4-2022

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

Sara E. Watson

Paul Smith

Jessica Snowden

Vida Vaughn

Lesley Cottrell

See next page for additional authors

Creator(s)
Sara E. Watson, Paul Smith, Jessica Snowden, Vida Vaughn, Lesley Cottrell, Christi A. Madden, Alberta S. Kong, Russell McCulloh, Crystal Stack Lim, Megan Bledsoe, Karen Kowal, Mary McNally, Lisa Knight, Kelly Cowan, and Elizabeth Yakes Jimenez

Received: 7 September 2021 | Revised: 7 December 2021 | Accepted: 11 December 2021

DOI: 10.1111/cts.13220

REVIEW

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

Sara E. Watson[1] | **Paul Smith**[2] | **Jessica Snowden**[3] | **Vida Vaughn**[4] | **Lesley Cottrell**[5] | **Christi A. Madden**[6] | **Alberta S. Kong**[7] | **Russell McCulloh**[8,9] | **Crystal Stack Lim**[10] | **Megan Bledsoe**[11] | **Karen Kowal**[12] | **Mary McNally**[13] | **Lisa Knight**[14] | **Kelly Cowan**[15] | **Elizabeth Yakes Jimenez**[7]

[1]Department of Pediatrics, University of Louisville and Norton Children's Hospital, Louisville, Kentucky, USA

[2]University of Montana, Missoula, Montana, USA

[3]University of Arkansas Medical Sciences, Little Rock, Arkansas, USA

[4]University of Louisville, Louisville, Kentucky, USA

[5]West Virginia University, Morgantown, West Virginia, USA

[6]University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, USA

[7]University of New Mexico Health Sciences Center, Albuquerque, New Mexico, USA

[8]Department of Pediatrics, University of Nebraska Medical Center, Omaha, Nebraska, USA

[9]Children's Hospital and Medical Center, Omaha, Nebraska, USA

[10]Department of Psychiatry and Human Behavior, University of Mississippi Medical Center, Jackson, Mississippi, USA

[11]Children's Mercy Hospital, Kansas City, Missouri, USA

[12]Nemours Children's Health System, Wilmington, Delaware, USA

[13]Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, USA

[14]University of South Carolina, Columbia, South Carolina, USA

[15]University of Vermont, Burlington, Vermont, USA

Correspondence
Sara E. Watson, 571 S. Floyd St., Ste 128, Louisville, KY 40202, USA.
Email: sara.watson@louisville.edu

Funding information
This study was funded by the National Institutes of Health (NIH) grants: NIH: UG1 OD024954; NIH: UG1 OD024952; NIH: U24OD024957; NIH: UG1 OD030016; NIH: UG1 OD024950; NIH: UG1 OD024947; NIH: UG1 OD024953; NIH: UG1 OD024942; NIH: UG1 OD024943; NIH: UG1 OD024958; NIH: UG1 OD024946; NIH: UG1 OD024956; NIH: Lesley Cottrell UG1 OD024955. Funding is through the NIH ECHO

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

(Environmental Influence on Child Health Outcomes) ISPCTN (IDeA States Pediatric Clinical Trials Network)

one study conducted in an urban or suburban or unspecified community setting ($n = 23$ articles; 85%); fewer ($n = 10$; 37%) reported on studies that spanned urban and rural settings or were set in rural areas. More studies discussed recruitment facilitators ($n = 25$ studies; 81%) and barriers ($n = 19$; 61%) versus retention facilitators ($n = 15$; 48%) and barriers ($n = 8$; 26%). Descriptions of recruitment and retention barriers and facilitators were primarily experiential or subjective. 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.

INTRODUCTION

Well-designed and executed clinical trials improve patient outcomes by informing evidence-based clinical medicine and public health interventions.[1] However, clinical trials have consistently under-represented pediatric and adult participants from rural communities.[2–4] 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.[5,6]

Previous studies have identified a number of general barriers to participation in pediatric clinical trials.[7–10] 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).[7,10–13] Study procedures that are perceived to cause discomfort or stress may also negatively influence participant enrollment and retention.[8,14–16] Some of these barriers may apply evenly across the United States pediatric population, but others (e.g., transportation barriers) may have a disproportionate impact on rural participants.

To address the pervasive under-representation of rural populations in pediatric clinical research, it is important to summarize what is currently known about factors specific to rural areas that affect recruitment and retention for pediatric clinical trials. As part of a 2011 commentary discussing recruitment barriers and challenges for pediatric psychology treatment outcomes research, Lim and colleagues conducted a systematic search for other studies examining this topic and found only two studies focused on recruitment-related issues in rural pediatric settings.[4] No recent scoping or systematic reviews have been conducted to synthesize the literature on this topic for rural pediatric populations, indicating the need to conduct a scoping review.[17] The objectives of this scoping review are to describe the volume of the available literature on barriers and facilitators that impact pediatric clinical trial recruitment and retention specific to rural populations, to examine how researchers are assessing barriers and facilitators of recruitment and retention, and to identify knowledge gaps for this topic area.

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.[18]

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 that impact pediatric clinical trial recruitment and retention in rural populations.

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,[19] 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.[20] 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.[21] 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

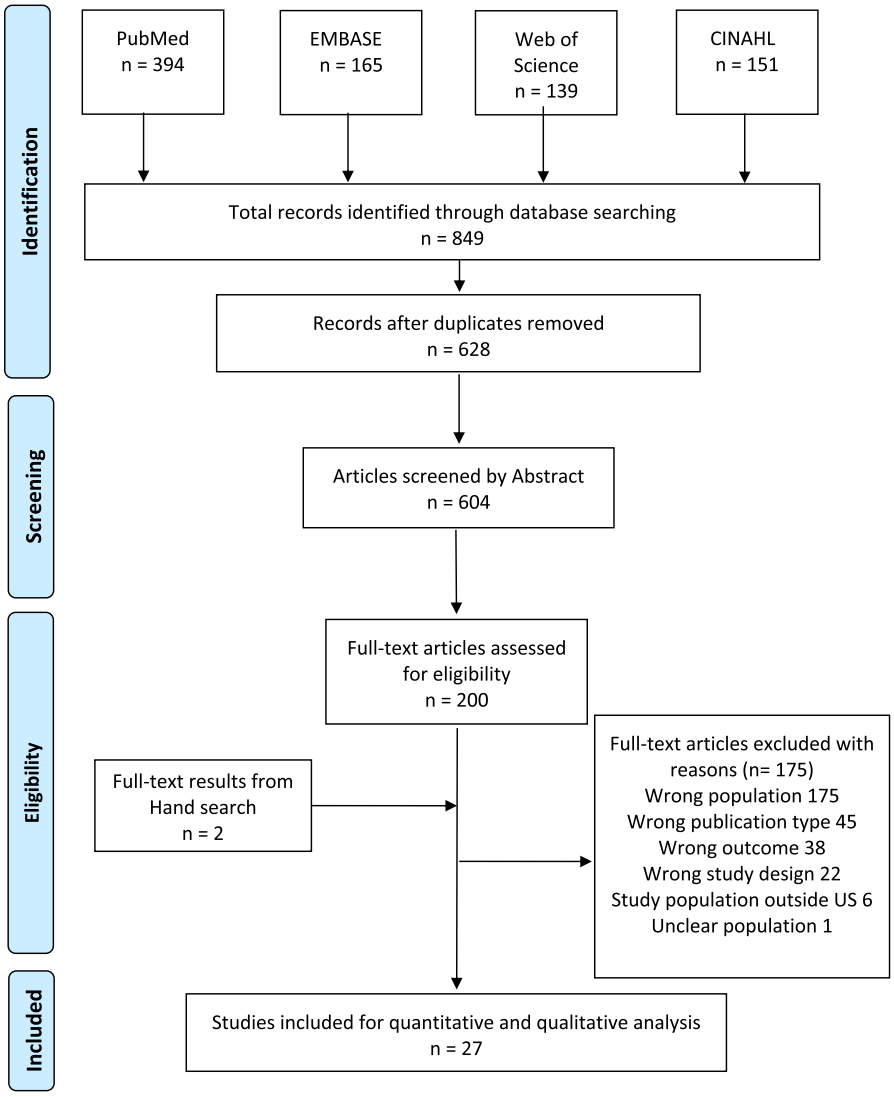

FIGURE 1 Flow chart illustrating each step of conducting a scoping review examining facilitators and barriers to recruitment and retention in studies conducted in rural and other community-based settings[56]

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,[22–32] although, in some cases, the conclusions were supported by completing analysis of study records or interviews or by conducting focus groups or surveys with study staff, site personnel, or participants.[33–38] Two articles compared recruitment or retention outcomes across similar studies that used different recruitment or retention methods or frameworks.[39,40] 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).[41] Two articles examined relationships among child, caregiver, family, neighborhood, or county-level characteristics and recruitment or retention measures.[42,43] The other articles included in this scoping review summarized the results of cross-sectional surveys[44–46] ($n = 3$ articles, 11%), or interviews,[47,48] 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[46] or school[23,26,28,36] personnel.

The articles summarized 31 studies, with the study recruitment or retention setting varying across articles and

TABLE 1 Study descriptions

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)[33]	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)[43]	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)[44]	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)[34]	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)[22]	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)[45]	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)

TABLE 1 (Continued)

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[a]	Urban community	Parents/guardians and children	266	N/A
Garcia, et al. (2017)[35]	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
			Unspecified community: US-Mexico border, San Diego, CA (1 RCT)	Children	597	Age range: 2.5–3 years
			Urban community (1 RCT)	Children	1065	Age range: 0–5 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)[23]	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

TABLE 1 (Continued)

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)[38]	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) Urban community (1 RCT)	Children Children	273 149	Age ranges: 3 to 7 years and 8 to 12 years 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)[36]	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)

TABLE 1 (Continued)

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
			Unspecified Community: US-Mexico border, San Diego, CA (1 RCT)	Children	597	Age range: 2.5–3 years
			Urban community (1 RCT)	Children	1421	Age range: 0–5 years
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 (5 Native American communities nationwide)	Parents/guardians and children/ adolescents	450	Age range: 2 to 5 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[b]	Urban Community	Adolescents	176	Age range: 10 to 18 yrs

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

[a]Numbers included in the table are for the primary study.

[b]Reports 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[23–27,29,32,33,35,37–42] ($n = 15$ articles, 56%) or an unspecified community setting[29,30,34,35,44,45,47,48] ($n = 8$ articles, 30%). Fewer articles reported on studies with recruitment or retention efforts that the investigators characterized as spanning both urban and rural community settings[31,36,40,43,46] ($n = 5$ articles, 19%) or on studies with recruitment or retention efforts that occurred exclusively or predominantly in areas that investigators defined as rural[22,28,29,35,40] ($n = 5$ 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.[22,28,29,35,40] 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.[31,36,43,46] 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.[46] 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.[43] 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.[43] 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[36] 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.[31]

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,[29,35] depression,[33] cardiovascular disease,[25] teen pregnancy,[23] drug abuse,[26] suicide,[35] school dropout,[22] and HIV,[37] as well as healthy lifestyle promotion,[24,30] and sports nutrition.[38] Other studies described recruitment or retention strategies for RCTs testing clinical treatments for obesity,[40,41] mood disorders,[42] or sleep and circadian disorders,[32] or interventions designed to impact social determinants of health, such as father involvement,[27] career development,[34] or enrollment in medical insurance.[39] 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.[44] Three studies described the results of cross-sectional surveys[45] or interviews[47,48] 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

TABLE 2 Recruitment facilitators identified by studies from articles included in scoping review, by setting[a]

Facilitators	Predominantly or exclusively rural ($n = 7$ studies) No. of instances reported	Other community settings[b] ($n = 18$ studies) No. of instances reported
Contact methods		
Face-to-face	2[20,26]	10[21-25,28,30,31,34,35]
Telephone	6[20,27(a,b),38(a,b),41]	8[24,25,27(c,d),34,38(c),39,41]
Email	2[20,27(a)]	5[25,27(c,d),34,46]
Flyers, postcards, mail	4[27(a,b),38(a,b)]	10[23,25,27,28,30,38–40,46]
Local media	3[27(a),38(a,b)]	3[22,39,40]
Community engagement in recruitment		
Bilingual/cultural factors	2[20,41]	4[22,27(d),35,41]
Recruitment by member of the community	2[20,27(b)]	11[21–23,25,28,30,31,34–36,39]
Community partners/advisory committee	2[27(a,b)]	5[25,27(c,d),34,35]
Letter of support from tribal leaders	1[20]	–
Connection to university	1[20]	–
Recruitment through schools	2[27(a,b)]	2[23,40]
Logistical considerations		
Convenient location for study activities	4[20,26,27(a),41]	9[21,24,25,27(d),29,35,39,41,46]
Convenient time for study activities	1[20]	9[21,22,24,25,29,30,35,43,46]
Incentives	4[20,27(a,b),41]	13[23,24,27(c,d),28,30,35,36,39–41,43,46]
Research procedures		
EMR/claims database for identification	–	3[29,38(c),39]
Opt-out process	–	1[38(c)]
Electronic tracking database and reminders	–	1[21]
Rolling recruitment	1[26]	–
Patient orientation sessions	1[20]	–
Other		
Show empathy for parents and concern for child	–	1[45]
Approach parent at non-stressful time	–	1[45]
Emphasis on importance of study, share results	–	3[36,45,46]
Travel assistance	–	3[27(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.

[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 or a single study that covered different settings.

[b]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[a]

Barriers	Predominantly or exclusively rural ($n = 1$ study) No. of instances reported	Other community settings[b] ($n = 18$ studies) No. of instances reported
Contact methods		
Difficulty contacting potential participants	–	2[21,24]
Logistical considerations		
Not enough study staff support	1[20]	4[25,27(c),31,44]
Lack of resources for study teams	1[20]	5[3,21,31,34,43]
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[3,25,30,31,34-36,42,43,45,46]
Parent's marital status	–	1[40]
Weather	–	1[27(c)]
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.[27] are: (a) CNOHR I, (b) CNOHR II, (c) GIFVT, and (d) TSHS.

Abbreviation: EMR, electronic medical record.

[a]Barriers 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.

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

TABLE 4 Retention facilitators identified by studies from articles included in scoping review, by setting[a]

Facilitators	Predominantly or exclusively rural ($n = 3$ studies) No. of instances reported	Other community settings[b] ($n = 12$ studies) No. of instances reported
Contact methods		
Letters to parent/guardian	2[33(a,b)]	5[32,33(c,d),37,39]
Contact for re-engagement	1[33(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]	3[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	3[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	–	3[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[26]	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.[33] 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.

DISCUSSION

Overall, we identified six studies that were conducted in predominantly or exclusively rural settings[22,28,29,35,40] and four studies that were conducted across urban and rural settings[31,36,43,46] 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

TABLE 5 Retention barriers identified by studies from articles included in scoping review, by setting[a]

Barriers	Predominantly or exclusively rural ($n = 1$ studies) No. of instances reported	Other community settings[b] ($n = 7$ studies) No. of instances reported
Community engagement		
Inadequate support from family/friends	–	1[35]
Logistical considerations		
Time for participant	–	4[30,35,37,40]
Conflict with other obligations	–	2[23,35]
Distance for participant	–	1[40]
Inadequate resources or incentives	2[33(a,b)]	3[23,33(d),35]
Delay between recruitment and study start	–	1[23]
Coordination of group sessions	–	1[23]
Employment status of caregiver	–	1[37]
Research procedures		
Staff turnover	–	3[23,25,33(d)]
Time for staff	1[33(b)]	2[33(c,d)]
Study procedures[c]	–	3[30,35,36]
Study topic not viewed as important	–	1[37]

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

[a]Barriers 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]Including activities were repetitive, questions were embarrassing, emotional burden.

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.[49,50] Across US federal agencies, several different definitions of rurality are used.[51] 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[51,52]; this definition has evolved over time.[53] 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.[51,54] 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.[50] 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.[49] 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[55] 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),[22,29,30,35] Black (10 articles),[23,27,29,31,33,35,39,41,44,45] Hispanic/Latino (8 articles),[22,24,29,33,35,37,39,44] sexual and gender minority (1 article),[36] or disability communities (1 article).[34] 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).[23,27,29–31,33,34,36,37,39,44,45] 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.

ACKNOWLEDGEMENTS

The authors wish to extend thanks to Amy Wilson, PhD, RN, and Phyllis Nader, BSE, for their assistance with this project.

CONFLICT OF INTEREST

The authors declared no competing interests for this work.

REFERENCES

1. Chalmers TC, Smith H Jr, Blackburn B, et al. A method for assessing the quality of a randomized control trial. *Control Clin Trials*. 1981;2(1):31-49.
2. Friedman DB, Foster C, Bergeron CD, Tanner A, Kim S-H. A qualitative study of recruitment barriers, motivators, and community-based strategies for increasing clinical trials participation among rural and Urban populations. *Am J Health Promot*. 2015;29(5):332-338.
3. Baquet CR, Commiskey P, Daniel Mullins C, Mishra SI. Recruitment and participation in clinical trials: socio-demographic, rural/urban, and health care access predictors. *Cancer Detect Prev*. 2006;30(1):24-33.
4. Lim CS, Follansbee-Junger KW, Crawford MS, Janicke DM. Treatment outcome research in rural pediatric populations: the challenge of recruitment. *J Pediatr Psychol*. 2011;36(6):696-707.
5. Leider JP, Meit M, McCullough JM, et al. The state of rural public health: enduring needs in a new decade. *Am J Public Health*. 2020;110(9):1283-1290.
6. Bolin JN, Bellamy GR, Ferdinand AO, et al. Rural healthy people 2020: new decade. Same Challenges. *J Rural Health*. 2015;31(3):326-333.
7. Patterson CA, Chavez V, Mondestin V, Deatrick J, Li Y, Barakat LP. Clinical trial decision making in pediatric sickle cell disease: a qualitative study of perceived benefits and barriers to participation. *J Pediatr Hematol Oncol*. 2015;37(6):415-422.
8. Brody JL, Annett RD, Scherer DG, Perryman ML, Cofrin KM. Comparisons of adolescent and parent willingness to participate in minimal and above-minimal risk pediatric asthma research protocols. *J Adolesc Health*. 2005;37(3):229-235.
9. Kim SH, Tanner A, Friedman DB, Foster C, Bergeron CD. Barriers to clinical trial participation: a comparison of rural and urban communities in South Carolina. *J Community Health*. 2014;39(3):562-571.
10. Hamm MP, Scott SD, Klassen TP, Moher D, Hartling L. Do health care institutions value research? A mixed methods study of barriers and facilitators to methodological rigor in pediatric randomized trials. *BMC Med Res Methodol*. 2012;12:158.
11. Barakat LP, Patterson CA, Mondestin V, et al. Initial development of a questionnaire evaluating perceived benefits and barriers to pediatric clinical trials participation. *Contemp Clin Trials*. 2013;34(2):218-226.
12. Barakat LP, Schwartz LA, Reilly A, Deatrick JA, Balis F. A Qualitative study of phase III cancer clinical trial enrollment decision-making: perspectives from adolescents, young adults, caregivers, and providers. *J Adolesc Young Adult Oncol*. 2014;3(1):3-11.
13. Rajakumar K, Thomas SB, Musa D, Almario D, Garza MA. Racial differences in parents' distrust of medicine and research. *Arch Pediatr Adolesc Med*. 2009;163(2):108-114.
14. Brody JL, Turner CW, Annett RD, Scherer DG, Dalen J. Predicting adolescent asthma research participation decisions from a structural equations model of protocol factors. *J Adolesc Health*. 2012;51(3):252-258.
15. Brody JL, Scherer DG, Annett RD, Turner C, Dalen J. Family and physician influence on asthma research participation decisions for adolescents: the effects of adolescent gender and research risk. *Pediatrics*. 2006;118(2):e356-362.
16. Robiner WN, Yozwiak JA, Bearman DL, Strand TD, Strasburg KR. Barriers to clinical research participation in a diabetes randomized clinical trial. *Soc Sci Med (1982)*. 2009;68(6):1069-1074.
17. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol*. 2018;18(1):143.
18. Tricco AC, Lillie E, Zarin W, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*. 2018;169(7):467-473.
19. Rural Health Information Hub (RHI Hub). Is there a healthcare workforce shortage in rural areas?2020. https://www.ruralhealthinfo.org/topics/health-care-workforce.
20. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan-a web and mobile app for systematic reviews. *Syst Rev*. 2016;5(1):210.
21. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-381.
22. Cruz TH, Davis SM, FitzGerald CA, Canaca GF, Keane PC. Engagement, recruitment, and retention in a trans-community, randomized controlled trial for the prevention of obesity in rural American Indian and Hispanic children. *J Prim Prev*. 2014;35(3):135-149.
23. Grunbaum JA, Labarthe DR, Ayars C, Harrist R, Nichaman MZ. Recruitment and enrollment for Project HeartBeat! Achieving the goals of minority inclusion. *Ethn Dis*. 1996;6(3–4):203-212.
24. Guzman A, Richardson IM, Gesell S, Barkin SL. Recruitment and retention of Latino children in a lifestyle intervention. *Am J Health Behav*. 2009;33(5):581-586.
25. Markoe Hayes S, Chapple S, Ramirez C. Strong, smart and bold strategies for improving attendance and retention in an after-school intervention. *J Adolesc Health*. 2014;54(3 Suppl):S64-S69.
26. Hooven C, Walsh E, Willgerodt M, Salazar A. Increasing participation in prevention research: strategies for youths, parents, and schools. *J Child Adolescent Psychiat Nurs*. 2011;24(3):137-149.
27. Julion WA, Sumo J, Bounds DT. A tripartite model for recruiting African-Americans into fatherhood intervention research. *Public Health Nurs*. 2018;35(5):420-426.
28. Peterson AV, Mann SL, Kealey KA, Marek PM. Experimental design and methods for school-based randomized trials. Experience from the Hutchinson Smoking Prevention Project (HSPP). *Control Clin Trials*. 2000;21(2):144-165.

29. Tiwari T, Casciello A, Gansky SA, et al. Recruitment for health disparities preventive intervention trials: the early childhood caries collaborating centers. *Prev Chronic Dis*. 2014;11:E133.
30. Tomayko EJ, Prince RJ, Cronin KA, et al. Healthy Children, Strong Families 2: A randomized controlled trial of a healthy lifestyle intervention for American Indian families designed using community-based approaches. *Clin Trials*. 2017;14(2):152-161.
31. Wise M, Pulvermacher A, Shanovich KK, Gustafson DH, Sorkness C, Bhattacharya A. Using action research to implement an integrated pediatric asthma case management and eHealth intervention for low-income families. *Health Promotion Practice*. 2010;11(6):798-806.
32. Yu SH, Gumport NB, Mirzadegan IA, Mei YJ, Hein K, Harvey AG. Addressing the challenges of recruitment and retention in sleep and circadian clinical trials. *Behav Sleep Med*. 2020;18(1):23-34.
33. Bansa M, Brown D, DeFrino D, et al. 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. *J Natl Med Assoc*. 2018;110(2):130-142.
34. Crane KT, Gold PB, Brodock A, Fabian ES, Morris TR. Engaging and retaining youth SSI recipients in a research demonstration program: Maryland PROMISE. *J Vocat Rehabil*. 2019;51:137-144.
35. Garcia RI, Tiwari T, Ramos-Gomez F, et al. Retention strategies for health disparities preventive trials: findings from the Early Childhood Caries Collaborating Centers. *J Public Health Dent*. 2017;77(1):63-77.
36. Shattuck D, Hall JL, Green A, et al. Recruitment of schools for intervention research to reduce health disparities for sexual and gender minority students. *J Sch Nurs*. 2020;36(4):258-264.
37. Villarruel AM, Jemmott LS, Jemmott JB, Eakin BL. Recruitment and retention of Latino adolescents to a research study: lessons learned from a randomized clinical trial. *J Spec Ped Nurs*. 2006;11(4):244-250.
38. Kafka T, Economos C, Folta S, Sacheck J. Children as subjects in nutrition research: a retrospective look at their perceptions. *J Nutr Educ Behav*. 2011;43(2):103-109.
39. Flores G, Portillo A, Lin H, et al. A successful approach to minimizing attrition in racial/ethnic minority, low-income populations. *Contemp Clin Trials Commun*. 2017;5:168-174.
40. McCullough MB, Janicke D, Odar Stough C, et al. Barriers to recruitment in pediatric obesity trials: comparing opt-in and opt-out recruitment approaches. *J Pediatr Psychol*. 2017;42(2):174-185.
41. Hartlieb KB, Jacques-Tiura AJ, Naar-King S, Ellis DA, Jen KL, Marshall S. Recruitment strategies and the retention of obese urban racial/ethnic minority adolescents in clinical trials: the FIT families project, Michigan, 2010–2014. *Prev Chronic Dis*. 2015;12:E22.
42. Young AS, Seidenfeld AM, Healy KZ, Arnold LE, Fristad MA. Predicting enrollment in two randomized controlled trials of nonpharmacologic interventions for youth with primary mood disorders. *J Affect Disord*. 2018;235:368-373.
43. Basson AA, Yoo M, Chi DL. Recruiting adolescents from Medicaid enrollment files into a neighborhood oral health study. *JDR Clin Trans Res*. 2019;4(3):255-261.
44. Brown DL, Cowdery JE, Jones TS, Langford A, Gammage C, Jacobs TL. Adolescent knowledge and attitudes related to clinical trials. *Clin Trials*. 2015;12(3):212-214.
45. Cunningham-Erves J, Deakings J, Mayo-Gamble T, Kelly-Taylor K, Miller ST. Factors influencing parental trust in medical researchers for child and adolescent patients' clinical trial participation. *Psychol Health Med*. 2019;24(6):691-702.
46. Greenberg RG, Corneli A, Bradley J, et al. Perceived barriers to pediatrician and family practitioner participation in pediatric clinical trials: Findings from the Clinical Trials Transformation Initiative. *Contemp Clin Trials Commun*. 2018;9:7-12.
47. Greenberg RG, Gamel B, Bloom D, et al. Parents' perceived obstacles to pediatric clinical trial participation: Findings from the clinical trials transformation initiative. *Contemp Clin Trials Commun*. 2018;9:33-39.
48. Owen-Smith AA, Sesay MM, Lynch FL, Massolo M, Cerros H, Croen LA. Factors influencing participation in biospecimen research among parents of youth with mental health conditions. *Public Health Genomics*. 2020;23(3–4):122-132.
49. Hall SA, Kaufman JS, Ricketts TC. Defining urban and rural areas in U.S. epidemiologic studies. *J Urban Health*. 2006;83(2):162-175.
50. Roberts ME, Doogan NJ, Tanenbaum E, et al. How should we define "rural" when investigating rural tobacco use in the United States? *Subst Abus*. 2021;42(4):788-795.
51. Health Resources & Services Administration. Defining Rural Population. https://www.hrsa.gov/rural-health/about-us/definition/index.html. Updated October 2021. Accessed July 1, 2021.
52. United States Census Bureau. Urban and Rural. https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html. Updated October 8, 2021. Accessed November 8, 2021.
53. Census Bureau. Urban Areas for the 2020 Census-Proposed Criteria. https://www.federalregister.gov/documents/2021/02/19/2021-03412/urban-areas-for-the-2020-census-proposed-criteria. Updated February 19, 2021. Accessed November 8, 2021.
54. U.S. Department of Health and Human Services. Defining Rural Population. https://www.hhs.gov/guidance/document/defining-rural-population. Updated June 25, 2020. Accessed November 8, 2021.
55. Crenshaw K. Demargenalizing the intersection of race and sex: A black feminist critique of antidiscrimination doctrine, feminist theory, and antiracist politics. University of Chicago Legal Forum. 1989:139-168.
56. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Medicine*. 2009;6(7):e1000097.

SUPPORTING INFORMATION

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

How to cite this article: Watson SE, Smith P, Snowden J, et al. Facilitators and barriers to pediatric clinical trial recruitment and retention in rural and community settings: A scoping review of the literature. *Clin Transl Sci*. 2022;15:838-853. doi:10.1111/cts.13220