

Recruitment realities in community-based hybrid trials: An implementation science case example from the Smoke-Free Home SafeCare Study

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Abstract

Introduction: Community-based implementation trials are critical for establishing the real-world impact of prevention programs. However, these trials occur within complex service systems where organizational constraints, workforce instability, and participant recruitment barriers can hinder program implementation and threaten equitable reach. Successful recruitment is essential for trial validity, and for determining who ultimately benefits from evidence-based interventions. Practical guidance on identifying and addressing participant recruitment challenges in implementation trials remains limited. This case example examines parent recruitment barriers and responses within an ongoing Hybrid Type 1 effectiveness-implementation trial of Smoke-Free Home SafeCare (SFH-SC), a braided intervention designed to increase smoke-free home rules and reduce child maltreatment risk among parents of young children.

Methods: Using an iterative stakeholder-informed recruitment adaptation approach, the study team: (1) assessed recruitment barriers through interviews with community-based SafeCare providers enrolled in the trial (N = 15); (2) partnered with a health communication specialist to redesign parent recruitment materials and messaging; and (3) modified recruitment protocols to reduce participant burden.

Results: Parent recruitment data tracked quarterly from August 2022 through December 2025 demonstrated steady increases in screening and enrollment, with the largest quarterly gains occurring after full implementation of all recruitment strategies.

Conclusions: This case example highlights participant recruitment in implementation trials as an ongoing process that benefits from continuous monitoring, stakeholder engagement, and adaptation to ensure that trial participants reflect intended populations. We conclude with recommendations for greater transparency in reporting recruitment barriers and responsive adaptations, emphasizing their importance for advancing equitable public health outcomes.

Introduction

Community-based implementation trials are essential for closing the well-known research-to-practice gap because they provide data on intervention effects in real world service system settings. However, systems are often characterized by complex organizational, clinical, community, and social dynamics (Curran et al., 2012; Smith & Wilkins, 2018; Westerlund et al., 2019). Successful execution of these trials depends on participant recruitment and engagement strategies that function within the same multilevel systems in which interventions are ultimately delivered, requiring coordinated participation across multiple stakeholder groups (Williams et al., 2025). Participant recruitment is often shaped by factors operating across system, organizational, provider, and participant levels, making it a significant challenge in the design and execution of implementation trials. These challenges may be particularly salient in behavioral health and child maltreatment prevention research, where families often navigate cumulative stressors (Hunter & Flores, 2021; Slack et al., 2017; Younas & Gutman, 2023) and providers manage high caseloads, workforce instability, and burnout (Travis et al., 2016). In these contexts, participant

recruitment requires approaches that are responsive to the realities of the interconnected systems and the lived experiences of both families and frontline providers.

Despite the recognition that implementation occurs within dynamic and complex contexts, relatively little literature provides practical guidance for researchers on how to respond when recruitment and engagement strategies fail during implementation trials. To address this gap, we present a case example from an ongoing community-based Hybrid Type 1 effectiveness-implementation study evaluating Smoke-Free Home SafeCare (SFH-SC). SFH-SC is a braided intervention that integrates two effective interventions: SafeCare®, an 18-week parenting program that addresses child maltreatment risk in families with young children (Whitaker et al., 2020), and Some Things Are Better Outside (STBO), an evidence-based intervention that reduces secondhand smoke exposure in the home (Kegler et al., 2015; Perry et al., 2024; Self-Brown et al., 2023). The trial launched in 2022 in partnership with two well-established statewide SafeCare implementations (Oklahoma, Iowa) where tobacco use rates were above-average (CDC & National Center for Chronic Disease Prevention and Health Promotion, 2018). SafeCare is delivered by community-based organizations who partner with child welfare and family prevention systems to provide services to families at-risk or reported for child physical abuse or neglect. Providers from those organizations (i.e., the professionals who deliver SafeCare to families), were the means by which we recruited parents into the study. In this case example, we describe the parent recruitment barriers encountered in the trial, the strategies used to address them, and the lessons learned to inform future implementation research and practice in community-based settings. Our goal here is not to evaluate the effectiveness of the individual recruitment strategies, but rather to share learnings that may inform future community-based implementation science research.

Case context

Although the recruitment of SafeCare providers in the trial progressed as planned, parent recruitment did not. Despite our SafeCare state research partners serving upwards of 600 families per year, only three eligible parents enrolled during the first five months of recruitment. We initially hypothesized that several factors were contributing to recruitment difficulties. First, the parent eligibility criteria were highly restrictive. Initial criteria limited trial participation to 1) mothers of children 0 to 5-years-old enrolled in SafeCare implemented within the child protection system settings in Oklahoma or Iowa, 2) a tobacco user lives in the home, 3) no smoke-free home rules in the family home, and 4) mother is fluent in English. Second, recruitment relied solely on providers to introduce the study to the parents on their SafeCare caseload, distribute fliers, describe the study, and connect interested parents with the university-based research team. Third, the study launched in January 2022, amid the ongoing COVID-19 pandemic recovery. Families and child welfare providers already faced significant stress prior to the pandemic; however, COVID-19 further intensified these pressures, and shifted service delivery expectations and increased workloads.

Development of the Iterative Stakeholder-Informed Recruitment Adaptation Approach

Our original parent recruitment protocol, developed pre-pandemic and consistent with previously conducted SafeCare trials (Self-Brown et al., 2018; Self-Brown et al., 2017; Whitaker et al., 2020), was challenged by the COVID-recovery era, which impacted program delivery and the lives of providers and families. To address recruitment barriers, the study team engaged in an adaptive recruitment response process involving three interconnected strategies (described in detail below).

Strategy 1: Gather Feedback Stakeholder Feedback

Our study team gathered stakeholder feedback via semi-structured interviews with study e providers enrolled in the trial (N = 15). In the interviews, providers described non-modifiable and modifiable barriers to parent recruitment. Non-modifiable barriers were generally related to structural conditions affecting families, including cumulative social, economic, and service system stressors (many parents were engaged in multiple programs within the service system). Collectively these conditions limited parents' capacity to participate in research. Modifiable barriers to parent recruitment included parents' general distrust of research, and our study materials and approach to parent recruitment. Additional themes emerged around the clarity and tone of study recruitment messaging, provider comfort introducing the study to SafeCare parents, and the growing number of Spanish-speaking families being served.

Providers reported that the recruitment materials were not appealing to parents. For example, our initial materials emphasized research participation rather than family-centered benefits, had limited visual appeal, and competed with community resource fliers distributed at the same time—all of which led parents to overlook our recruitment fliers. Providers also described stigma related to discussing in-home smoking habits with parents, particularly when starting SafeCare services with a new family and when families had an open child welfare case. Collectively, these factors made providers hesitant to discuss the study with parents in fear of undermining their rapport building efforts.

In addition to identifying modifiable recruitment barriers, providers offered recommendations that informed our initial protocol modifications. To address concerns that the recruitment materials were visually unremarkable and unlikely to capture parents' attention, providers recommended developing culturally responsive materials with more engaging visuals and clearer, positively framed study messaging. Providers also suggested alternative referral procedures that would allow them to connect interested parents with the research team without directly addressing smoking behaviors. Finally, providers noted that many Spanish-speaking families on their caseloads smoked in the home and therefore met that inclusion criterion. Because study materials and procedures were available only in English, and initial inclusion criteria restricted these parents from participating, Spanish-speaking families were being excluded from the trial. Yet, both SafeCare and Some Things Are Better Outside being routinely delivered in Spanish in ongoing community-based implementations.

Strategy 2: Engage Additional Expertise

The study team considered an expansion of the team science approach beyond traditional public health and implementation science experts. We determined that we needed a health communication specialist with expertise in community-based implementation trials to help us redesign our parent-facing materials and messaging. Grounded in communication science, the health communication specialist guided a reframing of recruitment messaging for parents to emphasize partnership and child health, create multimodal materials (flyers, videos, magnets), simplify language across texts, and increase transparency about study expectations. These revisions aimed to increase trust in research, reduce stigma, and position parents as partners in improving child health. Importantly, these recommendations largely aligned with themes and suggestions identified in the provider interviews.

Strategy 3: Data-Driven Recruitment Protocol Refinement

Guided by research team deliberation and detailed consideration of provider and communication specialist feedback, we implemented recruitment protocol changes iteratively as IRB approvals, staffing, and budget allowed. We also conducted a process evaluation by closely tracking the number of parents we engaged with as we implemented the changes. Collectively, these adaptations were intended to improve study accessibility, reduce burden, and increase alignment between recruitment procedures and real-world service delivery contexts. Our recruitment protocol refinement included the following:

1. **SafeCare Partnership and System Expansion** from 1) two states to ten states, and 2) broadening recruitment from SafeCare only implemented within the child protection system to those also operating within high-risk prevention settings.
2. **Extended the parent recruitment window** from requiring completion of the trial baseline assessment to take place before the parent started the SafeCare program to allowing completion of the baseline assessment any time before the SafeCare module in which the Some Things are Better Outside content would be delivered (Safety or Health). Because the SafeCare program consists of three 6-week modules, this change expanded the recruitment window by up to 12 weeks, allowing enrollment from approximately prior to Session 1 through Session 12 of the 18-session program.
3. **Broadened caregiver eligibility** from 1) mothers to also include fathers and other primary caregivers, and 2) caregivers that were fluent in either English **or** Spanish. Specifically, we translated project advertisements and research assessments into Spanish and provided SafeCare Providers with SafeCare and STBO Spanish materials.
4. **Reduced SafeCare provider study burden** by simplifying referral procedures, clarifying provider recruitment scripts, and removing study screening responsibilities from providers. We asked providers to shift from pre-screening parents prior to referring them to our research team to connecting us with all interested parents. We also offered a small incentive (\$5) to parents for completing the initial eligibility screening call.

Results

We report data collected between August 2022 and December 2025 summarizing our iterative stakeholder-informed recruitment adaptation approach. The process evaluation documents that parent recruitment increased as we began to implement the new strategies. The largest increase occurred between Q2 and Q3 of 2024, when 22 additional parents were recruited and enrolled following implementation of all protocol modifications. This finding underscores the value of adopting a comprehensive, rather than piecemeal, approach to participant engagement. Figure 2 displays cumulative parent screening and enrollment over time. While recruitment remains ongoing at the time of submitting this manuscript, the trajectory demonstrates that iterative, stakeholder-informed recruitment adaptations can help to restore momentum in community-based implementation trials, even after early setbacks.

Discussion

Community-based implementation trials are conducted in complex service systems, where recruitment success depends on the alignment between research procedures, implementation context, and stakeholder priorities. Although implementation science has made substantial progress in identifying and testing implementation strategies alongside innovations, comparatively little attention has been devoted to identifying ways that we can improve the operations of the research itself, particularly how to navigate and respond to the day-to-day realities of conducting trials within real-world service settings. In this case example, we describe how we identified, learned from, and responded to the recruitment failures and operational challenges encountered during trial implementation. By detailing our learning process, we aim to provide practical insights that others can build upon and to highlight the importance of maintaining curiosity, flexibility, and responsiveness throughout the research process, not only during trial design but also during trial execution. More broadly, we hope this account contributes to growing a platform within the implementation science literature for sharing lessons learned about research operations, enabling the field to more rapidly improve the conduct of implementation research and ultimately accelerate progress toward closing the research-to-practice gap.

Lesson 1: Stakeholder Feedback Loops are Essential

Notably, implementation contexts and service settings may evolve between grant development and trial launch, requiring researchers to adapt to changing organizational and community conditions. Implementation trials can benefit from built-in, rapid feedback loops that enable researchers to learn from end-users in real time, to adjust, monitor, and refine recruitment strategies accordingly. In this case example, SafeCare provider interviews highlighted recruitment barriers and challenges that were modifiable and recommended strategies to address them. Embedding planned rapid feedback mechanisms into implementation trials allow for continuous improvement and the identification of study challenges before they become entrenched into study operations. Based on our learnings, we recommend that implementation research teams continuously center the voices of the communities they serve throughout all phases of the research process. Doing so can help identify opportunities to make research more acceptable, accessible, and feasible for participants while ensuring that both the

research and the innovations under study function effectively within the complex, multilevel systems in which they are implemented.

Lesson 2: Implementation Teams Need Broader Expertise

A second lesson we learned was the importance of broadening our definition of "team science." Implementation research teams are often composed primarily of experts from behavioral health and related disciplines. While this expertise is essential, implementation studies can benefit from including professionals from a wider range of fields, such as systems engineering, systems science, human-centered design, and communication studies, to strengthen both the innovations being implemented and the operational aspects of implementation research.

In our case example, the addition of expertise in health communication science transformed our recruitment approach and improved how we communicated with parent participants. Developing multimodal, engaging recruitment materials increased clarity, reduced stigma, and may have contributed to stronger rapport between parents and the research team. Although we expanded our team mid-study, the resulting materials coincided with increases in parent recruitment and highlight the value of integrating health communication expertise from the outset of implementation research. Initial outreach and engagement strategies are critical to study success, particularly when working with populations that may face competing demands, distrust of research, or other barriers to participation. Investing in communication expertise early in the research process can support implementation teams to develop effective, participant-centered recruitment and engagement approaches from the trial start.

Lesson 3: Adapt Protocols to Reflect Real-World Contexts

Implementation trials must strike a balance between methodological rigor and the realities of the research enterprise, while also being responsive to service delivery and settings within a constantly changing world. When research procedures are overly restrictive and rigid, they can impede recruitment, limit participation, and create burdens that reduce the relevance of study findings to routine practice. Consistent with principles of pragmatic trial design, protocol modifications may be necessary to ensure that studies remain feasible and that participating populations, providers, and settings reflect the conditions under which interventions are ultimately delivered (Zatzick et al., 2023). While we may not experience another global pandemic in our lifetime, we, as researchers, need to evolve to the often-changing lived experiences and needs of the communities and populations we serve. Expanding parent eligibility criteria, widening the enrollment window, adding states and implementation settings, and reducing the added burden associated with research activities were all pragmatic protocol modifications that enhanced the fit between our trial and SafeCare standard community practice. Rather than compromising the study's aims, these changes improved our capacity to evaluate the braided intervention delivered in routine service settings.

Lesson 4: The Field Needs Reporting Mechanisms for Sharing Real-World Challenges

Many challenges encountered during community-based implementation trials are discussed informally among colleagues, at conferences, in webinars, or through professional networks. However, with a few noted exceptions, these experiences and lessons learned are rarely documented in the peer-reviewed literature where they can benefit a broader audience (Greer et al., 2020; Williams et al., 2025). As a result, there is limited access for scientists to learn from others and improve *how* our science is being conducted.. In the absence of this form of shared learning, we as a field can perpetuate the misconception, particularly for early career implementation scientists, that recruitment difficulties reflect solely on shortcomings of research teams and implementation sites, rather than the challenges inherent in working within service systems.

Our experience highlights this gap. When recruitment challenges emerged in our trial, we responded by adapting our protocol as quickly as possible to remain on track with study timelines. In searching the literature for guidance, we found relatively few published examples describing recruitment barriers, operational challenges, or real-time protocol modifications within pragmatic and hybrid effectiveness-implementation trials. As new recruitment strategies were introduced over time, a natural time-series pattern emerged that allowed us to observe how adaptations corresponded with changes in parent recruitment. Through this process, we recognized the importance of documenting and sharing these experiences to support transparency and collective learning across the field, beyond what we are testing in the trials themselves.

While relatively uncommon, a few recent studies have begun to address this need by describing recruitment barriers and adaptation strategies in greater detail. For example, Williams et al. (2025) presented a multilevel framework, assessment guide, and strategies used to achieve recruitment and retention goals across different stakeholder levels of their trial. We argue that case-based reporting formats are particularly valuable for capturing the iterative, context-dependent nature of implementation research and for documenting how research teams respond to operational challenges as they arise. Greater recognition and publication dissemination of these experiences could accelerate learning across studies and strengthen the implementation science field, and the dissemination and accessibility of our innovations.

Conclusions

This case example highlights the practical challenges and adaptations required to conduct implementation trials in real-world service settings, while underscoring the importance of documenting and disseminating these experiences and lessons learned to advance the field. The primary contribution of this paper is not the identification of a single set of recruitment best practices. Rather, we propose an iterative stakeholder-informed recruitment adaptation approach as a pragmatic framework for responding to operational challenges that are common, based on our experience, during implementation trials. The parent recruitment challenges encountered in our trial reflected a misalignment between the original recruitment strategy, developed 3 + years prior as part of the grant submission process, and the current realities faced by families and providers in a post-pandemic context. Through stakeholder

engagement, interdisciplinary collaboration, and protocol refinement, we improved the acceptability of our study procedures to meet the needs of the target population, ultimately strengthening parent recruitment.

This case example also serves as a call to action for greater transparency and shared learning regarding the operational realities of implementation research. Moving forward, implementation science would benefit from broader, more systematic reporting of study setbacks alongside successes. Creating opportunities to have these dialogues with a broader audience can accelerate collective learning and strengthen the infrastructure needed to conduct rigorous and successful implementation research. Such efforts are essential not only for improving individual trials, but also for advancing the broader goals of implementation science by reducing the research-to-practice gap, supporting equitable implementation, and ensuring that evidence-based interventions reach the populations they are intended to benefit.

Declarations

Author Contribution

Author Contributions: Conceptualization: SSB, KG, EP; Methodology: SSB, KG, EP; Formal analysis and investigation: EP, MR Writing - original draft preparation: SSB, EP; Writing - review and editing: EP, MR, KG, MM, DJ, JM, CS, JH, KK, MK; Funding acquisition: SSB, MK; Resources: National Cancer Institute

Data Availability

Data are available by request of email to the lead author.

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Figures



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Figure 1

Comparison of the Original Trial Flyer (LEFT) to Updated Trial Flyer (RIGHT)

Figure 2: Cumulative Number of Parents Screened for Eligibility and Enrolled Across Each Quarter and Year

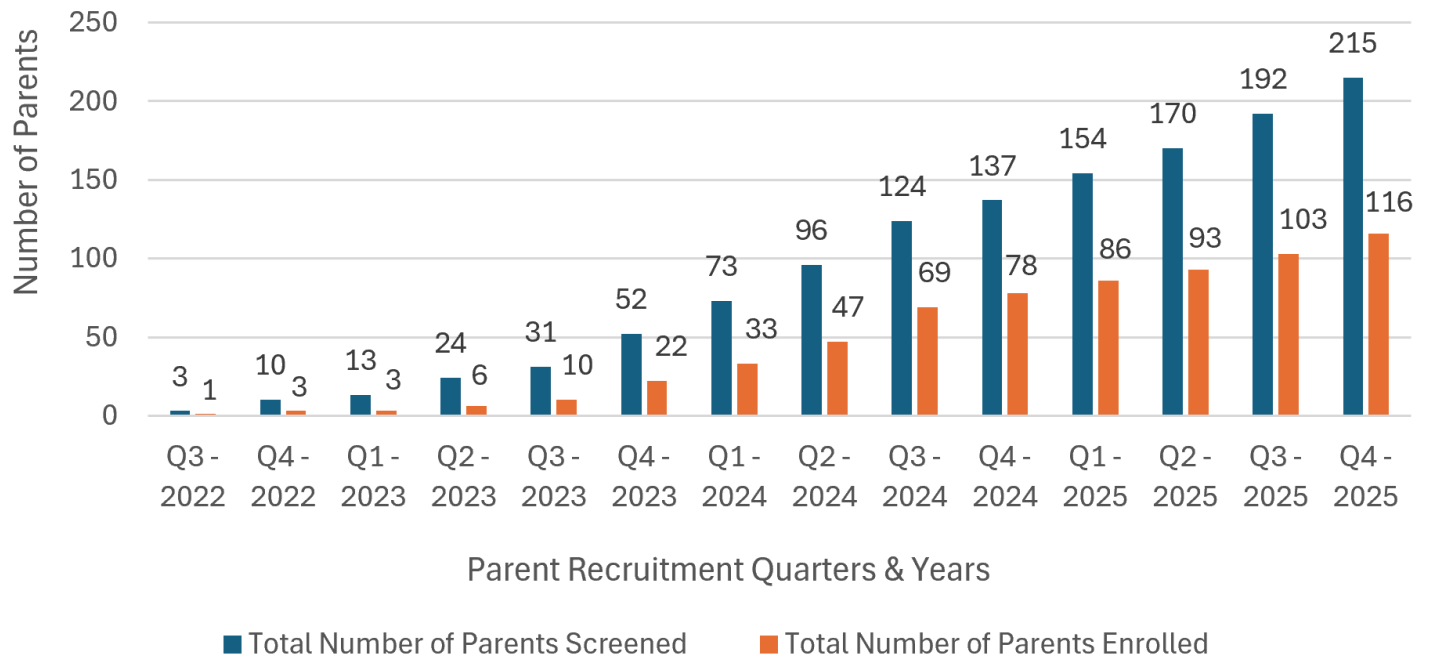


Figure 2

Cumulative Parent Screening and Enrollment Across Study Quarters During the Iterative Stakeholder-Informed Recruitment Adaptation Process