ESC European Society of Cardiology

European Journal of Cardiovascular Nursing (2025) **24**, 808–812
https://doi.org/10.1093/eurjcn/zvae158

Methods Corner

Challenges and strategies for effective recruitment and retention of participants in clinical research studies

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Received 25 October 2024; revised 30 October 2024; accepted 30 October 2024; published 3 January 2025

Effective recruitment and retention of participants in clinical research studies are critical to be able to draw meaningful and valid conclusions in research studies. However, there are multiple challenges related to communication, generalizability, and logistics. Researchers must address and overcome these challenges to ensure robust research outcomes. Effective strategies include honest and clear communication, awareness of reasons for (non)-participation, incentivization, and reimbursements of expenses as well as co-designing interventions and research protocols. This paper outlines common issues in participant recruitment and retention and provides practical strategies to overcome challenges.

Keywords Recruitment • Retention, • Communication • Generalisability • Co-design

Learning objectives

- Recognize common challenges that may be associated with recruitment and retention of participants in clinical research studies
- Identify strategies that improve recruitment and retention of participants in clinical research studies
- Summarize fundamental aspects to be considered in clinical research studies to enhance recruitment and retention of participants

Introduction

Recruitment in clinical research entails identifying and enrolling eligible participants based on the inclusion criteria and the planned sample size within a defined time frame. Retention involves maintaining active involvement of participants throughout the entire study duration (e.g. data collection, adherence to an intervention, and follow-up). Recruiting and retaining participants is crucial for the validity and reliability of research results.[1] Unfortunately, only 50% of all clinical research studies successfully recruit the intended sample size.[1] Of the trials that successfully recruited their planned sample size, only 50% recruited the intended sample size during the predetermined time frame.[1–3] Effective recruitment and retention require a structured, multifactor, and multilayered approach to reach a diverse sample.[4,5]

One of the major pitfalls in recruitment is Lasagna's law, which refers to researchers' tendency to overestimate the pool of available participants who meet the inclusion criteria and would be willing to enrol in a clinical trial.[6] A lower-than-prespecified overall sample size affects the power and effect size of the trial, which precludes the conduct of a full intention-to-treat analysis, and consequently introduces bias.[1,4] In a randomized trial, for example, insufficient power may become a problem if participant characteristics between groups differ and correlate with the outcome measures of the trial. Retaining participants ensures the completeness of data collection. Attrition is problematic as it can affect the study findings and compromise study validity and can potentially occur when participant data are missing at one or more measure points.[7]

Unfortunately, effective recruitment and retention strategies are often not assessed in clinical research studies. This paper addresses challenges in recruitment and participant retention and suggests practical strategies to deal with these difficulties. The content is based on

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literature and discussions at an international research workshop in April 2024 at Linköping University, Sweden, where international researchers within the field of cardiovascular nursing from different clinical backgrounds discussed the problems they face in relation to recruitment and retention in their studies.

Challenges of recruitment and retention in clinical studies

Challenges in communication

Honest and clear communication about the expectations from the researchers to the eligible study participants, e.g. about the content of the study and what participation entails, is important. When researchers are not honest and clear, this could lead to misconceptions about research participation. Eligible study participants may be reluctant to participate due to possible adverse effects or drop out (attrition) of the study due to unexpected adverse events. Furthermore, during the trial, participants could experience excessive time commitments, which may result in individuals leaving the study before final follow-up.[8] Adequate communication is important to preventing mistrust in researchers or healthcare systems, especially regarding the privacy and security of the study participants.[8,9]

The informed consent document is a tool for adequate communication. However, this document often contains technical language and detailed information that can be difficult for individuals with low literacy to comprehend. This can lead to misunderstandings about the research purpose, procedures, and potential risks.[10] When potential participants cannot fully understand the informed consent, they may feel overwhelmed or distrustful, leading them to decline their participation.

Logistical challenges

Research studies may require frequent visits to the data collection site, posing a significant burden for those who live far away or lack reliable transportations. Transportation barriers can limit enrolment and could even be the primary reason for not participating.[3,11,12] These challenges are particularly relevant for individuals living in rural or underserved areas. Geographical isolation can result in longer travel times and higher costs, further discouraging participation.[13] Furthermore, individuals may need to balance research participation with work schedules and may not be able to afford taking time off from work to participate in study visits.[3,11]

Challenges in generalizability

A frequently used inclusion criterion is that participants must understand and speak the language of the geographical location where the trial is conducted. This can result in a lack of diversity in the study population, which is important for generalizing research findings.[10,14] Even if individuals with low literacy decide to participate, their lack of understanding can affect their adherence to the study protocol. They might miss study visits or are not able to comply to the study requirements, leading to higher dropout rates and potentially skewed results.[10,14]

Challenges in generalizability could also occur due to socio-economic disparities, such as income, education, and access to healthcare, which could influence participation rates. Individuals with lower socio-economic backgrounds could experience greater barriers to enrolling in trials or staying in the trials, like the costs for transportation or family obligations, which could lead to disparities in research representation.[15,16]

Strategies for recruitment and retention

Building relationship and trust

Effective communication about research can be achieved by building relationships and trust with the community where the research will be conducted, prior and during the study. This is an important strategy to overcome barriers to enrolling underrepresented populations in clinical research studies.[11] Another strategy is to have a diverse research team (different clinical and cultural backgrounds) and include key members of the relevant community in the research team.[11] The key persons could be members of patient organizations, cultural organizations, or cultural mediators. One example is from the Women's Health Initiative study,[17] in which they planned to recruit a representative sample of minority postmenopausal women, between 50 and 79 years. They appointed minority recruitment centres and made efforts to ensure that the staff, especially those involved in recruitment, were configured to reflect the population of interest. For those centres recruiting in Hispanic communities, access to bilingual recruitment staff and/or interpreter service was seen as essential. As recruitment strategies to recruit members of minority groups, they presented information about the study at churches, social gatherings, and organizations frequented by members of these groups, or meeting with tribal leaders to gain access to American Indian women.

Another example of effective recruitment strategies was a study involving the Hispanic population that announced the study during church meetings, in local Hispanic print media, on Spanish television and radio stations, and at local health fairs.[18]

Dedicated and transparent information

To optimize retention and prevent attrition, it should be clear what is expected from participants when agreeing to be included in the study.[11] This includes research objectives, procedures, risks, and benefits of the study. Once participating in the study, a reminder system might be useful to remind participants about their follow-up study visits, for example, by text messages before the actual visit, or make a clear overview of the study visits together with the participant during the first visit.[3]

Dedicated time for the research visits

Given that participants often volunteer their valuable time and efforts to contribute to the study, study visit should be organized efficiently. As a strategy to improve retention of participants, the researcher or clinician should ensure sufficient dedicated time for the study visits, in which the focus is solely on the participant and their contribution. One approach is academic detailing, which is an interactive educational initiative aimed at training healthcare professionals, providing unbiased, non-commercial, evidence-based information and education to the patient, with the goal of enhancing patient care.[19] The basis of academic detailing is a one-to-one discussion between a trained healthcare professional (the academic detailer) and, for example, a patient.[19] As an intervention, academic detailing is worthy of additional study because it lends itself well to planning and assessing a prioritized list of important educational outcomes. An example of a study using academic detailing is the HELP-AF study,[20] where clinicians used academic detailing with the aim of nurses understanding on how to identify and address barriers and enabling factors relevant to a desired behavioural change in patients with atrial fibrillation, while providing patient education through structured educational visits.

Creating a sense of togetherness

It is considered important to sustain regular communication with participants, providing ongoing support and cultivating a sense of

community by means of support groups, newsletters, or online forums.[3] Sharing research outcomes after the clinical trial with the participants (e.g. newsletter, social media, or website) could give a motivation for participants to stay in the trial. Individual participant outcomes as part of a clinical trial, e.g. if the participant improved on the main outcome of the study, could be given after participation.[3]

Study materials in various formats and languages

To address the challenge of recruiting participants who experience health and/or literacy problems or do not speak the language, it has been suggested to provide study materials in various formats and provide culturally sensitive materials in different languages.[11] For instance, these materials could take the form of cartoons, self-explanatory text accompanied by pictures that participants can relate to, or the use of videos and virtual reality to illustrate study procedures. An example is to provide a multimedia digital informed consent with dynamic, interactive audiovisual elements.[21] Compared with a paper version of the informed consent, participants in this study found the digital informed consent more satisfactory, perceived the digital form as ease of use, felt higher ability to complete the consent independently, and had a shorter perceived time to complete the consent process.[21]

Incentives and reimbursement of expenses

Providing incentives includes reimbursement of expenses, e.g. parking or public transport, and practical support such as transportation assistance by offering taxi or ride share services, lunch vouchers, or childcare services could be considered to provide.[3,11,22] While some research groups offer onsite childcare, many lack access to a volunteer pool (such as undergraduate or graduate students) or a child-friendly environment.[23]

A meta-analysis[24] showed an improvement in response and consent rates when participants were offered incentive payment, even when participants received a small incentive. It is however important to keep in mind that fairness in payment and protection from undue influence of payment on the informed consent process are crucial but distinct ethical considerations.[25]

Co-designing interventions and research protocols

Co-designing interventions and research protocols with the target population could potentially ensure inclusivity and relevance.[26] This could give valuable insights and cultivate a sense of ownership and empowerment among participants. A scoping review[27] assessing the use of co-design in nutritional research showed that co-design was most often used for intervention development and scarcely across all stages of research, e.g. the inclusion process of the study or the dissemination of result results. Involving end users equally in designing and developing healthcare interventions aligns with person-centred care. However, it involves balancing implementation and sustainability requirements against end users' needs and preferences, and it is important to recognize that co-design processes can be time-consuming.

Include a budget for recruitment and retention activities

To secure adequate staff resources to perform these activities recruitment and retainment activities should be part of the study budget.[28] Research has shown that there is little guidance about staff time needed to recruit and support lay members and researchers properly.[29] This means that the true cost of recruiting patients and the public in research is unknown, and often the cost of recruitment is higher than calculated for on funding applications (see example in *Table 1*) as illustrated in[30] a study that found that they only budgeted for 7% of the total costs of their recruitment.

Table 1 Examples of recruitment and retention costs that could be included in the budget of grant applications

Examples for costs in recruitment and retention

- Costs for advertisement and social media campaigns
- Communication outreach programmes and partnership with local (patient) organizations
- Costs for recruitment platforms (e.g. Thread, Clara Health, Study KIK, or Trialbee)
- Costs for maintaining the use of secure databases to track participants progress and serve as clinical/research databases (e.g. RedCap, Castor EDC, and Medidata Rave)
- Regular newsletters or updates to keep participants and research staff informed
- Salary for recruitment coordinators and support staff
- Training costs for staff involved in recruitment activities
- Costs for initial screening tests and assessment
- Compensation for participants for their time and travel
- Costs for support services such as childcare
- Gifts or vouchers to encourage participation and maintain engagement
- Incentives for participants who complete the study

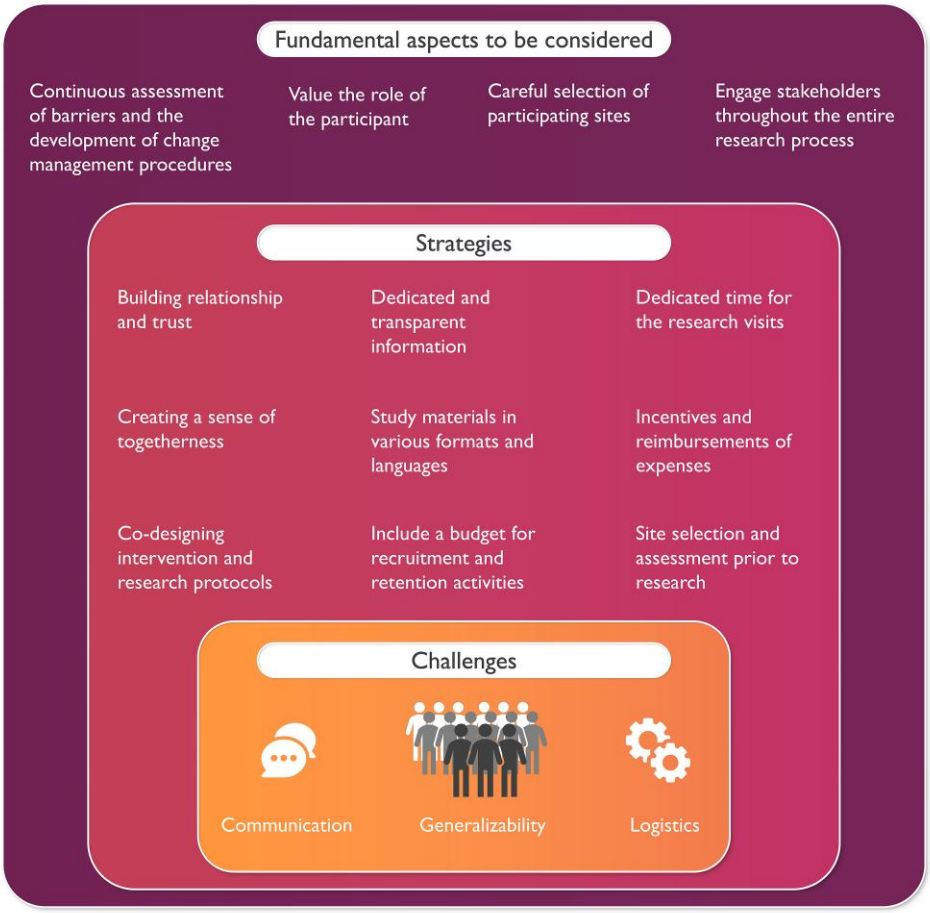
Site selection and assessment of recruitment and retention prior to trial

Selecting sites, e.g. a multicentre trial, should be based on well-considered data-driven decisions, for example, including sites with sufficient availability of the trial's target population. It is advised that the staff capacity, available resources, and necessary expertise at potential sites will be evaluated. In pilot testing an intervention, it is important to not only test the protocol but also test recruitment and retention in the clinical research study or with adjustments of methods and/or recruitment sites if enrolment targets are not met.[11] This would also reduce the risk of overestimating the pool of available participants. Another strategy, which should be part of all clinical research studies/research, is to monitor recruitment and retention during the clinical trial to be able to intervene and adapt accordantly and at an earlier time. An example where they monitored recruitment and retention is a randomized weight loss and hypertension management trial,[31] where new recruitment and retention strategies were developed during the trial and implemented when needed.

Fundamental aspects to be considered in clinical studies

Based on the strategies above that are supported by evidence,[32] there are four fundamental steps to be considered that contribute to improved recruitment and retention in research (*Central Illustration*).

(1) *Continuous assessment of barriers and the development of change management procedures.* Before starting clinical research study, it



Central Illustration Challenges, strategies, and fundamental aspects to be considered in recruitment and retention.

is advised to estimate recruitment, including estimating how many patients need to be screened, how many are eligible, and how many patients agree to participate. Obstacles that may affect effective recruitment and retainment of participants in the research study should be identified. At the same time, development of a mitigation plan to anticipate on this, preferably prior to starting enrolment, is needed, such as expanding eligibility criteria or adding more recruitment sites might be necessary. Retention rates of 85–90% in clinical studies are generally considered acceptable.[33] When retention rates are lower than expected, it may be necessary to enhance participation engagement, provide support services, or increase incentives.

(2) *Value the role of the participant.* It is important to reduce the burden of patients to a minimum which can be achieved by mapping the patient journey[34] and keeping their participation burden to a minimum. At the same time, incentives and reimbursement or return of value for their participation should be considered.

(3) *Careful selection of participating sites.* If trials focus on specific sites to recruit from, it is not only important to investigate the availability of the target population but also perform recruitment and retention feasibility assessments which may include previous involvement in clinical research studies, available resources, and the capacity and expertise (e.g. diagnostic or therapeutic equipment, clinical and/or academic experts in the associated field) to recruit the target population. The outcome of such assessment may lead to further education or facilitation of recruitment sites.

(4) *Engage stakeholders throughout the entire research process.* From designing the trial to writing up the results, participants as well as other stakeholders (e.g. those individuals, groups, and organizations that might be involved or affected by the trial) should be actively involved in every phase of the trial. This includes the strategies as mentioned before (*Central Illustration*) and will result in enhanced recruitment and retention and ultimately in the impact of trial outcomes.

Conclusion

The success of clinical studies relies on multiple aspects, including effective recruitment and retention strategies. Assessing barriers and facilitators to recruitment and retention of participants in clinical studies, valuing the participants' role, performing a recruitment and retention feasibility assessment, and engaging stakeholders throughout the entire research process are important practical considerations to keep in mind when designing a clinical study.

Acknowledgements

The authors would like to thank the participants of the international research workshop at Linköping University (Sweden) for the discussions on retention and recruitment.

Funding

FORTE 2021-01903; FORTE 2023-01604.

Conflict of interest: none declared.

Data availability

Not Applicable.

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