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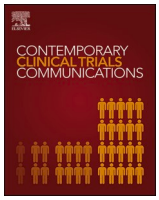

Pediatric subspecialty healthcare providers' views of recruitment during a randomized controlled trial of a mobile health intervention

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ABSTRACT

Background: Randomized clinical trials (RCTs) enrolling pediatric populations often struggle with recruitment. Engaging healthcare providers in the recruitment process may increase patients' and caregivers' willingness to participate in research. The purpose of this study was to understand the perspectives of pediatric subspecialty healthcare providers considering recruiting patients to participate in an mobile health (mHealth) RCT.

Methods: We conducted 9 semi-structured interviews and 1 focus group with a total of $N = 11$ providers from various disciplines before the initiation of an mHealth RCT addressing medication nonadherence. Then, we conducted 5 follow-up interviews and 1 follow-up focus group with a total of 8 of these providers several months later. We used thematic analysis to generate themes describing providers' views of the RCT and patient recruitment.

Results: Providers indicated that they were willing to recruit for this study because they believed that the intervention sought to address a significant problem. They also thought it made sense to intervene using technology for this age group. However, many providers thought that certain patients (e.g., those with mild, shorter-lasting adherence difficulties) were the most appropriate to recruit. They described how keeping the trial front of mind facilitated recruitment, and they advised researchers to use strategies to promote their ongoing awareness of the study if conducting similar research in the future.

Conclusion: Pediatric healthcare providers are important stakeholders in mHealth intervention research. Engaging them in participant recruitment is a complex endeavor that might promote patient enrollment, but their views of research and demanding clinical roles are important to understand when designing study procedures.

1. Introduction

Successful participant recruitment is foundational to conducting high-quality, generalizable, scalable, and cost-effective clinical research [1–3]. Recruitment difficulties can lead to less timely and precise estimates of intervention efficacy [4], inhibiting the impact of research on patient care. Recruitment challenges are widespread—different studies have found between 20 and 69% of randomized controlled trials (RCTs) fail to meet their recruitment targets [5–7]. Among RCTs enrolling pediatric populations, slow recruitment is a major contributor to premature discontinuation of the research [8].

One strategy for improving recruitment to RCTs is having the patient's healthcare provider make the initial invitation to eligible patients. For example, in a qualitative study of parents of pediatric patients recruited to an RCT, every participant indicated they preferred to first hear about RCTs from their child's healthcare provider [9]. However, the role of the provider in recruiting patients for RCTs is complex. Providers must balance two ethical imperatives: maintaining trial integrity and ensuring patient autonomy [10]. Ethical considerations are even more complex when enrolling pediatric patients, as both caregiver and child willingness to participate are important to respect and children are designated as a vulnerable population in research [11].

A small number of studies have examined how healthcare providers view the patient recruitment process. In a qualitative study of physicians

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and nurses conducting research with their patients, providers described taking a gatekeeper role, identifying patients who were most appropriate for a study [10]. They reported their engagement in recruitment was influenced by 1) their perceptions of each patients' suitability for a trial, based on their assessment of the patient's cognitive and mental health status, language and cultural background, geographic location, family support, and disease status; and 2) the constraints the providers faced to engaging in recruitment, such as the complexity of the RCT, details of the consent process, and time limitations. Based on survey research with oncology providers, administrative burden and lack of formal mechanisms for eligibility screening were some of the greatest barriers to provider engagement in RCT recruitment [12]. However, more research is needed to understand how providers navigate RCT recruitment, especially since none of these studies have focused on pediatric providers to our knowledge.

Healthcare providers may be most familiar with RCTs testing the efficacy of medications or medical treatments, but it is worth considering how healthcare providers approach patient recruitment to RCTs testing mobile health (mHealth) interventions, which provide medical services or healthcare support via mobile devices. Examples of mHealth interventions include mobile applications, text message communication, wearable monitors, and tele-healthcare via videoconferencing. Despite a growing body of evidence to support mHealth interventions [13,14], many providers still express skepticism about this treatment modality, expressing concerns about matters such as privacy, usability, and efficacy [15,16]. There are several factors that impact clinicians' willingness to adopt mHealth in their practice, which could also impact their willingness to recruit patients to mHealth RCTs. For example, clinicians' adoption of mHealth tools is influenced by 1) technological factors, including usefulness, ease of use, design, compatibility, technical issues, content, personalization, and convenience; and 2) social and organizational factors, including workflow related, patient related, policy and regulations, culture, attitude or social influence, monetary factors, evidence base, and awareness [17]. It is important to understand how providers view mHealth interventions when developing RCT recruitment procedures, since they may play an influential gatekeeping role.

1.1. Present study

This study examined qualitative data collected during interviews or focus groups with pediatric subspecialty healthcare providers who were invited to recruit adolescent and young adult patients to the parent study—an RCT comparing different mHealth interventions targeting medication adherence. We sought to better understand how pediatric healthcare providers viewed the mHealth interventions offered in the parent study, their willingness to invite patients to participate, and what factors might support or inhibit their engagement in study recruitment. Since we aimed to enroll patients who were already struggling with adherence, we expected trial recruitment might be especially challenging as some of the same psychosocial barriers can inhibit both study recruitment and treatment adherence [18]. Therefore, an a priori aim of the parent study was to gain a rich understanding of the recruitment process to inform larger, follow-up implementation trials.

2. Methods

2.1. Setting and sample

This study was conducted at Children's Hospital Los Angeles (CHLA), a large, urban, free-standing pediatric hospital. From August 2020–August 2021, we were recruiting participants to a three-armed RCT testing three different mHealth interventions. One condition enrolled participants in an mHealth intervention called Cell Phone Support [19], which is an adherence-promoting mHealth intervention involving phone calls made each weekday by a coach to provide social support, medication reminders, problem-solving coaching, incentives, and referrals. The other two RCT conditions were a text-message version of Cell Phone Support also delivered by a human coach, and an active control condition involving automated text message reminders. Inclusion criteria were 1) provider and patient agreement that medication adherence is currently <80%, 2) access to a cell phone, 3) ability to speak and understand English, and 4) being 15–20 years old. Exclusion criteria was cognitive impairment precluding engagement in the consent/assent process or study protocol. Patients with four different chronic illnesses were targeted for recruitment to enroll a heterogenous population. In line with family preferences for learning about RCTs from providers [9], recruitment procedures began with healthcare providers directly inviting patients to participate in the trial. The principal investigator (PI) emailed providers periodically throughout the study period to remind them that recruitment was open.

This study focuses on interviews or focus groups with providers engaged in recruitment to this RCT, which was a planned secondary aim of the parent study. We directly invited 14 providers using purposeful sampling to identify a mix of professional disciplines; $N = 11$ enrolled in the study. Two declined to participate due to busy schedules, and one did not respond to the invitation. The healthcare providers who consented to participate were physicians, nurses, psychologists, social workers, and care coordinators. Our goal was to organize as many focus groups as possible to facilitate discussion between providers that could illuminate how recruitment occurred and was experienced in the context of teams and clinics. We aimed to understand how pediatric mHealth research could fit into the team-based environment. However, we also offered individual interviews if scheduling time with each provider would be more convenient for them.

2.2. Design

Providers who were engaged in patient recruitment to this mHealth RCT were eligible to enroll in the qualitative portion of this study and could participate in interviews or focus groups before and a few months after RCT enrollment began. We obtained electronic informed consent from provider participants while interacting with participants on the teleconferencing platform. Therefore, we were able to observe them on their device and assure that the timing of their signature was immediate after we provided the link to the consent form. Providers were compensated with $25 gift cards for participating in each interview or focus group.

We conducted the first round of interviews and focus groups with 11 providers between August 2020 and October 2020. Providers were given the option of choosing either an interview or a focus group. We conducted a second round of interviews and focus groups with eight of the original 11 providers between April 2021 and September 2021. Most providers selected the interview option, with one focus group of two participants held in the first round and one focus group of three participants in the second round. This study took place during a time period heavily impacted by the COVID-19 Pandemic, which required the use of videoconferencing software and caused a major pivot to tele-healthcare across the hospital.

Interviews and focus groups were facilitated by the PI, a clinical psychologist affiliated with the same employer as the participants in this study. This author is a white, cisgender woman with about 10 years of experience in behavioral health interventions. The author had had prior collegial clinical or research experiences with six of the participants, never having met five of the participants before the interviews or focus groups. Interviews and focus groups were facilitated and audiorecorded via WebEx, a videoconferencing platform. Recordings were transcribed by research assistants, and the PI checked each transcript against the original recording for accuracy. Transcripts were uploaded to Dedoose software for organization, coding, and analysis [20]. This study was approved by the CHLA Institutional Review Board.

2.3. Measures

The PI created the interview and focus group guide with input from co-authors (Table 1). The same guide was used for interviews and focus groups. The interview guide was constructed to elicit providers' views of the mHealth interventions under study in this RCT and attitudes about patient recruitment to this and similar studies.

2.4. Analysis

Analysis was guided by the research questions: 1) how did healthcare providers view this mHealth RCT?; 2) what affected their willingness to invite patients to participate?; and 3) what factors supported or inhibited their engagement in study recruitment? Qualitative data were analyzed using thematic analysis [21,22]. This is an inductive method and a reflexive process, through which researchers generate themes from participant data, rather than using a pre-existing coding framework. For this study, we also used some thematic coding procedures by iteratively co-developing a codebook to organize our analysis of the data [23]. The PI and one of three undergraduate research assistants earning course credit reviewed each transcript, taking notes and generating initial codes. Differences of opinion were discussed between coding pairs until a consensus was achieved. Once the coders applied the finalized codes to each transcript, the PI pulled reports of coded excerpts and co-authors collaboratively identified themes and subthemes.

3. Results

3.1. Participant and recruitment descriptive characteristics

Of the 11 providers to participate in the pre-RCT interviews and focus groups, three were physicians, three were social workers, two were nurses, two were psychologists, and one was a care coordinator. Eight of the original participants took part in follow-up interviews or focus groups after the RCT had been running for several months. Two were social workers, two were nurses, two were psychologists, one was a physician, and one was a care coordinator. In the parent study, our goal was to enroll $N = 72$ patients; however, providers only recruited 55 patients to participate of whom only 34 participants enrolled. See Table 2 for details. The average length of an interview/focus group was 27.44 min ($SD = 7.16$ min) with a range from 17 to 37 min. We were only able two organize two focus groups because scheduling with providers proved very difficult. We were most able to engage providers in the study by making ourselves available flexibly within times that worked for their individual schedules.

Table 1
Interview/focus group guide segment.

Prior to Opening Enrollment in the Subspecialty Clinic
What kind of healthcare do you provide at Children's Hospital Los Angeles?
What do you think of the idea of a cell phone support intervention, where adherence facilitators will call or text young people struggling with adherence for 5 min a day, to support them in improving their adherence?
How useful would it be?
What could go wrong?
What would make you more likely to refer a patient to such an intervention?
What would your concerns be about referring a patient to such an intervention?
Any other thoughts?
Several Months after Enrollment Began in the Subspecialty Clinic
What kind of healthcare do you provide at Children's Hospital Los Angeles?
Were you aware of the study to deliver cell phone support to your patients struggling with adherence, taking place over the past few months?
Did you refer any patients (please don't share identifying information)?
Why did you or didn't you?
What would make you more likely to refer a patient to such an intervention?
What would your concerns be about referring a patient to such an intervention?
We are thinking of conducting a larger trial of this intervention across multiple sites. What advice do you have for us in that effort?
Any other thoughts?

Table 2
Characteristics of participants targeted for recruitment.

	Referred *n*	Enrolled *n* (%)
Total study population	55	34 (61.8)
Primary diagnosis		
Clinic A	16	10 (62.5)
Clinic B	4	0 (0.0)
Clinic C	15	10 (66.7)
Clinic D	20	14 (70.0)
Participant age		
<15	4	0 (0.0)
15	6	4 (66.7)
16	2	2 (100.0)
17	7	6 (85.7)
18	21	13 (61.9)
19	10	6 (60.0)
20	5	3 (60.0)
Participant sex		
Male	26	18 (69.2)
Female	29	16 (55.2)

Note. Four participants younger than 15 years old were referred and not eligible due to age-based inclusion criteria.

3.2. Qualitative themes

Theme 1. The intervention seeks to address a significant problem. Nearly all providers agreed medication adherence is difficult for many adolescents and young adults in their care. They indicated that they thought the interventions under study in this RCT had a worthwhile goal of supporting patients this age in taking their medications more regularly. They described how adolescent nonadherence was a serious matter that could be stressful as providers (e.g., "It's so scary.") and frustrating (e.g., "Fighting them tooth and nail."). Several providers reported they lacked the "resources and manpower" to implement adherence support as fully as they wished in their clinics, leading them to appreciate the opportunity to refer patients to this RCT.

Theme 2. Technology makes sense for this age group. Providers generally agreed that delivering adherence-promoting interventions via youths' cell phones was appropriate. For example, a provider said: "I'm really in support of that … You know, these teens now, that's what works. Social media, electronics, anything that can be done that way is much more convenient for them and that's what they know." They described the idea of mHealth intervention as "interesting," "beneficial," and "useful." Several reported already recommending mHealth adherence support in their regular care, such as recommending alarms and reminder applications. For example, a provider said:

> "I talk to them about different strategies like get the app. There's different apps to help with remembering to take medication, or … time it on your phone. You know, now we have so much technology to help with things so I will come up with strategies with them around that to help remind them to take their medication."

One provider mentioned feeling even more positively about mHealth in the context of the COVID-19 Pandemic:

> "One thing that I've done, especially, especially during COVID, is that I've really recommended using technology more than before. In terms of reminders and, and things like that, especially a cell phone. It just seemed like with less human interaction, it seemed like our patients would seem to need more constant reminders."

Theme 3. The intervention is a good fit for certain patients. Many providers indicated that they believed the mHealth interventions included in this RCT would be helpful for some, but not all of their patients. For example, a provider described intentionally identifying certain types of patients to recruit into the study:

> "So those were mainly the high-functioning, more independent teenagers. Where those are kids that were truly just forgetting because of convenience … It was that they were just being normal teenagers almost? And forgetting. And we thought that [the RCT] would be really useful. And I know that other providers thought it would be really useful for those patients."

A different provider described the type of patient they would consider recruiting to the RCT: "I think if they're not so far off the ladder, do you know what I mean? Like if they're really still close, we can just grab them back and pull them in. So, like a short-term problem, it would be best for."

Whereas providers viewed patients with milder adherence difficulties as best for the RCT, they also expressed doubts about whether the interventions would be sufficient to help patients with more severe difficulties underlying their poor adherence or that could complicate engagement with the intervention. For example, they expressed doubt that the interventions would benefit patients with significant mental health concerns (e.g., major depressive disorder, oppositional/defiant disorder), cognitive impairments, developmental delays, or intense psychosocial/family stressors.

Theme 4. Keeping the RCT front of mind facilitated recruitment. Several providers described how recruitment was easiest when the RCT stayed in their everyday awareness. For example, they reported that shortly after emails from the PI, reminders from their clinic leadership, or batches of flyers arriving through inter-office mail, their teams would remember the RCT and easily identify more patients to recruit. However, once the study faded from mind, they would not remember to offer the research opportunity to patients. Aside from recent reminders about the RCT, recruitment could also stay "front of mind" if teams integrated recruitment into their typical clinic flow. For example, a provider said:

> "I mean I think, just between me and [co-worker], it was just something that we use as a referral source. For you know, anyone who was struggling with nonadherence … Most of it was if the coordinator or the doctor or someone came to us and said, 'Hey, like this person is struggling taking meds,' or 'Their levels are low.' We would talk about a few things. We would talk about getting them in therapy, doing some family work if that, you know, if there was some barrier that way. And then, like a referral to your, the research. Just, generally, whenever we had a high awareness of some kind of nonadherence we'd, kind of just led to that discussion."

In addition, the RCT stayed in providers' awareness if the target problem—nonadherence—was a significant concern in their ongoing clinical duties. For example, a provider explained:

> "I know that it stays in the front of your mind if it would really help you out as a provider … If you were really, if it was causing more grief and more headaches and more hours out of your day if your patient wasn't being compliant. And you knew of something that could help them. I think that would be , probably the biggest motivator [to recruiting a patient to the RCT]."

Theme 5. Barriers to engaging in recruitment. Providers shared several difficulties they faced in recruiting patients to the RCT. Several referenced difficulties fitting this task into their already busy work schedule. In addition, providers explained that it was hard to keep the details of the research study straight. For example, several reported difficulty keeping track of the inclusion criteria (e.g., a provider explained: "Well, yeah, I don't remember exact ages."). In addition, some reported it was confusing because the same PI had conducted similar research studies in the past, and they were not sure which were still recruiting, and which were closed. For example, a provider said, "I think it was also kind of confusing because a lot of [the patients] had done the other study, and were finishing, but then this is like a new kind of study with a different component." Other barriers included adapting and delivering clinical services in the context of COVID-19 precautions. For example, a provider described how early in the Pandemic they did not recruit as many participants because they saw fewer patients, and later in the pandemic, they saw so many patients they had little time to address study recruitment:

> "I think there was kind of a lull, at the beginning, just because of, you know, all the restrictions. We were kind of trying to figure like who needs to come in, especially because all of our kids, you know, they're immunocompromised. I think what I've noticed was at the beginning we would just see a handful of the patients, but … as, you know, the months kept going, we just quickly ramped up to our normal. So, like definitely we're back up to our normal plus, just because, you know, maybe there was a little bit of backlog."

Theme 6. Advice for improving recruitment procedures. Providers indicated that repeated reminders were the best way to keep them engaged in recruiting. They reported it would not be annoying to get frequent reminders and referenced other RCTs that sent more frequent reminder emails than this study. One provider said:

> "I know that it's just a matter of just awareness and maybe you reminding. Because I think, like there was maybe something that, you know, you probably blasted to us or, you know, Doctor [de-identified] said, 'By the way, this is happening, you know, please keep in mind, you know, or give out the little flyer.' I think it's just the matter of maybe either coming to present, or just kind of like, you know, periodically, or through the people that you already have a context with, you know. Like somebody saying, 'Hey, do you mind just plugging in another word for our study?' And so that way as providers are seeing these adolescents during their clinic visits, that, you know, we can be a little more mindful about like saying, 'Hey, you know-,' … But I think the thing is that, you know, we get bogged down."

Some providers suggested integrating study recruitment more smoothly into the clinic flow. For example, one provider suggested it would be helpful for the receptionist to flag patients who were eligible based on age criteria as they checked into appointments, and then remind the providers to invite the patients to participate in the RCT. Another explained:

> "I think it comes down to convenience for both the providers and the patient. You know? Where it makes their life easier, too. And so anyway to streamline that enrollment … Make the provider's life easier, too, 'cause they wouldn't have to think too hard about it. It could just be a QR code that they could scan, or something like that, that would be really quick and easy."

The interviewer asked several participants directly if they would find rewards for participating in recruitment helpful (e.g., payments to providers for recruiting participants, pizza parties, gifts). None found this idea compelling. However, they did support the idea of printing study details on pens or notepads, to keep the RCT in their everyday awareness and remind them of inclusion criteria.

4. Discussion

In this study, we gained insight regarding how pediatric subspecialty providers view RCT recruitment. On the one hand, providers in the current study explained how they cared deeply about their patients' welfare and were motivated to recruit for RCTs testing interventions which could address significant problems. They were motivated to recruit patients to participate in the study because they viewed medication adherence as important, and did not have enough time, resources, or interventions to address adherence as effectively as they wished. This highlights how providers may be more motivated to recruit for studies due to potential benefits for their patients, rather than simply in service of scientific discovery. Understanding this attitude could impact study design choices; for example, perhaps providers would be more willing to

recruit to studies with competing active interventions rather than those with treatment-as-usual control groups. In addition to their positive view of the intervention's goals, the providers in this study thought mHealth modalities held promise. They did not express skepticism of technology described in other literature [15,16]. Rather, they pointed out how this generation of youth is very comfortable on their phones and described other technological supports they already recommended in their practice.

Despite their interest recruiting patients to this RCT, many providers reported they faced difficulties keeping the study front of mind, tracking details like inclusion criteria, and distinguishing similar studies from one another. The barriers they described were similar to those endorsed in prior qualitative and survey research with adult healthcare providers [12]. The providers in this study advised researchers to make efforts to keep study recruitment in their awareness, such as repeated reminders and tangible objects (e.g., pens, notepads) with study information. Furthermore, providers suggested streamlining recruitment, such as through using mobile applications, which is consistent with other research on physician attitudes about mHealth [24].

Providers also shared about their approach to identifying patients for recruitment. What the pediatric providers described in this study is similar to what Bell and colleagues learned in their qualitative research with providers involved in research—providers assess the "suitability" of a patient when recruiting them to participate in RCTs [10]. These results suggest that providers may develop their own unwritten inclusion and exclusion criteria. The current RCT sought to enroll any patient struggling with medication adherence who met the age and language criteria, so long as they had access to a cell phone and sufficient cognitive capacity to engage in the research. However, some providers believed the interventions would be most effective for patients with short-term or mild adherence challenges, which may have reduced variability in the RCT sample and decreased sample size. Clinical trial investigators might address this by universally screening patients for eligibility and providing clearer instruction to providers about inclusion criteria.

We did not meet our recruitment goals for this RCT. Future mHealth researchers should consider other strategies beyond engaging providers in the recruitment process. There is some evidence that the following strategies can improve recruitment to mHealth interventions: targeting geographically broad zones of patient residence, allowing self-referrals, focusing on unmet patient needs, patient and public involvement, regular monitoring and communication, and early exclusion for not meeting inclusion criteria [6]. Other strategies to boost recruitment include increasing people's awareness of the health problem being studied (e.g., attending an educational session, watching a video); telephone reminders; including a questionnaire in the invitation to participate; monetary incentives; using an 'open' (where both patient and clinician know the given treatment) rather than masked design; and making trial materials culturally sensitive [25,26].

4.1. Limitations

This study has several limitations. First, as a small qualitative study, the results are not definitive, but rather provide a basis for hypotheses that should be further investigated using deductive methods. Further, due to the small sample, we could not compare themes across clinics. Also, we only enrolled providers who chose to participate in these interviews and focus groups for minimal compensation. These providers may be especially supportive of research efforts at the hospital and provide a positively biased perspective. However, several provider participants ultimately performed very little recruitment for this RCT, so there may be some variation in motivation to engage with research across the sample. Unfortunately, we were unable to schedule many focus groups due to providers' scheduling barriers, and mostly facilitated individual interviews. This may have led themes to be conceptualized more on the individual provider level, rather than the team or clinic level. In addition, we did not assess demographic characteristics of our sample, which limits the context available for interpreting the results of this study. This study was conducted during the COVID-19 Pandemic, when providers' practice changed dramatically to emphasize telehealth services. Their experience of recruiting participants to this RCT may have been impacted by this historic event and be less generalizable to historical periods with fewer public health restrictions or more in-person clinical care.

5. Conclusions

This qualitative study suggests that pediatric healthcare providers may be more willing to recruit participants for RCTs when they believe the intervention seeks to address a significant problem. Healthcare providers in this study were supportive of using mHealth interventions with adolescents and young adults. However, it is important to understand they may consider certain patients a better fit for the intervention, beyond the explicit study inclusion or exclusion criteria. Efforts to keep the study front of mind and streamline procedures could improve provider engagement in recruitment. Future researchers should investigate whether these factors can effectively boost pediatric RCT recruitment, leading to more timely, precise results which could improve health outcomes for youth.

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Declaration of competing interest

None of the authors have a conflict of interest to disclose.

Data availability

The data that has been used is confidential.

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