Recruitment in Community Intervention Studies

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Community Intervention Studies

- Large-scale community participation
- Recruitment and target date of completion
- Vaccine drug trials
- Vulnerable population
- Specific objectives
- Specific inclusion & exclusion criteria
- Safety of participants
- Integrity of data
- Phase III clinical trials

Recruitment

- Aims to enlist appropriate participants representing target population
- Enroll required number to fulfill sample size requirements & power of study within expected duration of time
- Recruitment & Retention (keeping participants in study) of sufficient number of participants are serious methodological concerns influencing validity of research findings

Recruitment Methods

A. General Awareness strategies
   - Education & awareness campaigns/ trial promotion
   - Community outreach & engagement support

B. Advertisements
   - Traditional media advertising (radio, TV, print)
   - Posters, flyers, pamphlets, brochures
   - Digital advertising (social media, website, google ads, eNews, blog post)

C. Third Party Vendors
   - Outsourcing to third-party provider specializing in marketing & advertising

Chaudhari N, et al. *Perspect Clin Res* 2020; 11:64-9.

Barriers to Site Recruitment

- Finding eligible participants that meet inclusion/exclusion criteria
- Onerous visit schedules for participants (distance, frequency, time)
- Insufficient resources for recruitment activities
- Time for governance/ review
- Time for ethics submission and review
- Lack of knowledge/ willingness of clinicians to refer
- Competing priorities of the site
- Access to participants living in rural or remote areas
- Inadequate study feasibility
- Low awareness/ poor access to information of trial
- Insufficient reimbursement for recruitment
- Length & complexity of participant ICF

Zahren C, et al. *Clinical Trials* 2021; 18(5):594-605.

Enablers to Recruitment

- Adequate site staff & resources to perform recruitment activities
- Adequate site budget for recruitment activities
- Active investigator in the recruitment process
- Good referral networks at site, clinician, institutional level
- Access to a quality database or electronic medical records
- Clear recruitment strategy & assigned responsibilities for recruitment plan
- Efficient turnaround time for ethical review
- Shorter & less complex participant ICF
- Adequate reimbursement for participants
- Better site training on protocol requirements
- Access to 3rd party recruitment aids (referral apps, registries, service providers)
- Better site staff training to explain consent forms

Zahren C, et al. *Clinical Trials* 2021; 18(5):594-605.

Recruitment Strategies

- Participant-centric approach: why participants are hesitant to participate in clinical trials
  - Heightened concerns around safety, placebos, burden of trial such as time commitment (travel time to study sites, multiple check-ins)
  - Information about study (study materials), placebo, overall trial safety, schedule of visits & what tests to be done, travel reimbursement
  - Clinical trail recruitment agency with strong nonprofit partnerships (patient advocacy groups, etc)

Recruitment Strategies

- Clinician/hospital recruitment/referral network
- Patient contact: information materials (appropriate design & translation); promotion (newsletters, advertisements, events, press release, community sessions)
- Support for site recruiters (training on recruitment to recruiting staff)
- Monitoring & systems (reminders, use of existing registers, phone call for queries)
- Incentives (site recruitment targets, feedback, monetary)
- Study design (relevance, patient-public involvement, widening inclusion criteria)
- Resources (site, additional & networks)
- Human Factors (relationships & communication; face-to-face initiation visits, regular contact with recruitment staff)

Bower P, et al. *Trials* 2014; 15:399.

Consequences of Suboptimal or Failed Recruitment

- Extended duration of trial
- Increased costs
- Reduced study statistical power
- Invalid or inconclusive study results
- Changes in inclusion or exclusion criteria that may influence final outcome
- Termination of trial
- Loss of funding for individual clinics
- Late surge of recruitment activity creates uneven workload & other administrative problems
- Prolonged recruitment phase affect participant retention & compliance
- Adverse effect on staff morale

Hunninghake DB, et al. *Control Clin Trials* 1987; 8(Supp):6S-30S.

Recruitment Misconduct

- Recruitment misconduct involves unethical or fraudulent practices
- Ethical recruitment is critical in clinical trials with impacts on participant safety, study integrity, and scientific validity
- Wrongdoing in research: intentional, knowing or reckless fraudulent behavior (fabrication, falsification, plagiarism, misrepresentation or other practices that deviate from international or national guidelines or codes of conduct for responsible research)

Devine EG, et al. *Clinical Trials* 2013; 10:935-948.

Common Types of Recruitment Misconduct or Wrongdoing

- Misrepresentation of eligibility criteria (participants falsely deemed eligible)
- Coercion & undue influence (participants pressured to join, esp vulnerable population)
- Inadequate informed consent (failures in fully informing participants of risks & benefits)
- Over-recruitment or ghost participants (enrolling participants who do not exist; providing misleading recruitment data; manipulation of recruitment data)
- Imposter participants (participants with fraudulent identification)
- Participants enroll in multiple studies simultaneously (objective of generating income/ “professional subjects”, concealment of health information, fabrication or exaggeration of symptoms)

Consequences of Recruitment Misconduct

- Participants: risk to safety, long-term health impacts, breach of trust
- Research integrity: data distortion, invalid or skewed results, delays in approval, retraction of studies
- Research resources: pharmaceutical and biological companies additional costs
- Public trust: damage to the credibility of clinical research & pharmaceutical companies

Peng Lee C, et al. *Contemp Clin Trials* 2018; 72:146-157.

Strategies to Avoid or Minimize Recruitment Misconduct

- Feasibility assessment:
  - Determine if site has appropriate expertise, right facilities, & resources for the trial
  - Find out what other sites are potentially involved in same trial & whether there is geographical overlap that could impact recruitment
  - Maintain open lines of communication among clinicians in area to discuss trials, identify overlapping populations of potential participants or demand on resources, best practices, barriers, etc

Zahren C, et al. *Clinical Trials* 2021; 18(5); 594-605.

Strategies to Avoid or Minimize Recruitment Misconduct

- Start-up
  - Undertake up-front trial planning & start-up activities before recruitment commences
  - Identify key staff, clarify roles & responsibilities
  - Develop a realistic & methodical participant recruitment plan
- Recruitment
  - Identify optimal method for participant recruitment
  - Utilize a diverse set of methods & strategies for minimizing chance of sampling/enrolling professional research subjects, or deception & fabrication to qualify for inclusion to the trial
  - If there are changes in the method of recruitment not mentioned in the original protocol, amendments should be made first for approval by the ethics review committee before implementing the additional recruitment method

Zahren C, et al. *Clinical Trials* 2021; 18(5):594-605.

Community Recruitment

- Community-based recruitment can complement clinic/hospital recruitment of participants to fill the enrollment demands of large studies depending on prevalence of disease condition & complexity of eligibility requirements
- This strategy engages with people & offers opportunity for information dissemination & education on disease & the clinical trial in quicker time. Collateral benefits to community include opportunities for screening & medical consults.
- Social preparation & assessing socioeconomic & cultural profile of community, including health-seeking behavior & health service system are necessary factors to consider when planning the strategies & activities for community-based recruitment

Ladia MAJ, et al. *J Clin Epi* 2018; 102:78-86.

Community Recruitment

- Engage community members in the research re benefits to study recruitment, participant participation, building partnership & trust with the community, creation of materials & processes tailored to community's specific characteristics
- Engagement of community personnel into the research team ensured that research is relevant to the community, addressed its specific needs, and benefit community with results

Key Points

- Adopting a community-based recruitment strategy must be decided at the planning stage for efficient coordination of activities.
- Recruitment should be conducted under specific inclusion/exclusion/withdrawal criteria aimed at “promoting & safeguarding the rights, safety, and well-being of all trial participants.
- Participant selection & recruitment consider various ethical concerns: (1) conflict of interest of sponsors, investigators, & recruitment team; (2) protection of privacy & confidentiality of participant information; (3) informed consent & recruitment modalities; (4) vulnerability of participants; (5) incentives & compensation for subjects; (6) community considerations.

Key Points

- Ethical recruitment in clinical trials prevent risks of misconduct & ensure participant safety.
- Recruitment misconduct & wrongdoing threaten both participant safety & the integrity of research findings. Efforts to identify & exclude ineligible participants are important to the integrity of research findings.
- Multifaceted approach using various methods & strategies are crucial to prevent & detect recruitment misconduct in clinical trials.

Lecture of Dr MLA Gonzales at PHREN, Oct 2024.

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- Lecture of Dr Ma. Liza Antoinette M. Gonzales during the Philippine Health Research Ethics Network (PHREN) 10th General Assembly on October 11, 2024