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# Recruitment and Retention of Underrepresented Populations in Clinical Trials

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## INTRODUCTION

Clinical trials are important for testing whether medical treatments are safe and effective. However, many clinical trials do not include enough participants from diverse racial, ethnic, and socioeconomic groups. This can make it difficult to apply research results to all populations. This literature review examines the reasons why some groups are underrepresented in clinical trials and evaluates strategies to improve recruitment and retention. Studies show that barriers such as transportation, work schedules, childcare responsibilities, and financial costs can limit participation. Communication challenges and mistrust in research may also reduce enrollment. Evidence suggests that active and participant-centered strategies such as phone calls, text reminders, and community partnerships can improve participation. Together, these barriers show that multi-dimensional recruitment strategies improve retention. Overall, the research indicates that combining multiple strategies is more effective than relying only on traditional recruitment methods.

## OBJECTIVE

- Identify and categorize the primary structural, financial, and relational barriers that limit trial participation among underrepresented groups.
- Compare the efficacy of passive recruitment methods (flyers, mailed letters) against active participant-centered outreach strategies (phone calls, SMS reminders).
- Evaluate multi-component models (combining simplified consent tools, transit support, and community engagement) to determine optimal framework design for participant retention.

## METHODS

A systematic literature review was conducted using primary, peer-reviewed sources. Key subtopics analyzed included structural and logistical obstacles, active vs. passive engagement strategies, interactive consent technology, and community-partnered decentralized trial models.

## RESULTS

Top 5 factors that would improve recruitment within each domain

| | Ranked 1st or 2nd (*n*) | % |
|---|---|---|
| **Incentive Factors** | | |
| Offering gift card incentives for participants' time and effort | 140 | 70.4% |
| Offering reimbursement for parking and transportation costs | 84 | 42.2% |
| Offering reimbursement for other study related costs like food and childcare | 55 | 27.6% |
| Gift cards being available electronically, rather than in physical form | 42 | 21.1% |
| Participants' ability to claim gift cards at a wide range of merchant or retailers | 42 | 21.1% |
| **Location Factors** | | |
| Reduction in the # of required in-person visits | 124 | 67.4% |
| Option to conduct in-person visits at additional sites/locations | 68 | 37.0% |
| Option of video visits with physician/staff | 47 | 25.5% |
| Converting in person data collection to online surveys | 46 | 25.0% |
| Ability to text participants for scheduling, recruiting, and/or protocol questions | 34 | 18.5% |
| **Research Literacy Factors** | | |
| Strong relationship between clinician and potential participant | 130 | 71.0% |
| Good reputation of the research institution | 72 | 39.3% |
| Education materials related to the study/drug/device | 61 | 33.3% |
| Videos that explain what research is | 58 | 31.7% |
| Website or other online resource that explains the study | 26 | 14.2% |

**Table 1: Conceptual Framework of Interacting Barriers to Clinical Trial Diversity.** Multiple factors including health literacy, institutional mistrust, protocol complexity, and structural obstacles (work schedules, travel distance, childcare) interact with system-level factors (underrepresented research workforce, implicit bias) to create major gaps in clinical trial recruitment and retention. Addressing these overlapping challenges requires active multi-component recruitment strategies rather than reliance on single traditional clinic-based approaches (adapted from Heffernan et al., 2023).

## RESULTS

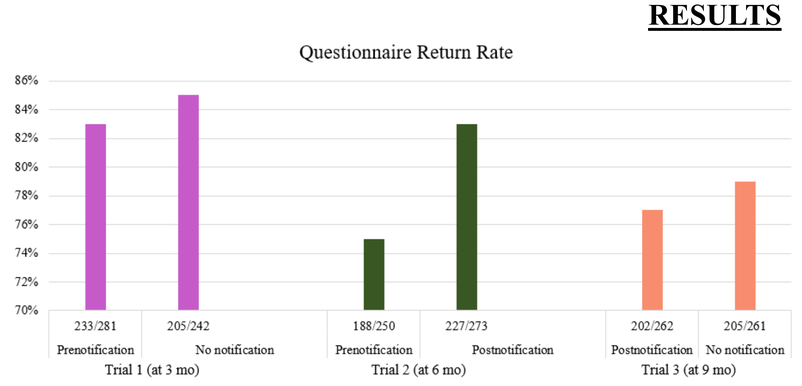
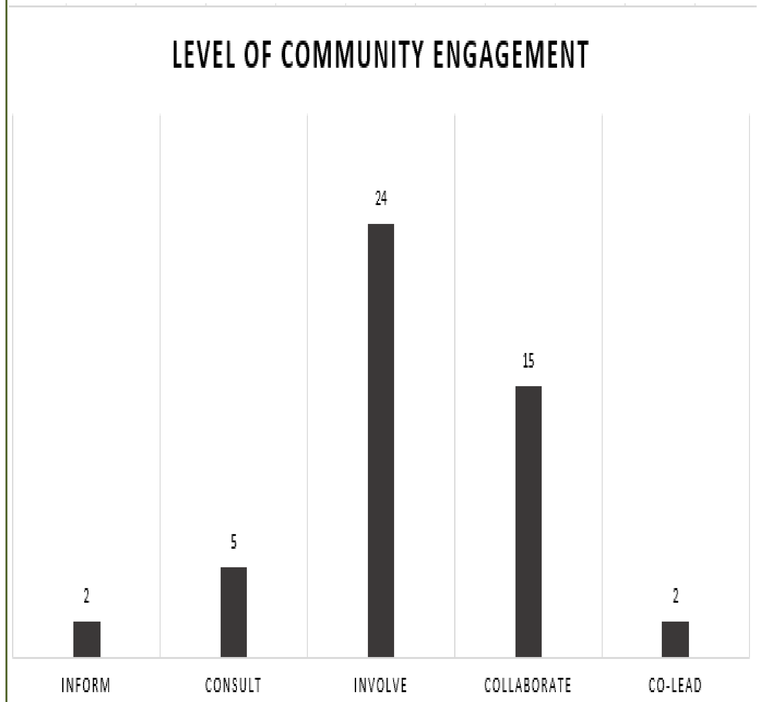



**Figure 1: Improvement in Trial Follow-Up Adherence via SMS Text Reminders.** In a randomized trial evaluating engagement strategies, post-notification SMS reminders sent shortly after mailing follow-up questionnaires significantly increased response rates to 83.2%, compared to 75.2% for pre-notifications ($p=0.025$), demonstrating that active post-outreach messaging improves participant retention (data from Keding et al., 2016).
*Note: Graph adapted and re-visualized from Keding et al. (2016). Non-significant secondary metrics excluded for clarity to focus exclusively on primary response rates and median return times.*

## RESULTS




**Primary Recruitment Outcomes**

**Inform:** Effective for basic recruitment, but lacks community input in material design

**Consult:** Helps build baseline trust and validates the study to local residents.

**Involve:** Effective for reaching hard to reach population and tailoring study material.

**Collaborate:** Builds deep trust, improves retention, and produces well informed interventions.

**Co-lead:** Integrates community skills directly, reduces participation barriers, and ensures community benefit.

**Figure 2: Levels of Community Engagement and Recruitment Outcomes in Clinical Trials.** Categorization of 48 clinical studies across the Spectrum of Community Engagement reveals that active community involvement (n=24) and collaboration(n=15) yield the strongest improvements in participant enrollment, retention, and institutional trust compared to passive information sharing (adapted from Brockman et al., 2023).

## FUTURE DIRECTIONS

- **RCTs needed:** Conduct randomized controlled trials directly comparing single component interventions against multi-component recruitment under identical conditions.
- **Measure structural supports:** Directly measure the isolated and combined impact of specific incentives (direct transit vouchers, paid time-off compensation, on-site childcare).
- **Evaluate digital barriers:** Assess digital consent tools to ensure technology-driven trials do not create new digital divide for lower-income or rural populations.
- **Long-term community models:** Investigate the long-term sustainability of community advisory boards and local healthcare partnerships across multi-year clinical trials.

## CONCLUSIONS

- **Passive methods are insufficient:** Informational readability alone does not overcome logistical, financial, or trust-related barriers.
- **Active engagement works:** Direct interaction through phone calls and text reminders substantially improves follow-up adherence and retention.
- **Multi-component integration is key:** Sustainable diversity in clinical trials requires multi-dimensional strategies that reduce structural burdens, utilize culturally responsive communication, and build local community trust simultaneously.

## REFERENCES