Facilitators and barriers to pediatric clinical trial recruitment and retention in rural and community settings: A scoping review of the literature

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Abstract

Children in rural settings are under-represented in clinical trials, potentially contributing to rural health disparities. We performed a scoping review describing available literature on barriers and facilitators impacting participation in pediatric clinical trials in rural and community-based (nonclinical) settings. Articles identified via PubMed, CINAHL, Embase, and Web of Science were independently double-screened at title/abstract and full-text levels to identify articles meeting eligibility criteria. Included articles reported on recruitment or retention activities for US-based pediatric clinical studies conducted in rural or community-based settings and were published in English through January 2021. Twenty-seven articles describing 31 studies met inclusion criteria. Most articles reported on at least...
INTRODUCTION

Well-designed and executed clinical trials improve patient outcomes by informing evidence-based clinical medicine and public health interventions. However, clinical trials have consistently under-represented pediatric and adult participants from rural communities. This under-representation affects the quality of care for rural populations, and likely contributes to the persistent health disparities related to rurality that are observed in the United States.

Previous studies have identified a number of general barriers to participation in pediatric clinical trials. Barriers that have been reported for children and families include a lack of understanding of clinical research, mistrust of the research process, and logistical challenges (e.g., language barriers, financial constraints, transportation barriers, and time/opportunity costs for working parents/caregivers). Study procedures that are perceived to cause discomfort or stress may also negatively influence participant enrollment and retention.

Recruitment and retention facilitators were similar across settings and included contacts/reminders, community engagement, and relationship-building, consideration of participant logistics, and incentives. Inadequate staff and resources were commonly cited recruitment and retention barriers. Few studies have rigorously examined optimal ways to recruit and retain rural participants in pediatric clinical trials. To expand the evidence base, future studies examining recruitment and retention strategies should systematically assess and report rurality and objectively compare relative impact of different strategies.

METHODS

We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping reviews (PRISMA-ScR) statement and checklist to guide the conduct and reporting of this scoping review.

Scoping review protocol

The scoping review protocol was developed using a Population or Participants, Intervention, Control or Comparison, Outcome (PICO) framework. The population was defined as children aged less than or equal to 21 years residing in rural areas, with clinical trials as the intervention. Outcomes of interest included results that described barriers and facilitators of recruitment and retention, and to identify knowledge gaps for this topic area.

Information sources and search

A research librarian conducted electronic searches in PubMed, CINAHL, Embase, and Web of Science using
either MeSH or keyword classifications of the following terms: rural, rural populations, child, adolescent, barriers to recruitment, refusal to participate, clinical trial, and clinical study. Based on the initial search, the terms rural or rural populations proved so limiting that these terms were removed for the final search, which was conducted in January 2021. The full electronic search strategy for the PubMed database is included as Supplementary Material.

Eligibility criteria

Articles reporting on recruitment or retention activities for a clinical study with a randomized controlled trial (RCT), cohort, case-control, case report/series, cross-sectional, qualitative, or survey design, conducted with participants living in the United States and published in English in the peer-reviewed literature through January 2021 were considered eligible. Review articles, commentaries, consensus statements, and theses or dissertations were excluded. Study participants had to be: (1) children ages 0–21 years or their caregivers or physicians/advanced practice providers of children, if the study addressed their perspectives on children’s participation in research; and (2) recruited from rural communities. However, during the process of conducting the review, the scoping review protocol and eligibility criteria were expanded to include articles in which study recruitment occurred in other (i.e., suburban and urban) community settings, as there were few studies with participants recruited in rural communities. Studies were considered to be conducted in a community setting if recruitment and retention activities occurred outside of a clinic or hospital. The scoping review team felt that information about facilitators or barriers of recruitment and retention for studies conducted in other community settings (e.g., schools and participant homes) might be relevant to conducting pediatric clinical trials in rural areas, as rural areas are often medically underserved, and hospitals and clinics are not always feasible as the key recruitment and retention partners.

Selection of sources of evidence

After the primary searches, identified citations were combined and duplicates were removed. The article selection process was then managed using Rayyan QCRI, a web application for collaboratively managing article selection during systematic reviews. The title and abstract for each article were independently screened by two reviewers (authors S.E.W., J.S., C.A.M., A.K., and E.Y.J.) to identify potentially relevant articles. The full text of potentially relevant articles was then reviewed for inclusion in the scoping review. Two assigned reviewers (authors S.E.W., P.S., J.S., L.C., C.A.M., R.M., C.S.L., M.B., A.W., M.M., L.K., K.C., and E.Y.J.) independently assessed each full-text article against the eligibility criteria. Discrepancies related to article inclusion were resolved by discussion between the two assigned reviewers, or by a third independent reviewer if needed. For articles with unclear recruitment setting (n = 5), authors were contacted for clarification (3 responses) before a decision was made about including the article in the scoping review.

Data charting process

Data from the included full-text articles were extracted by two independent reviewers (authors S.W., P.S., L.C., C.S.L., K.K., A.W., M.M., and E.Y.J.) using a REDCap form developed and tested by the review team. The REDCap form prompted systematic extraction of the following elements: author, year, title, study design, recruitment or retention setting, major participant in study intervention/activities (e.g., child, parent/caregiver, primary care provider), number of participants, age range of participants, and recruitment and retention barriers and facilitators. No assessment of risk of bias was performed.

Synthesis of results

Extracted data were summarized in tables. During the process of creating the tables, discrepancies related to the extracted data were resolved by discussion between the two individuals assigned to create and review the tables (authors S.E.W. and E.Y.J.) or by a third independent reviewer if needed.

RESULTS

Selection of sources of evidence

The initial search identified 849 articles (Figure 1). Of these, 221 articles were duplicates, leaving 628 articles for title and abstract screening, of which 200 were included in the full-text review. After full-text review, 27 articles met eligibility criteria for the scoping review.

Characteristics of sources of evidence

General characteristics of the articles included in the scoping review are summarized in Table 1. The articles
primarily reported on recruitment or retention strategies for RCTs, cluster-randomized trials, sequential multiple assignment randomized trials, cohort studies, or cross-sectional studies (n = 22 articles, 81%). Many articles described study team observations and “lessons learned” regarding use of different recruitment and retention approaches or frameworks, with some focusing on how recruitment and retention approaches had evolved over the course of a study. In most cases, these articles were narrative summaries of investigator experiences, although, in some cases, the conclusions were supported by completing analysis of study records or interviews by conducting focus groups or surveys with study staff, site personnel, or participants. Two articles compared recruitment or retention outcomes across similar studies that used different recruitment or retention methods or frameworks. One article compared recruitment and retention rates for participants who initiated contact with the study via different strategies (in clinics, in the community, or via informatics). Two articles examined relationships among child, caregiver, family, neighborhood, or county-level characteristics and recruitment or retention measures. The other articles included in this scoping review summarized the results of cross-sectional surveys (n = 3 articles, 11%), or interviews, or focus groups (n = 2 articles, 7%) that were conducted outside the context of a specific clinical trial, and focused on obtaining stakeholder feedback on general recruitment and retention efforts in clinical trials.

Almost all of the articles reflected on study team efforts to recruit or retain children or adolescents, child/adolescent-caregiver dyads, or caregivers. Five articles described efforts to involve stakeholders at sites as essential to recruitment and retention for community-based pediatric clinical trials. These stakeholders included non-investigator pediatric primary care or subspecialty physicians and advanced practice providers or school personnel.

The articles summarized 31 studies, with the study recruitment or retention setting varying across articles and
| Author (Year) | Title                                                                 | Study design                                                                 | Recruitment or retention setting | Major participant in study intervention/activities | Number of participants | Age range of participants |
|--------------|----------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------|------------------------|--------------------------|
| Bansa, et al. (2018) | A Little Effort Can Withstand the Hardship: Fielding an Internet-Based Intervention to Prevent Depression Among Urban Racial/Ethnic Minority Adolescents in a Primary Care Setting | Description of recruitment and/or retention strategies for an RCT: used study records and surveys and interviews with primary care providers and clinic staff | Urban community healthcare care setting | Adolescents | 11 | Mean age = 16.2 years |
| Basson, et al. (2019) | Recruiting Adolescents from Medicaid Enrollment Files into a Neighborhood Oral Health Study | Description of recruitment and/or retention strategies for a cross-sectional study: described differences in recruitment/retention measures by county rurality, neighborhood-level income and caregiver language preference | Rural (Hood River and Tillamook Counties in Oregon) and Urban Community (Multnomah County in Oregon) | Adolescents | 335 | Age range: 12 to 17 years |
| Brown, et al. (2015) | Adolescent Knowledge and Attitudes Related to Clinical Trials | Cross-sectional survey | Unspecified community (Southeast Michigan) | Adolescents | 82 | Age range: 13 to 18 years |
| Crane, et al. (2019) | Engaging and Retaining youth SSI Recipients in a Research Demonstration Program: Maryland PROMISE | Description of recruitment and/or retention strategies for an RCT: study records, interviews with study staff | Unspecified community (Maryland) | Adolescents | 997 | Age range: 14 to 16 years |
| Cruz, et al. (2014) | Engagement, Recruitment, and Retention in a Trans-Community, Randomized Controlled Trial for the Prevention of Obesity in Rural American Indian and Hispanic Children | Description of recruitment and/or retention strategies for an RCT: summary of investigator experience | Rural Community | Children | 1879 | Age range: 3 to 4 years |
| Cunningham-Erves, et al. (2019) | Factors Influencing Parental Trust in Medical Researchers for Child and Adolescent Patients’ Clinical Trial Participation | Cross-sectional survey | Unspecified community (Middle Tennessee) | Parents/guardians | 256 | N/A |

(Continues)
| Author (Year) | Title | Study design | Recruitment or retention setting | Major participant in study intervention/activities | Number of participants | Age range of participants |
|---------------|-------|--------------|----------------------------------|-----------------------------------------------|------------------------|----------------------------|
| Flores, et al. (2017)³⁹ | A Successful Approach to Minimizing Attrition in Racial/Ethnic Minority, Low-Income Populations | Description of recruitment and/or retention strategies for an RCT: compared attrition rates in primary study with retention strategic framework vs. two previous RCTs | Urban community | Parents/guardians and children | 266 | N/A |
| Garcia, et al. (2017)³³ | Retention strategies for health disparities preventive trials: findings from the Early Childhood Caries Collaborating Centers | Description of recruitment and/or retention strategies for a cluster RCTs or RCTs: study staff rated retention strategies | Rural Native American Community (2 RCTs) | Children | 1616 | Age ranges: 0–3 months and 3–5 years |
| Greenberg, et al. (2018)⁴⁶ | Perceived barriers to pediatrician and family practitioner participation in pediatric clinical trials: Findings from the Clinical Trials Transformation Initiative | Cross-sectional survey | Urban and rural unspecified community (national database of US physicians and national professional association e-mail listserv) | Non-investigator Pediatric Primary Care or Subspecialty Physicians/advanced practice providers | 136 | N/A |
| Greenberg, et al. (2018)⁴⁷ | Parents’ perceived obstacles to pediatric clinical trial participation: Findings from the clinical trials transformation initiative | Qualitative (interviews or focus groups) | Unspecified community (patient advocacy group and marketing research firm) | Parents/guardians | 24 | N/A |
| Grunbaum, et al. (1996)³³ | Recruitment and Enrollment for Project HeartBeat! Achieving the Goals of Minority Inclusion | Description of recruitment and/or retention strategies for a cohort study: summary of investigator experience with evolution of recruitment strategies over time | Suburban and urban community | Schools and children or adolescents | 678 | Age range: 8 to 14 years |
| Guzman, et al. (2009)²⁴ | Recruitment and Retention of Latino Children in a Lifestyle Intervention | Description of recruitment and/or retention strategies for an RCT: investigator description of recruitment/retention strategies | Suburban and urban community | Parents/guardians and children/adolescents | 123 | Mean age = 9.3 years |
| Hartlieb, et al. (2015)⁴¹ | Recruitment Strategies and the Retention of Obese Urban Racial/Ethnic Minority Adolescents in Clinical Trials: The FIT Families Project, Michigan, 2010–2014 | Description of recruitment and/or retention strategies for a sequential multiple assignment randomized trial: compared recruitment and retention rates for participants recruited through community, clinics or informatics | Urban community | Parents/guardians and children/adolescents | 186 | Age range: 12 to 16 years |
| Author (Year)          | Title                                                                 | Study design                                                                 | Recruitment or retention setting     | Major participant in study intervention/activities | Number of participants | Age range of participants |
|-----------------------|------------------------------------------------------------------------|-------------------------------------------------------------------------------|-------------------------------------|----------------------------------------------------|------------------------|---------------------------|
| Hayes, et al. (2014)²⁵| Strong, Smart and Bold Strategies for Improving Attendance and Retention in an After-School Intervention | Description of recruitment and/or retention strategies for an RCT: summary of investigator experience with evolution of recruitment strategies over time | Urban community                     | Children and adolescents                          | 517                    | Age ranges: 10 to 12 years and 14 to 16 years |
| Hooven, et al. (2011)²⁶| Increasing Participation in Prevention Research: Strategies for Youths, Parents, and Schools | Description of recruitment and/or retention strategies for RCTs: investigator description of principles and techniques used for recruitment and retention | Urban community                     | Schools, parents, and adolescents                 | 521 (study 1) + 615 (study 2) | Mean ages = 15.98 and 15.96 years |
| Julion, et al. (2018)²⁷| A Tripartite Model for Recruiting African Americans into Fatherhood Intervention Research | Description of recruitment and/or retention strategies for an RCT: investigator description of recruitment model and strategies | Urban community                     | Parents/guardians                                 | 157                    | N/A                       |
| Kafka, et al. (2011)²⁸| Children as Subjects in Nutrition Research: A Retrospective Look at Their Perceptions | Description of recruitment and/or retention strategies for an RCT: focus groups with participants | Urban community                     | Children                                           | 35                     | Age range: 7 to 10 years  |
| McCullough, et al. (2017)⁴⁰| Barriers to Recruitment in Pediatric Obesity Trials: Comparing Opt-in and Opt-out Recruitment Approaches | Description of recruitment and/or retention strategies for an RCT: compared recruitment rates for studies that recruited participants using opt-in or opt-out methods | Rural community (2 RCTs)             | Children                                           | 273                    | Age ranges: 3 to 7 years and 8 to 12 years |
|                      |                                                                        |                                                                               | Urban community (1 RCT)             | Children                                           | 149                    | Age range: 2 to 5 years  |
| Owen-Smith, et al. (2020)⁴⁸| Factors Influencing Participation in Biospecimen Research among Parents of Youth with Mental Health Conditions | Qualitative (interviews or focus groups)                                      | Unspecified Community (Georgia, Oregon, Southwest Washington, Northern California) | Parents/guardians                                 | 58                     | N/A                       |
| Peterson, et al. (2000)²⁸ | Experimental Design and Methods for School-Based Randomized Trials. Experience from the Hutchinson Smoking Prevention Project (HSPP) | Description of recruitment and/or retention strategies for an RCT: investigator description of strategies to recruit/retain school sites and retain participants | Rural, suburban, urban community (predominantly rural) | Schools and children or adolescents               | 8388                   | Age range: 8 to 18 years |
| Shattuck, et al. (2020)²⁶| Recruitment of Schools for Intervention Research to Reduce Health Disparities for Sexual and Gender Minority Students | Description of recruitment and/or retention strategies for a cluster RCT: qualitative analysis of study recruitment logs | Rural and urban community            | Schools                                            | 42                     | N/A                       |

(Continues)
| Author (Year) | Title | Study design | Recruitment or retention setting | Major participant in study intervention/activities | Number of participants | Age range of participants |
|--------------|-------|--------------|----------------------------------|-----------------------------------------------|------------------------|--------------------------|
| Tiwari, et al. (2014) 29 | Recruitment for health disparities preventive intervention trials: The early childhood caries collaborating centers | Description of recruitment and/or retention strategies for a cluster RCTs or RCTs: investigator description of community engagement strategies to enhance recruitment | Rural Native American Community (2 RCTs) | Children | 1616 | Age ranges: 0–3 mo and 3–5 yr |
| Tomayko, (2017) 30 | Healthy Children, Strong Families 2: A Randomized Controlled Trial of a Healthy Lifestyle Intervention for American Indian Families Designed Using Community-Based Approaches | Description of recruitment and/or retention strategies for an RCT: investigator description of community engagement strategies to enhance recruitment | Unspecified Community: US-Mexico border, San Diego, CA (1 RCT) | Children | 597 | Age range 2.5–3 years |
| Villarruel, (2006) 37 | Recruitment and Retention of Latino Adolescents to a Research Study: Lessons Learned from a Randomized Clinical Trial | Description of recruitment and/or retention strategies for an RCT: investigator description of recruitment and retention infrastructure and summary of retention survey conducted with adolescent participants | Urban community | Adolescents | 553 | Age range 13 to 18 years |
| Wise, et al. (2010) 31 | Using Action Research to Implement an Integrated Pediatric Asthma Case Management and eHealth Intervention for Low-Income Families | Description of recruitment and/or retention strategies for an RCT: summary of investigator experience with using action research to evolve recruitment strategies over time | Rural and urban community | Children or adolescents | 305 | Age range 4 to 12 years |
| Young, et al. (2018) 42 | Predicting Enrollment in Two Randomized Controlled Trials of Nonpharmacologic Interventions for Youth with Primary Mood Disorders | Description of recruitment and/or retention strategies for RCTs: examined child and family characteristics as predictors of study enrollment | Urban community | Children or adolescents | 119 | Age range 7 to 14 years |
| Yu, et al. (2020) 32 | Addressing the Challenges of Recruitment and Retention in Sleep and Circadian Clinical Trials | Description of recruitment and/or retention strategies for an RCT: investigator description of recruitment and retention barriers and facilitators | Urban Community | Adolescents | 176 | Age range 10 to 18 yrs |

Abbreviations: N/A, not applicable; RCT, randomized controlled trial.

*aNumbers included in the table are for the primary study.

*bReports results of 2 RCTs. Numbers included in the table are for the pediatric RCT only.
sometimes within an article. The majority of the articles reported on at least one study conducted entirely in an urban or suburban community setting (n = 15 articles, 56%) or an unspecified community setting (n = 8 articles, 30%). Fewer articles reported on studies with recruitment or retention efforts that the investigators characterized as spanning both urban and rural community settings (n = 5 articles, 19%) or on studies with recruitment or retention efforts that occurred exclusively or predominantly in areas that investigators defined as rural (n = 5 articles, 19%). Overall, more studies discussed recruitment facilitators (n = 25 studies, 81%) and barriers (n = 19 studies, 61%) versus retention facilitators (n = 15 studies, 48%) and barriers (n = 8 studies, 26%).

**Results of individual sources of evidence**

**Rural recruitment and retention**

Five articles detailed recruitment and/or retention strategies from six RCTs conducted in exclusively or predominantly rural areas. These studies were focused on prevention or treatment of dental caries, overweight/obesity, and smoking. In all five articles, the geographic site of recruitment or author attestation that recruitment sites were rural was used as the proxy for rurality, with Garcia and colleagues and Tiwari and colleagues reporting on RCTs that recruited from rural American Indian reservation areas (the Pine Ridge Reservation and Navajo Nation), Cruz and colleagues specifying that recruitment was exclusively with rural Head Start centers enrolling predominantly Hispanic or American Indian children in New Mexico, Peterson and colleagues indicating the inclusion of “predominantly...rural school districts” within 200 miles of Seattle, Washington, and McCullough and colleagues noting that participant contacts occurred at Cooperative Extension Services offices in rural counties in north central Florida.

**Mixed rural and urban community recruitment and retention**

Four articles reported on recruitment and/or retention strategies from four studies conducted across rural and urban settings. This included one article describing a cross-sectional survey that recruited medical providers nationally via email lists maintained by a physician database and the American Academy of Pediatrics. Proximity to the nearest academic medical center or children’s hospital was reported as part of describing the characteristics of providers included in the study, but the reporting of recruitment facilitators was not stratified by this proxy variable for rurality. Another article examined the relationship among county-level rurality, neighborhood-level income, and caregiver language preference and recruitment, and retention measures for adolescents identified via Medicaid records and approached about participating in a community-based oral health study. County-level rurality was determined according to the Oregon Office of Rural Health, which defines rural as a geographic area greater than 10 miles from a population center of greater than or equal to 40,000 people. The other articles detailed investigator experience with recruiting schools statewide in New Mexico for a cluster-RCT with the goal of promoting health equity for sexual and gender minority students and with recruiting low-income families from rural and urban counties in Wisconsin for an RCT examining the impact of monthly nurse case management delivered via telehealth, along with access to the Comprehensive Health Enhancement Support System’s Living with Asthma program, on outcomes for pediatric patients with asthma.

**Community recruitment in predominantly suburban or urban or unspecified community settings**

Twenty-three articles discussed recruitment and retention strategies for 21 studies conducted in predominantly suburban or urban community settings or in unspecified community settings. Most of these studies reported on recruitment or retention strategies for RCTs focused on prevention, including prevention of dental caries, depression, cardiovascular disease, teen pregnancy, drug abuse, suicide, school dropout, and HIV, as well as healthy lifestyle promotion, and sports nutrition. Other studies described recruitment or retention strategies for RCTs testing clinical treatments for obesity, mood disorders, or sleep and circadian disorders, or interventions designed to impact social determinants of health, such as father involvement, career development, or enrollment in medical insurance. One study conducted a cross-sectional survey with teens recruited in educational settings to assess their awareness of clinical trials and willingness to participate in them. Three studies described the results of cross-sectional surveys or interviews with parents examining factors related to their trust in medical researchers and willingness to consent to have their child participate in a clinical trial.
Recruitment facilitators

Studies that examined recruitment facilitators included seven conducted in predominantly or exclusively rural settings or across urban and rural settings, and 18 conducted in other community settings. Table 2 summarizes the number of times specific recruitment facilitators were indicated across studies, stratified by setting. Broadly, factors supporting recruitment efforts were divided into contact methods, community engagement in recruitment, logistical considerations, research procedures, and other factors. Across studies conducted in both predominantly or exclusively rural settings and other community settings, the most frequently mentioned facilitator category was contact methods. In rural settings, research teams frequently used the telephone and flyers or postcards to contact potential participants. In other community settings, telephone and flyers or postcards were also commonly used, with face-to-face contact also frequently cited as a recruitment facilitator.

Logistical considerations and community engagement in recruitment were also commonly highlighted as facilitators of recruitment. A wide variety of community engagement

| Facilitators                                      | Predominantly or exclusively rural (n = 7 studies) No. of instances reported | Other community settings (n = 18 studies) No. of instances reported |
|--------------------------------------------------|-------------------------------------------------------------------------------|------------------------------------------------------------------|
| Contact methods                                   |                                                                               |                                                                  |
| Face-to-face                                      | 220,26                                                                        | 1021,25,28,30,31,34,35                                          |
| Telephone                                         | 620,27(a,b),38(a,b),41                                                        | 824,25,27(c,d),34,38(c),39,41                                    |
| Email                                             | 220,27(a)                                                                     | 525,27(c,d),34,46                                               |
| Flyers, postcards, mail                          | 427(a,b),38(a,b)                                                              | 923,25,27,28,30,38–40,46                                       |
| Local media                                       | 327(a),38(a,b)                                                                | 322,39,40                                                      |
| Community engagement in recruitment               |                                                                               |                                                                  |
| Bilingual/cultural factors                        | 220,41                                                                        | 422,27(d),35,41                                               |
| Recruitment by member of the community            | 220,27(b)                                                                    | 1121,23,25,28,30,31,34–36,39                                   |
| Community partners/advisory committee             | 227(a,b)                                                                     | 525,27(c,d),34,35                                             |
| Letter of support from tribal leaders             | 220                                                                           | –                                                              |
| Connection to university                          | 220                                                                           | –                                                              |
| Recruitment through schools                       | 227(a,b)                                                                     | 223,40                                                        |
| Logistical considerations                         |                                                                               |                                                                  |
| Convenient location for study activities          | 420,26,27(a),41                                                              | 921,24,25,27(d),29,35,39,41,46                                 |
| Convenient time for study activities              | 120                                                                           | 921,22,24,25,29,30,35,43,46                                   |
| Incentives                                        | 420,27(a,b),41                                                                | 1323,24,27(c,d),28,30,35,36,39–41,43,46                       |
| Research procedures                               |                                                                               |                                                                  |
| EMR/claims database for identification            | –                                                                             | 329,38(c),39                                                  |
| Opt-out process                                   | –                                                                             | 138(c)                                                        |
| Electronic tracking database and reminders         | –                                                                             | 121                                                           |
| Rolling recruitment                               | 126                                                                           | –                                                              |
| Patient orientation sessions                      | 120                                                                           | –                                                              |
| Other                                             |                                                                               |                                                                  |
| Show empathy for parents and concern for child    | –                                                                             | 145                                                           |
| Approach parent at non-stressful time             | –                                                                             | 145                                                           |
| Emphasis on importance of study, share results    | –                                                                             | 326,45,46                                                    |
| Travel assistance                                 | –                                                                             | 327(c),40,46                                                  |

Note: Studies included by Tiwari et al.²⁷ are: (a) CNOHR I, (b) CNOHR II, (c) GIFVT, and (d) TSHS. Studies included for McColluh et al.³⁸ are: (a) E-FLIP, (b) Chirp, and (c) Launch.

Facilitators were examined at a study level. Some articles may be referenced in both setting columns, as they included multiple studies with different settings or a single study that covered different settings.

Includes studies with mixed rural and urban, predominantly suburban, or unspecified community settings.
methods were used in rural settings. In other community settings, recruitment by a community member was the most commonly discussed community engagement strategy. In rural settings, a convenient location for study activities and incentives were frequently mentioned as facilitating recruitment. These factors were also emphasized in other community settings, along with a convenient time for study activities.

Recruitment barriers

One study in predominantly or exclusively rural setting and 18 studies in other community settings discussed recruitment barriers. The number of times that specific recruitment barriers were indicated across studies is summarized in Table 3, stratified by setting. Factors detracting from recruitment efforts were divided into contact methods, logistical considerations, research procedures, and other factors. For the rural study, a lack of study staff and resources for recruitment were cited as barriers. The most common barriers to recruitment in other community settings also included lack of recruitment staff and resources, as well as family distrust or apprehension, lack of family time and interest, and a wide variety of factors associated with the participant burden and potential risks of study research procedures.

| TABLE 3 | Recruitment barriers identified by studies from articles included in scoping review, by setting
| --- | --- |
| **Barriers** | Predominantly or exclusively rural (n = 1 study) | Other community settings<sup>b</sup> (n = 18 studies) |
| **No. of instances reported** | **No. of instances reported** |
| Contact methods |  |  |
| Difficulty contacting potential participants | – |  | 21,24 |
| Logistical considerations |  |  |
| Not enough study staff support | 1 | 20 | 4 | 25,27<sup>c</sup>,31,44 |
| Lack of resources for study teams | 1 | 20 | 5 | 1,21,31,34,43 |
| Need to expand the age range | – |  | 1 | 31 |
| Need for implementation beyond the clinic | – |  | 1 | 31 |
| Lack of time/interest of family | – |  | 5 | 29,30,35,40,46 |
| Distance from site | – |  | 1 | 40 |
| Lack of insurance coverage for trial | – |  | 2 | 3,43 |
| Research procedures |  |  |
| Scary/painful procedure | – |  | 4 | 30,36,45,46 |
| Complicated study logistics | – |  | 2 | 21,45 |
| Child as a “guinea pig” | – |  | 1 | 43 |
| Child will lose privacy | – |  | 3 | 30,43,46 |
| Extended recruitment period | – |  | 1 | 23 |
| Rigorous run-in procedures | 1 | 20 | 1 | 29 |
| Side effects of treatment/unclear benefit | – |  | 2 | 36,43 |
| Did not like the study drug/topic | – |  | 2 | 30,40 |
| Other |  |  |
| Distrust/apprehension | – |  | 11 | 2,25,30,31,34-36,42,43,45,46 |
| Parent’s marital status | – |  | 1 | 40 |
| Weather | – |  | 1 | 27<sup>c</sup> |
| Community/peer perception | – |  | 2 | 30,34 |
| Child too young to participate | – |  | 1 | 43 |
| Timing of intervention | – |  | 1 | 24 |

*Note: Studies included by Tiwari et al.<sup>27</sup> are: (a) CNOHR I, (b) CNOHR II, (c) GIFVT, and (d) TSHS.

*Abbreviation: EMR, electronic medical record.*

<sup>a</sup>Barriers were examined at a study level. Some articles may be referenced in both setting columns, as they included multiple studies with different settings.

<sup>b</sup>Includes studies with mixed rural and urban, predominantly suburban, or unspecified community settings.
Retention facilitators

Three studies in predominantly or exclusively rural settings and 12 studies in other community settings assessed retention facilitators. The number of times that specific retention facilitators were indicated across studies is summarized in Table 4, stratified by setting. Factors positively influencing retention were categorized as contact methods, community engagement, logistical considerations, and research procedures. Contact methods and logistical considerations were commonly highlighted as important facilitators across both rural and other community settings. In rural settings, a wide variety of contact methods were cited, with letters to parents/guardians and visit reminders mentioned more than once. In other community settings, visit reminders were the most frequently mentioned retention strategy. Across both rural and other community settings, community engagement focused on

| Facilitators                                      | Predominantly or exclusively rural (n = 3 studies) | Other community settings (n = 12 studies) |
|--------------------------------------------------|--------------------------------------------------|-----------------------------------------|
| Contact methods                                  |                                                  |                                         |
| Letters to parent/guardian                        | $2^{33(a,b)}$                                    | $5^{32,33(c,d),37,39}$                  |
| Contact for re-engagement                        | $1^{38(b)}$                                      | $4^{33(c,d),37,39}$                    |
| Reinforcing importance of study                   | –                                                | $1^{37}$                               |
| Birthday cards                                   | $1^{33(a)}$                                      | $4^{22,33(c,d),35}$                    |
| Visit reminders                                   | $2^{33(a,b)}$                                     | $8^{20,22,23,25,30,33(c),35,37}$       |
| Social media (Facebook messenger)                | $1^{33(a)}$                                      | $1^{28}$                               |
| Community engagement                             |                                                  |                                         |
| Relationship building activities$^c$              | $2^{26,33(a,b)}$                                  | $6^{22,24,25,30,32,33(d)}$             |
| Culturally and linguistically appropriate study materials | –                                                | $1^{35}$                               |
| Involve community in developing retention strategies | $2^{33(a,b)}$                                     | –                                       |
| Logistical considerations                         |                                                  |                                         |
| Incentives                                       | $2^{26,33(a,b)}$                                  | $11^{20,22,23,28,30,33(c,d),35–37,40}$ |
| Home visits                                      | $1^{33(b)}$                                      | $4^{32,33(d),37,39}$                   |
| Telephone visits                                 | $1^{26}$                                         | $1^{30}$                               |
| Flexible time/location for study procedures       | –                                                | $5^{30,32,35}$                         |
| Transportation/parking vouchers                  | –                                                | $2^{22,40}$                            |
| Childcare for siblings                           | –                                                | $1^{40}$                               |
| Research procedures                               |                                                  |                                         |
| Consistent study personnel                        | –                                                | $4^{22,24,30,35}$                      |
| Study retention specialist/strategies$^d$         | $1^{28}$                                         | $6^{22–24,30,33(d),35,37}$             |
| Delivering results to participant                 | –                                                | $1^{40}$                               |
| Study cell phone (caller ID)                      | –                                                | $1^{22}$                               |
| Intervention integrated into school day           | –                                                | $1^{24}$                               |
| Distraction techniques during painful procedures  | –                                                | $1^{36}$                               |
| Research staff training on building relationships  | –                                                | $1^{37}$                               |

Note: Studies included by Garcia et al.$^{13}$ are: (a) CNOHR I, (b) CNOHR II, (c) GIFVT, and (d) TSHS.

$^a$Facilitators were examined at a study level. Some articles may be referenced in both setting columns, as they included multiple studies with different settings.

$^b$Includes studies with mixed rural and urban, predominantly suburban, or unspecified community settings.

$^c$Relationship building activities include building relationships with schools, study-wide events, empathetic and positive interactions, research staff addressing parent’s concerns, respect for youth privacy and confidentiality, and study staff participating in community activities.

$^d$Strategies used by retention specialists include: bilingual staff, member of community as retention specialist, frequent team meetings to communicate about retention, electronic tracking of contact information and participation, telephone calls, maintain participant contact information, maintain alternate contact information.
relationship building and incentives were frequently discussed retention facilitators. One rural study and a number of studies conducted in other community settings, mentioned including a retention specialist on the study team; this individual was often bilingual, from the community, and focused on forming ongoing relationships with participants and maintaining their current contact information.

Retention barriers

One study in a predominantly or exclusively rural setting and seven studies in other community settings assessed retention barriers. The number of times that specific retention barriers were indicated across studies is summarized in Table 5, stratified by setting. Factors negatively influencing retention were categorized as community engagement, logistical considerations, and research procedures. The rural study noted that inadequate study resources or participant incentives and inadequate staff time detracted from participant retention. In other community settings, many logistical considerations were cited, with lack of participant time being most common. Staff turnover and study research procedures that were repetitive, embarrassing, or sensitive were also frequently mentioned as retention barriers.

| TABLE 5 Retention barriers identified by studies from articles included in scoping review, by setting |
|---------------------------------------------------------------|
| Barriers | Predominantly or exclusively rural (n = 1 studies) | Other community settingsb (n = 7 studies) |
| Community engagement | No. of instances reported | No. of instances reported |
| Inadequate support from family/friends | – | 135 |
| Logistical considerations | | |
| Time for participant | – | 430,35,37,40 |
| Conflict with other obligations | – | 223,35 |
| Distance for participant | – | 140 |
| Inadequate resources or incentives | 223(a,b) | 333(d),35 |
| Delay between recruitment and study start | – | 123 |
| Coordination of group sessions | – | 123 |
| Employment status of caregiver | – | 137 |
| Research procedures | | |
| Staff turnover | – | 223,25,33(d) |
| Time for staff | 133(b) | 223(c,d) |
| Study proceduresc | | 30,35,36 |
| Study topic not viewed as important | – | 137 |

Note: Studies included by Garcia et al.33 are: (a) CNOHR I, (b) CNOHR II, (c) GIFVT, and (d) TSHS.

Overall, we identified six studies that were conducted in predominantly or exclusively rural settings22,28,29,35,40 and four studies that were conducted across urban and rural settings31,36,43,46 that focused on recruitment and retention for pediatric clinical trials. This indicates that little has been published on this topic in the 10 years since Lim and colleagues conducted their search.4 Across studies, there was no common definition of rurality, and it was often established based only on author report that a county or geographic area was rural. In about a third of the cases, the article contained too little information to determine the study setting (urban, suburban, and/or rural community setting). Only two studies examined retention in rural settings, with only one describing barriers to retention, highlighting a need for more study of effective retention practices for pediatric clinical trials in rural settings. We found a number of additional articles that examined recruitment and retention in other community-based settings, and there were commonalities in some of the recruitment and retention barriers and facilitators that were identified across rural and other community settings. Across studies, common recruitment and retention facilitators included contacts or reminders via telephone, flyers, postcards, or face-to-face interaction, community
engagement and relationship-building efforts, careful consideration of participant logistics, and incentives. Lack of study staff and resources were commonly cited as recruitment and retention barriers. Most of the articles that we identified were narrative summaries of investigator experience, with few articles taking a more in-depth qualitative or analytic approach to comparing different strategies or frameworks.

The lack of a common definition or clear communication of the rurality of the study setting or participant residence across studies made conducting this scoping review challenging. Study settings were often not clearly described, limiting reviewer ability to identify when recruitment or retention facilitators and/or barriers were specific to rural populations. Based on the practices observed while conducting this scoping review, standardizing approaches to defining rurality in pediatric clinical trials is likely necessary to facilitate future scoping or systematic reviews examining questions related to rurality. Defining rurality is surprisingly complex, with no established gold standard and many factors to consider, including access to health services, population density, proximity to urban areas, and commuting flow. Across US federal agencies, several different definitions of rurality are used. For example, the Census defines urbanized areas based on the number of individuals in the area and then considers people, housing, and land outside of urban areas to be rural; this definition has evolved over time. In contrast, the Office of Management and Budget (OMB) defines counties as metropolitan (urban), micropolitan (rural), or neither (rural) based on the number of individuals in the county. The Census approach may overestimate the number of people in rural areas by classifying suburban areas as rural, whereas the OMB approach may underestimate the number of people in rural areas by classifying rural areas within counties as urban. The definition selected is clearly consequential, with Roberts and colleagues noting heterogeneity between estimates of the proportion of the population defined as rural, ranging from 6–17%, when four different definitions of rurality (Census, OMB, Rural-Urban Commuting Areas, and Isolation) were applied. Similar heterogeneity was identified by Hall and colleagues. when applying five definitions (Census, OMB, Urban Influence Codes, Rural-Urban Continuum Codes, and Rural-Urban Commuting Area Codes) to breast cancer incidence rates. Rurality reporting guidelines for researchers could highlight strengths and weaknesses of each approach for defining rurality, based on study design, location, and intended outcomes. The guidelines could also address reporting standards for clinical trials that are conducted in exclusively or predominantly rural areas, as well as reporting standards for studies that cover both urban and rural areas or recruit across broad geographic areas.

Most of the studies reviewed were narrative summaries of investigator experience with recruitment and retention barriers and facilitators. Investigator insights are valuable but may be biased. There was limited or no information available about cost-effectiveness or relative impact of different recruitment or retention facilitators. This information is important for study planning, as limited staff and resources for recruitment and retention were frequently identified as a barrier across settings. The resources involved in implementing certain strategies, such as in-person contacts or community meetings, may substantially differ between rural and urban settings. Study designs that allow for direct comparison of different recruitment and retention approaches within and across settings could be helpful in better informing research practice.

This scoping review had some limitations. One limitation is that we did not include a “retention” term in our search, perhaps explaining our finding that there were fewer articles that discussed retention. Another limitation of this scoping review is that it was not designed to systematically examine recruitment and retention facilitators and barriers outside of the location. There are many other factors that can impact research participation, particularly for individuals that are traditionally under-represented in research. Intersectionality occurs when multiple social factors, such as rurality and discrimination related to race/ethnicity, sexual orientation, gender identity, or disability, result in compounding challenges for research participants. In this review, we included some studies that reported challenges and effective recruitment and retention approaches for individuals from Indigenous (4 articles), Black (10 articles), Hispanic/Latino (8 articles), sexual and gender minority (1 article), or disability communities (1 article). These articles noted that it was essential to have recruitment and retention staff who were familiar with the community culture and preferred languages and to minimize logistical barriers for caregivers and community partners; in addition, they identified the need for more resources to allow for intensive community stakeholder and participant engagement around research participation (e.g., by acknowledging historical trauma related to past research abuses, building relationships/trust through frequent contact, or identifying a shared agenda).

However, our search did not comprehensively identify all articles identifying barriers and solutions based on social factors beyond location or the intersection of multiple social factors. Future reviews could address this gap.

**CONCLUSION**

Few studies have rigorously examined ways to optimize recruitment and retention of rural participants in pediatric
clinical trials. To assist with expanding the evidence base in this area, researchers evaluating study recruitment and retention barriers and facilitators should consider systematically assessing and reporting the rurality of the study setting and/or participant location and objectively comparing relative impact and cost of different recruitment and retention strategies.

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CONFLICT OF INTEREST
The authors declared no competing interests for this work.

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**SUPPORTING INFORMATION**

Additional supporting information may be found in the online version of the article at the publisher’s website.

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