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Art of recruiting diverse pediatric samples for randomized clinical trials: A recruiter's perspective

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Abstract

Objective: Randomized Clinical Trials (RCTs) play a critical role in advancing our understanding of early brain development and its connection to behavioral outcomes. However, there is limited generalizability when research samples predominantly consist of individuals from higher-resourced communities who identify as White. This paper addresses the pressing issue of diversity in neuro-imaging, RCTs, and clinical research, focusing on the challenges, implications, and barriers to achieving diverse sample representation. The study aims to explore recruitment strategies and the role of well-trained, diverse research staff in recruiting and retaining underrepresented communities. This research provides valuable insights into the experiences of field recruiters working with diverse and disadvantaged populations, with the goal of informing effective recruitment practices while minimizing associated costs, time, and recruiter stress.

Method: We conducted interviews with experienced recruitment staff from large longitudinal clinical neuroimaging, schooling intervention, parenting intervention, and survey studies involving samples from highly diverse socio-economic families. Recruiters were invited to participate in semi-structured interviews to identify effective strategies for increasing the recruitment of underrepresented populations. Importantly, this research offered recruitment staff the opportunity to share their experiences with a peer researcher rather than their employer or principal investigators.

Results: The data yielded significant findings, including the impact of racial and cultural similarities on recruiters' experiences and methodologies for approaching families to increase the chances of enrollment. Families who recognize the benefits of a research study are more likely to consent, regardless of their social-cultural background; however, building trust is crucial for families to perceive a study as safe and credible. Pressure from funding agencies, research investigators, and field recruiters negatively affect recruiters. The initial impressions made by recruiters regarding the study play a key role in study enrollment and completion rates. Socio-cultural similarities, such as the language spoken between recruiters and participants, have a positive impact on enrollment. One recruiter noted, "I feel like it can be very helpful for recruitment if you can find something that you relate to. It always feels like I get a call-in brownie points in studies where I could recruit Hispanic families." However, recruiters who are observant, empathetic, and quick problem solvers tend to be more successful in recruiting participants.

Conclusions: The study findings build on various themes and offer specific methodological guidelines for improved recruitment and retention strategies. Increasing the diversity of research samples will enhance our understanding of pediatric research and contribute to the development of interventions that can improve outcomes for children and families. The study findings have the potential to enhance ethical recruitment and promote equal opportunities for families to participate in research that reflects the linguistic, ethnic, and racial diversity in the U.S.

Keywords: Pediatric samples; Diverse; Neuro-imaging; Clinical trials; Qualitative

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1. Introduction

Randomized clinical trials (RCTs) stand as the gold standard for testing the effectiveness of health interventions (Hariton & Locascio, 2018). When compared to other study designs, RCTs eliminate inherent bias through randomization, allowing for the construction of scientific knowledge about what works and why it works (Deaton & Cartwright, 2018). Importantly, RCTs, as a method of investigation, depend on large and diverse samples to yield statistically significant, reliable, and valid findings. Clinical studies that fall short of their target enrollment and equality ratios result in costly consequences (Fogel, 2018; Naidoo et al., 2020; Sun et al., 2022). Consequently, with less than 50% of research studies failing to achieve their target sample size and 55% of clinical studies terminated due to low participation, it is necessary to adopt tailored recruitment strategies for enrolling and retaining large and diverse study participants to ensure high-quality research investigations (Pharmaceutical Technology Enrolment Issues are the Top Factor in Clinical Trial Terminations, 2018; LaPlante et al., 2021; Desai, 2020).

Diverse samples in RCTs yield generalizable results. However, many of these studies grapple with diversity in their sample representation. The National Academies of Sciences, Engineering, and Medicine issued a report mandated by the U.S. Congress, urging researchers and funding bodies to enhance the inclusion of underrepresented populations in RCTs and clinical research (Frueh, 2022). Unfortunately, some reputable journals do not require authors to report diversity ratios in their publications. A recent study analyzed RCTs conducted in the United States from 2000 to 2020 and found that among 20,692 RCTs, 67% did not report race or ethnicity. Of the 43% that did report, a high median of 79.7% were White (Turner et al., 2022). Another study in 2019 discovered that only 20 out of 536 articles (3.7%) that conducted MRI scans reported participant racial information (Goldfarb & Brown, 2022). Neuro-science research has significantly influenced clinical treatments and public policies for decades (Dotson & Duarte, 2019). However, the lack of diversity in neuro-science research has limited its applicability to a diverse population. It is the responsibility of researchers to refrain from over-sampling families from high-resourced, homogenous, socioeconomic backgrounds who identify as White to enhance the quality and applicability of science and treatment for our diverse population.

In research, as in mathematics, a larger participant pool increases the probability of achieving diversity. The higher the number of participants enrolled and retained, the more diverse the participants will be. For many years, there has been underrepresentation of diverse populations in clinical research, limiting the impact of study results on the population (Flores et al., 2021). Recruiting a diverse sample in pediatric research is a concern for major research funding bodies such as the National Science Foundation and the National Institute of Health (NIH Peer Review, 2019). Although these bodies have implemented specific efforts to address these disparities, diversity in clinical trials remains low, with only 50% of RCTs meeting their target enrollment numbers (Sully, Julious, & Nicholl, 2013). Clinical trials that fail to achieve their recruitment goals also tend to exhibit low sample diversity, poor participant retention, and minimal scientific contribution (Fogel, 2018; Naidoo et al., 2020; Sun et al., 2022).

Recruiting diverse samples in pediatric research can be challenging. Significant barriers, stemming from both individual and communal factors, impact underrepresented minorities' participation in research activities. Historically unethical clinical practices have deterred Black and Brown communities (National Academies of Sciences, Engineering, and Medicine, 2022). Studies have demonstrated that low income household are significantly less likely to participate in clinical trials. For instance, Unger et al. (2013) found that lower-income patients had 32% lower odds of trial participation compared to higher-income individuals (12% vs. 17%), due to financial barriers. Persistent health disparities and research abuses in these populations have resulted in sustained disconnection, mistrust, and distrust of science, making it difficult to recruit non-White and lower-income family participants (Reuland et al., 2021; Lebensburger, 2013; National Academies of Sciences, Engineering, and Medicine, 2022). These factors greatly influence the poor engagement of underrepresented American groups, including Asian American, Black American, Latinx American, and Mexican American (Behringer-Massera et al., 2019; Haynes-Maslow et al., 2014; Hughes et al., 2017; James et al., 2017; Occa et al., 2018; Smirnoff et al., 2018). Understanding and aligning research recruitment strategies with cultural appropriateness has proven to be a useful strategy in building trust when recruiting and retaining diverse families in RCTs (Knobf MT, 2007).

Families may decline participation in RCTs if it doesn't align with altruistic motives or directly benefit them. A qualitative survey exploring the perspectives of Black Americans on research studies revealed that participants believed research would primarily benefit White Americans over themselves (BeLue et al., 2006). Other limitations include social and economic factors such as low earnings, inflexible work hours, long working hours, multiple jobs, poor collaboration between primary care and researchers, and unreliable transportation, making it difficult for individuals experiencing financial challenges to participate in research (Denhoff, 2015). Time is another contributing factor, as underrepresented groups, including Black women, are more likely to earn below the poverty line while simultaneously caring for children and older family members (Indorewalla et al., 2021). Time is of the essence when participating in clinical trials,

especially in pediatric neuroimaging studies, where children undergo MRI scans, EEGs, fNIRS, and exposure to various stimulations. Therefore, participating in neuroimaging studies can be challenging and time-consuming.

Recruitment strategies that involve specific efforts from research team members yield effective results. Research has shown that research staff who are diverse and adequately trained have higher success in recruiting and retaining underrepresented communities (Quinn et al., 2012). Other factors within researchers' control can make recruiting and retaining diverse populations easier. Collaboration between research staff and clinicians, building trust with families, adequate training in creative methods and supervision of recruiters, and primary care providers' recommendations to families can aid in recruiting and retaining participants in pediatric clinical research (Greenberg et al., 2018; Shneider, 2021; Stein et al., 2015).

Research staff members who directly interact with and successfully enroll diverse families provide valuable insights for understanding the facilitators, barriers, and strategies for recruiting and retaining participants in neuroimaging research and RCTs (National Academies of Sciences, Engineering, and Medicine, 2022). Qualitative research that employs one-on-one interviews is an excellent way to gain in-depth perspectives and personal experiences from healthcare workers involved in clinical studies. It explores the thoughts and feelings of research staff who have firsthand experience with recruitment successes and barriers to successes (Colorafi & Evans, 2016; Pope & Mays, 2000). To our knowledge, no study has analyzed the perspectives of field recruiters who specifically recruit a diverse and disadvantaged population for RCTs and clinical studies. And scarcely are recruiters' experiences represented in the literature to inform an efficient and effective recruiting experience. Hence, this qualitative paper seeks to inform researchers through the voices of diverse recruiters on how to train recruiters, maximize recruitment/retention of diverse participants while minimizing recruitment costs, time spent recruiting, and recruiter stress/discomfort.

2. Methods

2.1. Participants

Participants (n = 7) were former or current recruiters with 2–15 years of experience in recruiting highly diverse families at Houston's Texas Medical Center (TMC). These families included toddlers born prematurely, school-age children, and children in neonatal intensive care units, recruited to participate in various activities such as neuro-imaging, EEGs, surveys, and school-based interventions. Houston is the 7th most racially diverse city and the 4th largest city in the United States, as reported by U.S. News & World Report. TMC, situated at the heart of Houston, provides care to a predominantly diverse population. These participants are valuable because they shared their experiences with a peer recruiter who is also the principal investigator, rather than their employer.

Participants were recruited from the principal investigator's network through purposive sampling via email. We conducted interviews with participants to identify effective strategies for increasing the recruitment of underrepresented populations. All participants were female (100%), with at least a Bachelor's degree, consisting of 2 Black, 3 Hispanic/Latino, and 2 White individuals. (Figure 1.)

2.2. Procedure

Each participant received an email invitation to be interviewed about their recruiting experience. Participants who expressed interest were provided with a Teams Bookings link to select a suitable time slot for the interview. Consent was obtained as permission to proceed at the beginning of the interview. Confidentiality was upheld by removing the names from the transcripts. Interview questions such as "How do you build rapport during recruitment?" and "During active recruitment, do you feel patients connect with you based on shared social or cultural likeness?" (See Appendix A). The interviews were conducted virtually, recorded, and transcribed using the Microsoft Teams app. Each interview lasted between 45 and 60 minutes. The Dedoose software (Dedoose Version 7.0.23, a web application for managing, analyzing, and presenting qualitative and mixed-method research data, 2016) was employed to identify emerging themes and subtopics. Themes are defined as ideas that share similarities in nature. For instance, facilitators, barriers, ethics, cultural differences, and strategies were identified as themes, each containing several subtopics.

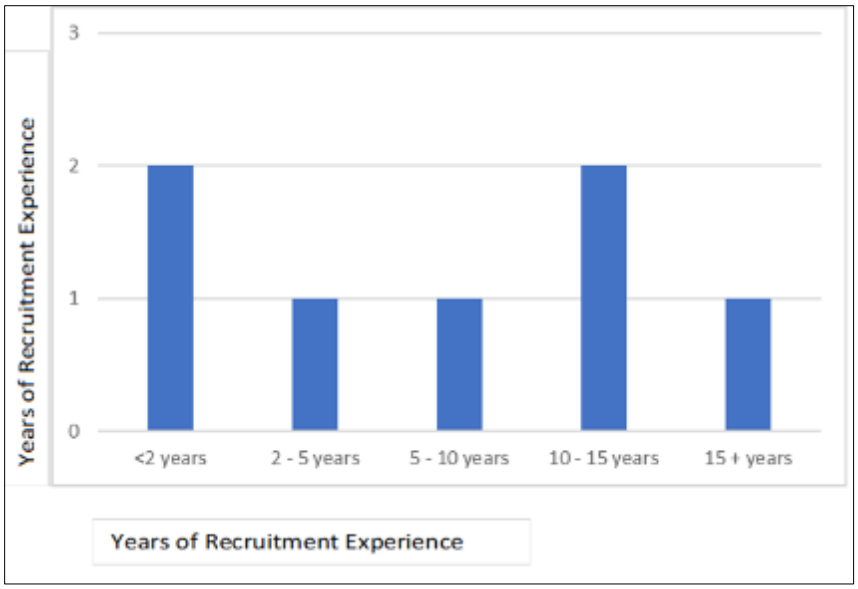

Figure 1 Years of pediatric clinical recruitment and number of participants per years of recruitment pediatric clinical recruitment

3. Results

We found five (5) overarching themes and twenty-nine (29) sub-topics across the data. In our analysis, we will be reporting on the themes and subtopics with the highest frequencies. (Figure 2.)

3.1. Facilitators

We defined Facilitators of Pediatric Clinical Recruitment as factors related to study design, recruitment context, or staff characteristics that increase the likelihood of enrollment and retention.

Good Rapport/First-Impression (n = 7), Recruiters' Knowledge of the Study (n = 7), Trust/Connection with the Recruiter (n = 7), Simple Study Design (n = 6), Similar Culture between Recruiter and Eligible Family (n = 5) were the thematic sub-topics under Facilitators that recruiters reported as the key factors that positively influenced participant enrollment and retention in RCTs. Good rapport and Trust sub-topics were seen in both Strategies and Facilitators.

When interviewees were asked how they build good rapport and trust with potential families, one participant with less than 2 years of experience reported as follows:

“I know when to approach (i.e., not going in when the child is crying) - getting the go-ahead to approach by the clinic staff. I introduce myself and appear friendly, smile, make eye contact with both parents. I build rapport by debunking/clarifying that I am not a doc or nurse to give a shot.”

This interviewee noted that clarifying their position as a recruiter vs. a doctor obliged to give injections to children for treatment may allow parents to be more receptive. Another interviewee said, “even before going to the clinic, I note the names of clinicians and patients, then I try to use it. For example, I use the child's first name and the doctor's name… basically name dropping.” This interviewee noted that using the family’s names helps build familiarity and trust for easier recruitment. A 10-year recruiter interviewee explains the reason she builds rapport with potential families: “I am usually discreet; I ask to talk to them in a less noisy area or patient room. When explaining the study, I am personable, not rushing, I never want them to feel like they're just something for someone to check off on their list in their day.” This interviewee wants families to feel seen and heard. Another interviewee who recruits from multiple clinical settings explains that the setting in which children are being recruited determines how they build rapport: “Rapport-building strategies depend on the setting and recruiter. With children in the ICU, I put my mommy heart on my sleeve… it helps that I'm a mom, and I can empathize with what the parents are going through.” They further detailed: “It's the worst day of their lives. That's not where they wanna be, and probably the last thing they wanna do is talk about research. Be very sensitive, don’t be robotic.” Leading with empathy is a key behavior this interviewee lives by when approaching families in critical care. In the opposite light, an interviewee offered advice for when rapport feels unyielding: “Importantly,

know when they're not willing to talk and now is not a good time, know when to proceed and when to stop… when it's better to just leave it there." Understanding the non-verbal and verbal cues of families allows this interviewee to know when to be persuasive or conclusive. For another interviewee, the relationship and trust go together:

"Establishing your relationship with their network such as their primary care doctors piques their interest and makes them trust us and be more receptive. As a recruiter, you don't appear random. It becomes easier to get them to listen and feel safe with you."

Using established relationships is a good tool in building rapport and trust with potential families. Here, trust and connection were highlighted as a major factor in increasing the likelihood of successful recruitment. One interviewee who has recruited in several pediatric settings believes that families need to like you before they can trust you: "As a recruiter, the first part is you; they have to like you to say yes to the intervention. They fall in love with you before the program. I mean, if they don't like you, then they're not going to really be engaged in the intervention." This interviewee believes that recruiters are the face of RCTs, and potential families connect with them before connecting with the study.

Knowledge of the study was identified as a sub-topic under Facilitators used to increase the chance of successful recruitment across all interviewees (n=7). A seasoned interviewee said that a key step is thoroughly knowing the study: "know everything about the study and what that means for their participation ahead of time… also, knowing the parameters of the study, having those conversations and meetings with the PIs to know what's allowed or not." Hence, communicating with the principal investigator can help recruiters understand their study better. Another interviewee elaborated on the benefit of knowing the script: "you don't want to mess up…telling them that they're gonna get X amount of money at week three when really they don't get it until the end." Knowing the script can help you communicate the script easily, transparently, and consistently to every family. What helps another recruiter is paraphrasing the script: "I summarize the information in the consent without using jargon for them to understand easily. I get acquainted with the project study requirements in detail, so I can answer any questions." Explaining the terms and conditions clearly to potential participants breeds successful recruitment over using jargon. When asked what can you do to ensure your best chance at a successful recruitment, one said,

"Being confident in knowing what it is you're trying to recruit them into, like being aware of any of the questions and things that they can ask you because if it seems like you're stumbling and stuttering, they're gonna lose a little trust, like you don't know what you're talking about, why would I sign up with you?"

Here, knowledge of the study translates into body language and confidence, which allows potential families to perceive recruiters and research studies as credible.

Simple study design was also identified as a facilitator (n = 5) of the study. Interviewees reported that studies that demand less involvement or invasion were likely to be more successful than other studies. One interviewee stated quite strongly: "I think as the requirements of the study increase, both healthy and unhealthy families' likelihood to participate decreases, but it decreases at a faster rate for healthy children." The more requirements a study presents, the less chance of successful recruitment. Another elaborated, "For example, if you have to get an EKG on the child, that would be invasive."

3.2. Barriers

We defined Barriers to Active Pediatric Clinical Recruitment as factors related to study design, recruitment context, or staff characteristics that create challenges that limit the sample size.

We observed specific sub-topics that arose as barriers to active pediatric clinical recruitment - pressure from principal investigators (n = 6) and increased medical risks in pediatrics (n = 7). All interviewees (n=7) explained that recruiting children in high-risk settings posed difficulties. They reported that families were more concerned with the survival and safety of their high-risk child over participating in a voluntary research study. However, interviewees also reported that, for families generally motivated to participate in research, the higher the health risk for their child, the more interested they are in signing up for studies that could benefit them. One participant with over 15 years of recruiting said,

"[as] the requirements of the study increase, both healthy and medically unhealthy children or families' likelihood to participate decreases, but it decreases at a faster rate for healthy children. Families who are medically unwell are a little bit more willing to do things because of their concern for their child and hoping that by participating in the study they will get answers or they'll get some type of intervention to help them care better for their child… where if you don't

have any concerns about your child and somebody's coming to ask you to do something, then it may feel like it's just something extra to do."

When asked about what might prevent families from saying 'yes' to pediatric studies, one interviewee said: "It depends on what the study is asking, if the study is asking them to do an MRI, I think MRIs scare adults. They can't imagine putting their baby through that, so there's just increased risk with such studies." The more frightening a study is perceived as, the more families refuse to participate. Interviewees also clarified that families who were lower in socioeconomic status tend to say 'no' to participating, and when they do say yes, they don't follow through with the requirements of the study due to socio-economic factors such as a lack of transportation to commute, multiple children to care for, lack of time, and caretaking demands from high-risk children. An interviewee said, "families trying to keep their high-risk children alive may view research studies as supplementary. It's not going to keep your child alive. I think a lot of the families with really high-risk children have different priorities, which is understandable." This interviewee has observed that families taking care of sick children are not able to participate due to demands of caretaking. Another interviewee talked about the misunderstandings families have about MRI scans and multiple clinic visits demanded for preemies, "Working with preemies, parents really worry about them in regards to their health, so they are a bit more cautious when signing up for anything. They might not know what an MRI is and say "oh, what is that?" We have to sort of tell them what it is and just reassure them it's safe. Also high-risk preemie babies, they have a lot of doctor's appointments and therapies and time restraint and having to come to the med center... so it's a bit more difficult for them to really consider it as opposed to the other ones." This false negative perception about MRI scans results in significant denials from families in participating in research. Also, multiple clinic obligations put a high load on families' time, which reduces their likelihood to participate in research studies. Another interviewee mentioned that families see their pre-term babies as fragile, and this deters them from partaking in research. "High-risk families already have so many extra doctor visits that come with being high-risk aside their usual checkups… they don't want to add more to their plate because they're already so consumed with the health of their delicate baby." Fears of the fragility of pre-term babies and necessary multiple doctors' visits put hesitation on families to willingly participate in time-consuming research. Multiple clinical research studies recruiting from the same clinics may be a barrier for families to participate, though another interviewee with less than 5 years of recruiting experience said, "the preterm families I tried to recruit were already involved in so many other studies and clinical trials, so they're like, I don't have the time, this is just too much. I just want to focus on my child." Competition among clinical studies recruiting from the same location may be a barrier to recruitment.

Another barrier to recruitment was pressure on recruiters and on potential participants. When we asked interviewees if they feel active recruitment puts pressure on them, one said, "I feel like recruiters know that they have a certain number and they feel anxiety about that sometimes, and their anxiety may cause them to be a bit pushy when recruiting." Having a target goal or a number of families to recruit may cause recruiters to be anxious, which may translate to being overbearing during recruitment. Another interviewee faced pressure and cognitive dissonance from principal investigators to reach out to potential families even when they didn't want to be contacted. "It's difficult to report to the PIs and have my own judgment, and they tell me that I should do something different when I was the person who felt out the family and how they responded to me." This interviewee needed to feel autonomy in their use of good judgment when enrolling families. Another interviewee responds to the pressure that may be indirectly put on families to say yes: "In the consent forms we say they have the ability to say no and it doesn't impact their medical care in any way, still we have to reassure them during recruitments. It's something recruiters can forget to say." The lack of being thorough and clarifying to families that participating in the research is optional may be putting indirect pressure on families to consent due to the fear of losing medical benefits, which may, in turn, lead them to not follow through because they were never interested. The timeline of the study may put pressure on potential families. One interviewee said,

"Families may think that the length of study time may put much pressure depends on the length of time families think. They think oh, that's 12 weeks, 13 weeks, that's a lot. It sounds like a lot, but that's where recruiters step in and tell them how it's all broken down and how it can be very manageable for them."

The nature of longitudinal clinical studies can put pressure on families where they feel they have to commit to an extended period of time, which can make them not consent. Another interviewee viewed pressure from the study in regards to making ends meet, "pressure comes from the actual study, when you have a limited group of people that you are actually choosing from, in a way, if you want the study to happen, it becomes added pressure." Another interviewee added, "when I think about the study and the time, there's a goal, and a certain timeline you have to follow. So that's like added pressure, you know, to actually make it happen." The nature of funded research studies with timelines and limitations may create added pressure on recruiters.

3.3. Cultural Awareness

We defined Cultural Awareness in Active Pediatric Clinical Recruitment as experiences based on cultural factors that were identified by recruitment staff working in diverse clinical settings.

All interviewees (n = 7) stated that they did not feel families disconnected from them based on any cultural context. One interviewee mentioned that sharing the same race or culture with a family did not necessarily indicate that they would consent to the study. "Shared cultural and social experience is good but not necessary. The most important thing is need. Shared likeness allows communication and cultural understanding, not necessarily consent." There must be a need for families before they agree to participate in a research study. Another interviewee mentioned that she felt families connected with her based on language. "With bilingual families, I feel they're more inclined to be like, 'Oh, you know, she also speaks Spanish,' and they can really express themselves." Another also said, "I have certainly felt that a patient is connecting with me based on 'Oh, I speak Spanish,' and they can really express themselves." Cultural connection, whereby a recruiter speaks the same language as the family, seems to foster a positive recruiting outcome.

We observed that families felt connected with recruiters who spoke the same language as them. One interviewee with over 15 years of experience detailed that she prefers to connect Spanish-speaking recruiters with Spanish-speaking potential families.

"A lot of the time, I feel like it can be very helpful for recruitment if you can find something that you relate to. It always feels like I get brownie points in studies where I could recruit Hispanic families. I felt like they did tend to connect with me more than probably my coworker, who was not Hispanic."

Lead recruiters match recruiters to families based on their spoken native language for easier recruitment. One interviewee with 12 years of experience who assigns recruiters to different potential families said,

"Whether that's biased or not, I feel like if I saw a family's name on paper, I can decide on what recruiter to send based on what language they speak. If you know that someone speaks Spanish, even if they also speak English but you know for a fact that their native language is Spanish. In my expertise, I would send a bilingual recruiter versus an English-only recruiter because that's their native language. I feel like they would feel more comfortable speaking Spanish to a native speaker."

Recruiting in the same language is helpful for potential families and recruiters to have a successful recruitment experience.

3.4. Ethics

We defined Ethics in Active Pediatric Clinical Recruitment as experiences or general reports of concern that highlight the need for consideration to improve ethical research conduct.

Interviewees emphasized the importance of being sensitive to families' responses to consent and helping them see the benefits of participating in research while maintaining ethical boundaries during active pediatric clinical recruitment. One interviewee expressed that their determination to attain high enrollment numbers influenced them to maintain a firm and confident demeanor while carefully balancing ethical considerations during active pediatric clinical recruitment.

"You are a salesperson, and in sales, you are showing the greatest benefit of something. This is research, so we also have to be honest about the downsides of things. You have to have enough bravado and confidence to even get them to listen but know when to back away."

The ability to know when to be persuasive and when to accept "no" for an answer is crucial for this interviewee.

While having a good relationship with established networks facilitated a smoother recruiting experience for research staff and was reported as an effective strategy, interviewees also noted negative implications of pediatric clinical recruitment site partnerships. Specifically, they expressed concern when recruitment site practitioners unintentionally interfered with the requirements.

"A provider said, 'Pick the girl, pick the girl. She's way better behaved for the study,' or 'They're not going to say yes, but you can talk to them.' Thus, providers sharing unnecessary information about eligible families with recruiters infringes on ethical boundaries."

Conducting research in minority populations where they are being over-surveyed poses ethical issues. For example, one participant expressed how this may be, "Black communities and Brown communities, let's be honest, people don't realize how over-surveyed these communities have been... they're fatigued." Choosing the right community to sample requires understanding the sampling history and the potential barriers for RCTs and clinical studies. Recruiting from different Black and Brown communities, rather than over-sampled ones, may be more effective, as over-sampled communities might be hesitant or fatigued due to past promises not being fulfilled. "Some research studies took advantage and may have promised this and that, and maybe nothing came with those promises or they didn't circle back with the community, so it makes people more hesitant." Not following through on promises with research participants breeds a lack of trust, which leads to future barriers to participating in other studies, especially from minority populations with a history of unethical research practices.

Transparency is an ethical concern for some recruiters. Every recruited family needs to understand the full scope of what they are consenting to in full detail. An interviewee with 12 years of recruiting experience reported that participants needed to know the commitment required to say "yes" to this research.

"I want them to know what they're getting themselves into and what the commitment is before they just say, 'Oh, yeah, I'll do it.' I'll explain to them what they are really getting into. I also offer to them that we can work around their schedule and provide transportation. I try to make it clear that they have to come these many times, but let's work it out - let's brainstorm. Yeah, so being honest is essential while presenting to make them understand exactly what they're getting into."

Another barrier that emerged was a lack of trust due to a lack of follow-up with participants in clinical studies. One interviewee recounted her experience where Black participants' DNA samples were collected but were never debriefed on how they would be used. An interviewee also talked about the lack of follow-up with participants and the use of their data samples.

"I'm sure families were wondering, 'Did they find out any connections? Are you going to circle back around and say what happened? You know, it's like my DNA is out there. I don't know where it is. I don't know what happened with that study.' Honestly, I think sometimes researchers have their ideas, but I think a better conversation with the recruiting staff is to tell the PIs that people are starting to wise up to these things and they want to know what's going to happen to their data."

Following up with participants after research and informing them about how their data was processed and used should be practiced, especially among minority populations with a history of malpractice.

3.5. Strategies

We defined Strategies for Active Pediatric Clinical Recruitment as factors related to study design, recruitment context, or staff characteristics that increase the recruitment sample size.

Key strategies include: Building an Initial Relationship: Building a good rapport with potential families was noted as an essential sub-topic under both Facilitators and Strategies. During active pediatric clinical recruitment, all interviewees reported that building a strong rapport is an effective strategy for gaining consent from potential families in clinical settings. All Interviewees (n=7) emphasized the importance of paying attention to both verbal and non-verbal cues from potential families. One interviewee, with over 15 years of experience in recruiting families, shared,

"I build rapport by being genuinely interested, paying attention, and actively listening to what they are saying. I match their temperament. For example, with quiet families, I speak more slowly. I maintain a generally positive and honest approach, help them problem-solve, and ask questions." Being sensitive to the temperament of families helps recruiters tailor their presentation to meet their needs.

All Interviewees (n=7) adhered to several key steps when presenting themselves to potential families: making eye contact, offering a warm and genuine smile, seeking permission to introduce the study before proceeding, accurately and seamlessly presenting the study using the recruitment script, matching the family's cadence, acknowledging other family members present in the vicinity, and, most importantly, having an in-depth knowledge of the study. One interviewee emphasized that recruiters need to be adaptable, cognitively flexible, and perceptive. They should have the ability to walk into a room, observe, and discern how to approach a potential participant, matching their energy and temperament. Sensing the atmosphere of the room helps recruiters become aware of how best to present the research study. Another interviewee explained how they build rapport with different participants to keep them engaged: "When

I notice that a family's language skills may be a bit lower or they are communicating more simply, I meet them at their level. I avoid using too much jargon or complex words and instead use simple sentences." The choice of words used to present research studies should be adapted to the families' vocabulary. One interviewee with over 5 years of experience stressed the importance of building a connection and trust during the first impression, saying, "I build rapport by learning their names and dropping names of their child, teacher, or doctor to bridge a connection and establish trust. Otherwise, they don't know who you are, and it feels like dealing with a stranger."

Utilizing Soft Skills and Going Off-Script: This sub-topic, where recruiters pass on information about the study without strictly adhering to a script, was mentioned by all interviewees. When asked if they go off-script while meeting with families, one interviewee with over 10 years of recruiting experience explained, "I go off-script not to provide different information but to simplify language or use different words. I do this when a parent appears lost, their eyes glaze over, or they seem distracted." Going off-script here means that recruiters use the recruitment script as a guide rather than reading it verbatim. Staying on script, as mentioned by an interviewee who recruits via phone and reads verbatim, involves rewording:

"I stay on script. I may reword the script to sound more authentic, but I stay within each paragraph. I may go off-script when answering questions that patients may have that are not covered in the script, such as transportation, etc. I am prompted to reword or expand when I notice that the patient is distracted, perhaps during conversations or while changing diapers, etc. I don't go off-script when they are attentive. In fact, I speak quickly so they don't lose focus."

THEMES and SUBTOPICS	**#participants**	**THEMES and SUBTOPICS**	**#participants**
FACILITATORS		**BARRIERS**	
Good Rapport/Connection/First-Impression	7	Medically at-risk patients	7
Trust with Recruiter	7	Pressure from Principal Investigators	6
Recruiters Knowledge of Study	7	Invasive Research Study Design	4
Simpler Study Design	6	Family no-shows and reschedules	4
Similar spoken language between Recruiter and Families	5	Poor Rapport skills	3
Recruiter's likeability/personality	3		
Participant's personality	3		
		CULTURAL DIFFERENCES	
		Connection based on cultural similarities	5
STRATEGIES		Cultural Disconnect	0
Building Initial Relationship: Trust/Rapport /First Impression	7	**ETHICS**	
Being prepared to pitch the study: Good script, having good presentation skills, being knowledgeable about the study, knowing the answers to FAQs;	7	Transparency	7
Adapting the pitch to suit families and their needs: Going off-script and staying on-script,	7	Pressure on families to participate	6
Recruitment Location	5	Recruiter's feelings of rejection	2
Scheduling Flexibility	5	Ethical sample demographic	2
Follow-up after recruiting	3	Informing participants about study after it's done	1
Scarcity mindset recruitment	3	Dr.'s/Provider's unsolicited Input about patients	1
Consent Participation & Recruiter Motivation	3	Ability for all to participate in research study	1

Figure 2 Overarching themes and sub-topics

Another in-person recruiter shared, "The script is a guide; I glance at it but use my own words. It's easier to gauge reactions when I'm not reading directly from the script. I can monitor their signals by making eye contact." Paraphrasing keeps the recruiters in tune and present during family recruitment, enabling them to capture reactions and make real-time adjustments for a more personalized and successful recruitment experience.

All interviewees strongly believed that a thorough knowledge of the study is one of the most critical factors in being prepared and presenting the study to families in the best possible way. One interviewee emphasized, "knowing your

study, appearing confident, understanding what you're talking about, and practicing your script beforehand are essential. Refresh your mind so you don't miss any important points." Preparation builds confidence for recruiters when meeting with families.

4. Discussion

Compared to other study types, RCTs are the gold standard for assessing the effectiveness of health interventions, as they eliminate bias through randomization. To ensure their success, large and diverse sample sizes are crucial, but many studies fail to reach their target enrollment, and numerous clinical trials are terminated due to low participation. Thus, tailored recruitment strategies are necessary to maintain the quality of research investigations (Hariton & Locascio, 2018; Treweek & Mitchell, 2010).

There is a significant lack of diversity in clinical studies, as highlighted by Congress and funding agencies and evidence in 67% of RCTs (Turner et al., 2022). A sufficiently large sample size is needed to establish strong evidence of intervention effectiveness, but recruiting families of children with high risk is difficult due to families' focus on the child's health and safety. Therefore, clinical studies that investigate pediatric interventions may struggle with reaching research goals and substantial financial contributions.

Recruiting is both an art and a science. In order for researchers to train recruiters to maximize successful recruitment efforts while reducing stress, cost, and wasted time, these helpful key practices obtained in this research should be enforced. The ability for one to learn the know-hows for successfully recruiting pediatric families involves building a good rapport upon first introductions, humanizing the recruiting process, interacting with families to make them feel seen, knowing and presenting the study parameters sensitively and accurately to families, and leaning in on the native language of potential families.

From the results, we see that cultural dissimilarity does not negatively affect recruitment, neither does socio-cultural similarities guarantee a connection between recruiters and potential families; rather, language is seen as a good connector between recruiters and families. Recruiters who can connect linguistically with families might have better success recruiting a diverse sample. Speaking the same language or using similar language styles allows families to feel like they can trust the recruiter; hence, they trust the study they are being recruited for, which helps with gaining more diverse participants.

Recruiters have good judgment in recruiting families because of how much time they spend interacting directly with families. Recruiting face-to-face with families allows recruiters to receive and understand the nuances which they can use in the moment during recruiting after obtaining consent. A recruiter can discern when a family wishes not to be contacted so often. Therefore, it is important for Principal Investigators to allow trained and seasoned recruiters to have autonomy to make informed decisions based on their discretion for the benefit of the research's success.

Pressure from study timelines, research goals, funding agencies, and research investigators poses feelings of anxiety among recruiters. When recruiters feel external pressure from principal investigators, they tend to take the rejections from families personally, which may affect their motivation for recruiting. Research investigators, on the other hand, feel pressure from funding agencies to produce good results to justify financial contributions and secure future proposals. This cycle affects investigators and recruitment staff in ripple effects.

Families from poor backgrounds find it difficult to participate in studies due to socio-economic challenges. They are more inclined to decline when approached due to a lack of time, lack of social support, multiple jobs, multiple caretaking of children, and when they do consent to studies, they lack the ability to follow through or may take longer to finish. This is both a recruitment concern and a retention concern. Helping families troubleshoot how they can be successful in research studies is necessary. Offering transportation to the research site, providing dinner for late data collections, having multiple staff members available to help families babysit while investigations are carried out are some of the ways to help problem solve.

The demographic of critically ill children naturally poses a barrier to recruitment due to challenges associated with these families, such as health, time, and socio-economic factors. It is necessary to build relationships with stakeholders who already have a connection with families, such as doctors, healthcare workers, social workers, etc., to create a familial experience for the families. An already fostered relationship with the family's clinic, doctor, or healthcare worker bridges the gap and makes it easier for families to feel comfortable talking to a stranger who is a recruiter.

Generally, studies with simpler designs, where the requirements of the research study are less invasive or time-consuming, yield favorable outcomes. Invasive studies where children are subjected to extensive examinations deter families from participating, especially when they misunderstand the risks involved. When studies require invasive or time-consuming procedures, such as MRI scans carried out at night, rigorous daily sample saliva collection, EKGs, EMGs, fNIRS, etc., families are discouraged and find it difficult to give their consent; hence, reducing participant numbers and resulting in a less effective study. It is more favorable to work directly with children at school or in their home than it is to work with parents who have to be present with the children or drive them to appointments. The time commitment for parents' participation, especially with parents with busy schedules, tends to yield lower participation.

Misunderstanding of study procedures and testing measures can lead to families refusing to consent. When families falsely believe that a particular test done on their child could cause harm, they are less likely to say no. For example, when a family believes that their preemie going through an MRI scan will somehow expose their children to radiation, they do not consent. It is the job for the recruiter to be aware of this myth and debunk it with facts and scientific evidence on what an MRI is and how it works. That being done, some families may still express weariness.

Furthermore, choosing the right community matters. Black communities are overly sampled yet hardly receive follow-up on how their data is being used. Research should explore reporting the use of data collected from all participants as a courtesy and fulfillment of promises when made. Researchers need to work beyond equity and move to justice for real and ethical changes to occur in scientific research. Principal Investigators may not have the necessary perspective to identify blind spots in pediatric clinical recruitment. It is the people recruiting every day who have the information required to make adjustments that could improve pediatric clinical recruitment and reduce possible ethical errors.

Limitations

One limitation of this study is the small sample size. We interviewed seven (n=7) female recruiters with varying years of recruiting experience. Although a larger sample size and diverse representation in terms of gender would enhance the generalizability of findings, it's important to note that each one-on-one interview averaged 60 minutes and produced a 50-page transcript. In other words, while the quantity of data was limited, the quality was high. Research has shown that the clinical research industry predominantly comprises more female recruiters (71.7%) than males (28.3%) (Zippia, n.d.). Future and larger studies should incorporate both qualitative and quantitative research methods to explore clinical recruitment in the field from the perspective of recruiters. The results and opinions of the interviewees may apply well to RCTs involving behavioral interventions versus control groups, but may not be applicable to RCTs focused on drug trials or other medical interventions. Additionally, it's worth noting that all recruiters in this study work in the Texas Medical Center, and their perspectives may not necessarily align with those of recruiters in different regions or countries. Data was collected in 2023, which could have been influenced by the post-COVID-19 pandemic.

5. Conclusion

The art of recruiting diverse samples in pediatric research recommends specific steps to be taken. When training and retraining study recruiters, strategies for success should include: building initial relationships, being prepared to present the study, adapting the pitch to suit families and their needs. These aspects are within the control of the recruiter. They can use their ability to build rapport with families, prepare the script, and tailor their presentation based on the family they are addressing. Facilitators that inherently aid the recruitment and retention process include trust in the recruiter, the recruiter's knowledge of the study and the study script, and the study investigation style. Trust emerges from the strategies employed. While all clinical trials cannot always be simplified, studies can critically evaluate the study protocol and methodology to identify processes that can be simplified or eliminated to reduce stress on families.

The thematic elements from this study also highlights the barriers to pediatric clinical studies. High-risk children are generally more challenging to recruit than healthier children. While pressure comes from the studies and investigators, it is the families who must be willing to participate and provide full consent for the research to progress, mainly through strategies influenced by recruiters. In such a culturally diverse world, this study finds that culture has little to do with family consenting to participate in clinical studies. However, families may feel more trusting of the research when recruiters speak their native language.

Recruiting families for clinical studies underscores the need for researchers to uphold certain research ethics, particularly transparency, voluntariness, and confidentiality. Families must understand what they are participating in and be willing to contribute while knowing that their data is protected and their impact will be shared with the community.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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Appendix A

Active recruitment is defined as going in-person to a site to talk to participants directly. For example, going to the clinics to talk to patients. I am going to ask you 10 questions about your experience as a recruiter. Every question is optional.

- How do parents differ in clinical recruitment when there is an increased child-risk? For example, have you experienced any differences related to recruiting parents of children with increased medical risks vs healthier babies?
- Can you tell me more about that?
- How do you build rapport during recruitment?
- When do you go off recruitment script? How do you do it while staying within study parameters?
- What signals prompted you to go off script?
- During active recruitment, do you feel patients connect with you based on shared social or cultural likeness?
- Can you share an instance when this has occurred or tell me more about that?
- During active recruitment, do you feel patients disconnect with you based on unshared social or cultural likeness?
- Can you share an instance when this has occurred or tell me more about that?
- What steps can you take; within your control, to increase your chances of successfully consenting a participant during active recruitment?
- Are there certain study design factors that can increase the number of consented participants during active recruitment?
- What do you value most about active recruitment?
- What do you dislike most about active recruitment?
- Have you ever felt that active recruitment put too much pressure on families to consent to study?
- Can you describe what made you feel so?
- Would you like to share anything else about your recruiting experience?