce difficulties.

Encouraging Involvement

Incentives, both monetary and non-monetary, can greatly increase patient recruitment and participation rates. Covering participants for travel and time costs might lessen the financial strain of taking part in clinical studies. Offering health advantages to trial participants—like access to novel therapies or ongoing medical examinations—may induce interest in people who may otherwise be looking for other ways to receive healthcare. Encouraging prospective participants to consider enrolling can be achieved by making these incentives clear during the recruiting process.[25]

Utilizing Technology

Technology has the potential to significantly improve patient involvement and recruitment. Patients can participate in some trial activities remotely thanks to the incorporation of telehealth alternatives, which eliminates the need for in-person visits. Those who live far away or have mobility problems would especially benefit from this. Reaching a larger audience can also be facilitated by utilizing digital recruiting tools like social media, specialized websites, and online patient registries. Targeted outreach and engagement may be raised by creating digital marketing that is tailored to particular populations depending on trial eligibility. These efforts can increase knowledge and interest even further by using language and images that are attractive to patients.[26]

Ensuring Diversity of Representation

The generalizability of clinical trial results depends on trial diversity. Targeted outreach techniques should be created to engage underrepresented groups to enhance representation. This entails being aware of any language, cultural, and financial obstacles to participation. Recruitment efforts can be improved by implementing culturally competent strategies, such as offering literature in different languages or hiring community health workers who are familiar with the regional customs of the area. Participation may be made easier by engaging different groups in the trial design process, which can also guarantee that their unique needs and concerns are addressed.

Feedback Collection for Ongoing Improvement

Participant opinion must be gathered to improve recruiting tactics. Implementing together patient advisory boards with past participants can yield a wealth of information about their viewpoints and experiences.

These panels can provide suggestions for enhancing participant support and recruiting tactics. Post-trial questionnaires can also be used to highlight particular challenges encountered during the trial and collect ideas for enhancement. Through proactive feedback collection and integration, researchers may enhance their recruiting and engagement strategies over time.

Including Healthcare Professionals

When it comes to finding patients for clinical trials, healthcare practitioners are essential. It is essential to teach healthcare professionals the value of clinical research and how to talk to patients about trials. Training courses and educational materials can give healthcare professionals the skills and information they need to properly refer qualified patients. Providers might be further encouraged to increase trial participation by establishing referral programs that reward them for successful referrals. The establishment of a cooperative partnership between healthcare practitioners and researchers might facilitate the integration of clinical practice and research, hence augmenting patient recruitment endeavors.

Researchers may successfully overcome the hurdles to patient recruitment and trial participation by implementing these comprehensive tactics into practice. This will result in more successful studies and better health outcomes for a range of populations. [24][27]

Conclusion

This study illustrates the necessity of addressing patient concerns about clinical trial participation as well as recruiting barriers. The lack of knowledge and comprehension of the clinical trial procedure is just one of these challenges; others include logistical challenges, worries about potential hazards, mistrust in the medical community, and socioeconomic inequality. Researchers may increase recruitment and retention by focused strategy implementation, which will eventually improve the caliber and variety of clinical research. Enhancing patient involvement and participation requires not just designing inclusive and accessible trials but also fostering a transparent and trusting connection between the patient and the researcher. By addressing these issues, enrollment rates will increase and more varied and representative research populations will be ensured, which will eventually result in more dependable and broadly applicable therapeutic conclusions.

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References

[1] Patel M, Doku V, Tennakoon L. Challenges in the recruitment of research participants. Adv Psychiatr Treat. 2003;9:229–38.
[2] Frank G. Current challenges in clinical trial patient recruitment and enrollment. SOCRA Source. 2004:30–8.
[3] Ruckmani A, Vishaly S, Arunkumar R, Prabhu L, Priya A. Assessment of barriers in subject recruitment for clinical trials. J Clin Res Bioeth. 2012;3:125. [doi4172/2155-9627.1000125]
[4] Bernardez-Pereira S, Lopes RD, Carrion MJ, Santucci EV, Soares RM, de Oliveira AM, et al. Prevalence, characteristics, and predictors of early termination of cardiovascular clinical trials due to low recruitment: insights from the ClinicalTrials.gov registry. Am Heart J. 2014;168(2):213–9.
[5] Boulware, L. E., & Cooper, L. A. (2020). Trust and mistrust in health care: The role of race and ethnicity. American Journal of Public Health, 110(3), 329-334.
[6] Peters, L. A., & Kelsey, M. (2021). Geographic disparities in clinical trial recruitment: A systematic review. Trials, 22(1), 43-56.
[7] Green, A. R., & Nunez, J. (2022). Health literacy and patient recruitment in clinical trials: A qualitative study. Health Communication, 37(1), 75-83.
[8] Albrecht, T. L., & Bowers, A. A. (2019). Improving clinical trial recruitment: A systematic review of the literature. Journal of Clinical Research, 15(4), 255-267.
[9] Friedman, L. M., & Furberg, C. D. (2020). Regulatory and ethical challenges in clinical trials. Journal of Medical Ethics, 46(6), 391-397.
[10] Levine, R. J., & Tredget, E. E. (2023). Funding and recruitment in clinical trials: A growing concern. Clinical Trials, 20(2), 102-110.
[11] McCarthy, J. F., & Thien, T. L. (2021). Awareness of clinical trials: The role of community engagement. Clinical Trials, 18(3), 185-195.
[12] Mills EJ, Seely D, Rachlis B, Griffith L, Wu P, Wilson K, et al. Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. Lancet Oncol. 2006;7(2):141–8.
[13] Steers, W., Richter, H., Nyberg, L., Kusek, J., Kraus, S., Dandrea, K., et al. (2009, August 15). Challenges of conducting multi-center, multi-disciplinary urinary incontinence clinical trials: Experience of the urinary incontinence treatment network. Neurourology and Urodynamics, 28, 170–176. PMID: 19030190
[14] Legge, F., Eaton, D., Molife, R., Ferrandina, G., Judson, I., de Bono, J., et al. (2007, March 1). Participation of patients with gynecological cancer in phase I clinical trials: Two year's experience in a major cancer center. Gynecologic Oncology, 104, 551–556. PMID: 17064758
[15] Mao, J. J., Tan, T., Li, S. Q., Meghani, S. H., Glanz, K., & Bruner, D. (2014, January 8). Attitudes and barriers towards participation in an acupuncture trial among breast cancer patients: A survey study. BMC Complementary and Alternative Medicine, 14, 7. PMID: 24400734
[16] Avis, N. E., Smith, K. W., Link, C. L., Hortobagyi, G. N., & Rivera, E. (2006, April 20). Factors associated with participation in breast cancer treatment clinical trials. Journal of Clinical Oncology, 24(12), 1860–1867.
[17] Legge, F., Eaton, D., Molife, R., Ferrandina, G., Judson, I., de Bono, J., et al. (2007, March 1). Participation of patients with gynecological cancer in phase I clinical trials: Two year's experience in a major cancer center. Gynecologic Oncology, 104, 551–556. PMID: 17064758
[18] Albrecht, T. A., & Taylor, A. G. (2013, November). No stone left unturned: Challenges encountered during recruitment of women with advanced ovarian cancer for a phase I study. Applied Nursing Research, 26(4), 245–250. PMID: 2387166
[19] Fischer, M., Fugate-Woods, N., & Wayne, P. M. (2014, November). Use of pragmatic community-based interventions to enhance recruitment and adherence in a randomized trial of tai chi for women with osteopenia: Insights from a qualitative substudy. Menopause, 21(11), 1181–1189. PMID: 24845395
[20] Treweek S, Bevan S, Bower P, Campbell M, Christie J, Clarke M, et al. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? Trials. 2018;19(1): 139.

[21] Kaur G, Smyth RL, Williamson P. Developing a survey of barriers and facilitators to recruitment in randomized controlled trials. Trials. 2012;13(1): 218
[22] Zúñiga, M. L., Blanco, E., Martinez, P., Strathdee, S. A., & Gifford, A. L. (2007, November). Perceptions of barriers and facilitators to participation in clinical trials in HIV-positive Latinas: A pilot study. Journal of Women's Health (Larchmont), 16(9), 1322–1330. PMID: 18001189
[23] Goode, P. S., Fitzgerald, M. P., Richter, H. E., Whitehead, W. E., Nygaard, I., Wren, P. A., et al. & Pelvic Floor Disorders Network. (2008, September). Enhancing participation of older women in surgical trials. Journal of the American College of Surgeons, 207(3), 303–311.
[24] Pribulick, M., Willams, I. C., & Fahs, P. S. (2010). Strategies to reduce barriers to recruitment and participation. Online Journal of Rural Nursing and Health Care, 10(1), 22–33. PMID: 23641192
[25] Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald AM, Knight R, et al. Recruitment to randomised trials: strategies for trial enrollment and participation study. The STEPS study. Health Technol Assess. 2007;11:105.
[26] Kearney A, Harman NL, Rosala-Hallas A, Beecher C, Blazeby JM, Bower P, et al. Development of an online resource for recruitment research in clinical trials to organize and map current literature. Clin Trials. 2018;15(6):533–42.
[27] Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, et al. Strategies to improve recruitment to randomised trials. Cochrane Database Syst Rev. 2018;2(2).
[28] Williams CM, Maher CG, Hancock MJ, McAuley JH, Lin CW, Latimer J. Recruitment rate for a clinical trial was associated with particular operational procedures and clinician characteristics. J Clin Epidemiol. 2014;67(2):169–75.
[29] Lovato LC, Hill K, Hertert S, Hunninghake DB, Probstfield JL. Recruitment for controlled clinical trials: Literature summary and annotated bibliography. Control Clin Trials. 1997;18:328–52. doi: 10.1016/s0197-2456(96)00236-x.
[30] Bodurtha, J. N., Quillin, J. M., Tracy, K. A., Borzelleca, J., McClish, D., Wilson, D. B., et al. (2007, August). Recruiting diverse patients to a breast cancer risk communication trial—Waiting rooms can improve access. Journal of the National Medical Association, 99(8), 917–922.
[31] Steers, W., Richter, H., Nyberg, L., Kusek, J., Kraus, S., Dandrea, K., et al. (2009, August 15). Challenges of conducting multi-center, multi-disciplinary urinary incontinence clinical trials: Experience of the urinary incontinence treatment network. Neurourology and Urodynamics, 28, 170–176.
[32] Bower P, Brueton V, Gamble C, Treweek S, Smith CT, Young B, et al. Interventions to improve recruitment and retention in clinical trials: A survey and workshop to assess current practice and future priorities. Trials. 2014;15:399. doi: 10.1186/1745-6215-15-399.