Original Empirical Research

Implementation Research & Practice

Implementation Research and Practice
Volume 5: Jan-Dec 2024 1–14

DOI: 10.1177/26334895241246203
journals.sagepub.com/home/irp

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Primary care-based screening and recruitment for an adolescent depression prevention trial: Contextual considerations during a youth mental health crisis

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Abstract

Background

Rising rates of adolescent depression in the wake of COVID-19 and a youth mental health crisis highlight the urgent need for accessible mental healthcare and prevention within primary care. Digital mental health interventions (DMHIs) may increase access for underserved populations. However, these interventions are not well studied in adolescents, nor healthcare settings. The purpose of this study was to identify barriers and facilitators to screening and recruitment activities for *PATH 2 Purpose (P2P): Primary Care and Community-Based Prevention of Mental Disorders in Adolescents*, a multi-site adolescent depression prevention trial comparing two digital prevention programs within four diverse health systems in two U.S. states.

Method

This qualitative study is a component of a larger Hybrid Type I trial. We conducted semi-structured key informant interviews with clinical and non-clinical implementers involved with screening and recruitment for the P2P trial. Informed by the Consolidated Framework for Implementation Research (CFIR), interviews were conducted at the midpoint of the trial to identify barriers, facilitators, and needed adaptations, and to gather information on determinants that may affect future implementation.

Findings

Respondents perceived the P2P trial as valuable, well aligned with the mission of their health systems. However, several barriers were identified, many of which stemmed from influences outside of the healthcare settings. Universal and site-specific outer setting influences (COVID-19 pandemic, youth mental health crisis, local community conditions) interacted with Inner Setting and Innovation domains to create numerous challenges to the implementation of screening and recruitment.

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Conclusion

Our findings emphasize the need for ongoing, comprehensive assessment of dynamic inner and outer setting contexts prior to and during implementation of clinical trials, as well as flexibility for adaptation to unique clinical contexts. The CFIR is useful for assessing determinants during times of rapid inner and outer setting change, such as those brought on by the COVID-19 pandemic, youth mental health crisis, and the corresponding exacerbation of resource strain within healthcare settings

Clinical trial registration

PATH 2 Purpose: Primary Care and Community-Based Prevention of Mental Disorders in Adolescents https://www.clinicaltrials.gov/study/NCT04290754.

Plain Language Summary: Adolescent mental health problems such as depression, anxiety, and suicidal behavior are prevalent, and have been increasing in the wake of the COVID-19 pandemic. In 2021, the Surgeon General declared a "youth mental health crisis," and the American Academy of Pediatrics issued a joint statement declaring a national youth mental health emergency. Accessible, affordable, evidence-based interventions are needed to prevent the development of depressive symptoms into major depressive disorder. The integration of digital mental health interventions (DMHIs) into primary care may reduce access barriers. Primary care clinical settings are well suited to identify individuals at-risk for developing depression, and facilitate preventive treatment planning. While preventive DMHIs for adolescents exist, more evidence is needed on their effectiveness, and how to best integrate them into healthcare. Our study team interviewed primary care-based staff, administrators, and clinical providers involved with implementing screening and recruitment activities for the P2P trial, a randomized controlled trial comparing the effectiveness of two digital depression prevention programs. Respondents shared experiences with trial recruitment in their settings, including perceived challenges. Our findings suggest that multiple factors influenced recruitment, including influences situated outside of the clinical settings, such as the COVID-19 pandemic and worsening adolescent mental health. These influences interacted with factors affecting recruitment inside of health clinics, such as demands on staff and provider time, and perceived importance of prevention programming versus other initiatives. Identifying these influencing factors during the trial helps to inform considerations for planning future integration of similar programs into primary care settings.

Keywords

prevention, implementation evaluation, inner context, children/child and adolescent/youth/family, outer context, qualitative methods

Youth have experienced considerable adversity and disruption due to the COVID-19 pandemic, which contributed to a significant increase in adolescent mental health disorders (American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, Children's Hospital Association [AAP/AACAP/CHA], 2021). Globally, compared to pre-pandemic estimates, the prevalence of depressive symptoms has doubled among adolescents aged 12–18 years, with rates estimated at over 25% (Racine et al., 2021). Increasing depressive symptoms, major depressive disorder (MDD), and suicidal ideation and behaviors are being observed among adolescents across the United States (Centers for Disease Control and Prevention, 2023; Office of the Surgeon General [OSG], 2021) and internationally (Michaud et al., 2022). Therefore, identifying and promptly addressing emerging adolescent mental health concerns, such as depression, is of public health importance.

Primary care clinics are an important entry point to identify adolescent mental health concerns, particularly among underserved populations, such as families living in poverty and Black, Indigenous, (and) People of Color individuals who experience considerable structural access barriers (Baum et al., 2019; OSG, 2021; Prado et al., 2015). In these settings, adolescents at-risk for developing mental health disorders, such as MDD, may be identified before these disorders fully develop, as 54% of U.S. adolescents see a primary care provider at least annually (Rand & Goldstein, 2018), and the AAP strongly recommends screening for adolescent depression at yearly well-visits (Zuckerbrot et al., 2018). While the primary care setting may offer opportunity for the identification of adolescents experiencing or at-risk for mental health disorders, few integrated behavioral health models have demonstrated small-to-moderate effect sizes (Asarnow et al., 2015; Patel et al., 2013). Further, multiple barriers to integrating in-person behavioral health programming persist, including provider availability, stigma, implementation infrastructure, cost, and cultural acceptability (Embry, 2002; Farley et al., 2020; Merry, 2013; Patel et al., 2013; Van Voorhees et al., 2007).

Digital mental health interventions (DMHIs) have proliferated in recent years, especially in the wake of COVID-19 and the rapid transition to digital health care provision (Lattie et al., 2022; Noh & Kim, 2023; Stiles-Shields et al., 2023). DMHIs, in general, are thought to expand reach and reduce

access barriers to mental healthcare (Bergin et al., 2020; Lattie et al., 2022; Lehtimaki et al., 2021; Ramos & Chavira, 2022; Stiles-Shields et al., 2023). However, though widely available and possibly effective for the prevention of adolescent depression (Noh & Kim, 2023) few of these interventions are evidence-based for adolescents, and their implementation in healthcare settings has not been rigorously evaluated (Lattie et al., 2022; Lehtimaki et al., 2021; Stiles-Shields et al., 2023). Evidence on the effectiveness and implementation of preventive DMHIs with youth "at-risk" for developing mental health disorders (i.e., targeted preventive interventions), and with underserved populations, is especially lacking (Bergin et al., 2020; Noh & Kim, 2023).

One preventive DMHI for adolescents, Competent Adulthood Transition with Cognitive-behavioral and Humanistic Interpersonal Training (CATCH-IT) (Landback et al., 2009), previously implemented within primary care, has demonstrated effectiveness for preventing depressive episodes in adolescents (Gladstone et al., 2018; Saulsberry et al., 2013; Van Voorhees et al., 2008) as well as satisfactory cultural acceptability, cost-effectiveness, and implementation feasibility (Bansa et al., 2018; Eisen et al., 2013; Mahoney et al., 2017). However, more robust evidence from large, well-controlled clinical trials for such interventions is crucial (Bergin et al., 2020). In the present study, we explore the experiences of staff, providers, and administrators on the implementation of primary care-based screening and recruitment activities for P2P, a multi-site adolescent depression prevention trial comparing the effectiveness and evaluating the implementation of two digital, remote DMHI programs within primary care settings.

Method

Study Purpose

This qualitative study is a component of a larger hybrid type 1, randomized trial comparing the effectiveness of two online depression prevention programs for adolescents. Hybrid type 1 research designs test the effectiveness of intervention(s) while "gathering information about its delivery during the effectiveness trial and/or its potential for implementation in a real-world situation" (Curran et al., 2012, p. 219). The purpose of this study was to identify barriers and facilitators to primary care-based screening and recruitment activities for the P2P trial, as well as to glean insights on factors that may affect future implementation of these programs within diverse primary care settings, should they demonstrate effectiveness is this large clinical trial. Via key informant interviews, we sought to explore respondents': (a) perceptions of the trial, including acceptability and appropriateness for their settings and patient populations; and (b) experiences engaging in the process or oversight of screening and recruitment activities.

The P2P Trial

Screening and Eligibility

All study procedures received institutional review board approval. Recruitment began in January 2020 and is ongoing until late 2024, and over 600 adolescents (ages 13–19) have been enrolled. Briefly, the P2P trial identifies adolescents at-risk for developing depression using the clinically administered Patient Health Questionnaire (PHQ; Kroenke & Spitzer, 2002). Adolescents scoring between 7 and 18 on the PHQ-9 may be eligible for enrollment in one of two online, remote depression prevention programs. Notably, our original protocol designated potentially eligible adolescents as those with PHQ scores ranging from 7 to 14. During the COVID-19 pandemic, we expanded the PHQ scoring range to 18, as long as no suicidal thinking or behavior was reported (consistent with other exclusion criteria in the protocol). We made these changes due to increasing PHQ scores in our sample and concern that a cutoff score of 14 would exclude many participants who were not clinically depressed. Magson et al. (2021) reported a similar increase in depression scores for a longitudinal study, but noted that most adolescents were coping well with the pandemic. Our decision to include PHQ scores of 15–18 enables us to identify these adolescents and facilitate linkage with treatment, even if they are ineligible for our prevention trial.

Prevention Programs

Two prevention programs were developed from the evidence-based Coping With Depression-Adolescent course (Clarke & Debar, 2010), and similarly incorporate components of behavioral activation, cognitive behavioral therapy, and interpersonal psychotherapy. One program is a clinical therapist-led manualized group program consisting of fourteen 90-min scheduled sessions over the course of 8 months, plus two sessions for parents/caregivers. This program is evidence-based for the prevention of adolescent depression and has been previously implemented in healthcare settings (Brent et al., 2015; Garber et al., 2009). The COVID-19 pandemic necessitated the transition to online, remote delivery of this program (originally intended to be delivered in-person). The second program is a 14-module digital program for adolescents plus a five-module digital program for parents/caregivers, accompanied by three motivational interviews at 2 weeks, 2 months, and 6 months post-enrollment. This program has been previously evaluated in urban primary care settings, and has demonstrated effectiveness for preventing depressive episodes at 6 and 12 months (Saulsberry et al., 2013; Van Voorhees et al., 2008).

Clinic Randomization

Using a stratified cluster randomization scheme, primary care clinics within each health system were paired using an algorithm incorporating socio-

Table 1
Health System and Respondent Characteristics

Health System	Description	Location	Recruitment sites	Respondent type	Respondent #
System 1	Public university Health system including one hospital, two outpatient primary care clinics, and six FQHCs	Urban, IL	Two outpatient primary care clinics, six federally qualified health centers	Primary care providers (2); administrators (2); behavioral health providers (LCSW, psychologist) (11)	15
System 2	Private not-for-profit health system including 11 hospitals with 250 outpatient sites	Suburban, IL	Four outpatient clinics	Medical assistants (4), registered nurses (2), primary care providers (1), primary care provider/admin (1)	8
System 3	Not-for-profit independent health care provider, including one hospital and seven primary care clinics	Rural, IL	Six outpatient clinics	Research coordinators (2), primary care provider/admin (2), administrator (1), social worker (1), registered nurse (1), medical assistant (1)	8
System 4	Joint public university/private not-for-profit health system, including eight hospitals and 33 primary care locations	Urban, rural, suburban, KY	Eight outpatient clinics	Research assistant/coordinator (2), primary care provider/ admin (1), administrator (1)	4

demographic variables: number of adolescents seen in the past two years, ethnicity, race, Rural-Urban Commuting Area (United States Department of Agriculture Economic Research Service, 2021), clinic's zip code, and the Distressed Communities Index (Economic Innovation Group, 2021) scores of the five most common zip codes served. From the beginning of the trial, clinics were assigned to offer one of the two prevention programs. Descriptive information about health systems and clinic sites may be found in Table 1. Informed by previous studies (e.g., Gladstone et al., 2018), recruitment is conducted primarily in-person by clinical providers, research assistants, and support staff. Additional details about the P2P trial can be found elsewhere (Gladstone et al., 2022).

Implementation Framework

The Consolidated Framework for Implementation Research (CFIR) is a comprehensive determinants framework originally published in 2009 and updated in late 2022 (Damschroder et al., 2009, 2022a), utilized to predict or assess barriers and facilitators of implementation of a given innovation (Nilsen, 2015). The updated CFIR is comprised of five domains (Outer Setting, Inner Setting, Innovation, Individuals, and Process) consisting of 48 domain-specific constructs, and 32 sub-constructs. We applied the CFIR as an organizing framework to facilitate the description of implementation determinants of primary care-based recruitment for P2P at the mid-point of the trial, from the perspectives of implementers. Project-specific definitions of CFIR domains and constructs may be found in Table 2.

Innovation Definition

The CFIR conceptualizes an innovation as "the 'thing' being implemented" (Damschroder et al., 2022a). While both P2P prevention programs are fully virtual and remote, screening and recruitment occurs in-person, within the primary care setting. In the present study, we conceptualize "recruitment" broadly—to include all activities undertaken to facilitate enrollment. At minimum, recruitment activities include preliminary eligibility screening with PHQ; informing adolescents and families about the prevention program assigned that clinic; facilitating advancement to the next stages of the eligibility determination and consent process; and/or providing linkage to alternative mental health support for those uninterested or ineligible. While the present study assesses barriers and facilitators to trial recruitment, similar activities involving screening, providing education about the prevention programs, and facilitating linkage with the prevention programs or alternative resources would occur if implemented into practice beyond the trial period.

Implementation Outcomes

In the present study, we qualitatively assess the implementation outcome "implementation", or the extent to which screening and recruitment activities were in place or being delivered at the time of the interviews (Damschroder et al., 2022b).

Participants

We utilized purposive sampling to recruit respondents within each health system with varied organizational

Table 2
CFIR Domains and Constructs: Project-Specific Definitions

Domain	Domain definition	Construct	Construct definition	Examples
Outer setting	Macro- and mezzo-level factors originating from outside the implementing health clinics and systems, including the surrounding community	Critical incidents	The degree to which large-scale and/or unanticipated events disrupt implementation or the delivery of recruitment activities	COVID-19 pandemic; adolescent mental health crisis
		Local conditions	The degree to which economic, environmental, political and technological conditions enable the Outer Setting to support implementation of recruitment activities	Poverty in the community; racism in the community
		Local attitudes	The degree to which sociocultural values and beliefs encourage the outer setting to support implementation or delivery of recruitment activities	Mental health stigma within communities
Inner setting	The health systems and individual clinic sites where primary care-based recruitment activities are implemented	Mission alignment	The degree to which implementing and delivering the innovation is in line with the overarching commitment, purpose, or goals in the inner setting	Respondent support for the P2P trial
		Incentive systems	The degree to which tangible and/or intangible incentives and rewards or disincentives support implementation and the delivery of recruitment activities	Respondent desire for additional or different incentives
		Available resources	The degree to which resources are available to implement and deliver recruitment activities in the inner setting	Time and capacity limitations
		Relative priority	The degree to which implementing and delivering recruitment activities is important compared to other initiatives	Respondent views on the relative importance of P2P recruitment within individual clinic settings
Innovation	The implementation and integration of primary care-based recruitment activities for the P2P adolescent depression prevention trial	Innovation complexity	The degree to which recruitment activities are complicated, which may be reflected by their scope and/or the nature and number of its connections or steps	Multi-stage eligibility screening process; finding resources for ineligible adolescents
		Innovation adaptability	The degree to which the recruitment practices and activities can be modified, tailored, or refined to fit local context or needs	Issues with eligibility criteria limitations; exclusion criteria

Note. Domains and constructs are adapted from Damschroder et al. (2022a, 2022b).

roles. Each health system (HS) had at least one established site champion (physician and/or nurse/MA). Site champions were invited to participate in key informant interviews; they also provided contact information for other staff actively engaged with recruitment at their health site. We aimed to interview at least four respondents from each health system, including one to two respondents from each employment category: administrators, research/support staff; clinical providers. Eligible participants had direct involvement with the process or oversight of recruitment activities at one or more of the participating clinical sites (see Table 1). We contacted potential participants via email. Forty-two individuals were invited to participate; three declined due to limited availability and four were unable to be reached. Our final sample consisted of 35 individuals representing four health systems and 24 primary care clinics.

Data Collection

Semi-structured key informant interviews ($n = 35$) lasting 20 to 70 minutes were conducted virtually via Zoom between June 2021 and February 2022. Most interviews were conducted individually or in pairs. One group of behavioral health providers who provided referral, linkage, and care coordination were interviewed as a group. All respondents gave informed consent. AK and JSF were most directly involved with the process of data collection. They adopted a process wherein one functioned as the lead interviewer, and the other recorded field notes. Respondents were asked about their perceptions of the value and relevance for their clinical populations; their individual role in the recruitment process; the impact of the study recruitment on their workflow and/or clinic operations; availability of support and training; and feedback from service users. A semi-structured interview guide was utilized (Supplemental File). At the time of data collection, AK (Female, PhD, Social Work) was a postdoctoral research associate, and JSF (Female, PhD, Public Health) was an assistant professor at the University of Illinois Chicago. Interviews were audio-recorded and professionally transcribed. AK and JSF engaged in peer debriefing (Koch, 2006) following each interview, while tri-weekly debriefing sessions were implemented with all authors to discuss emerging findings.

Data Analysis

We applied hybrid thematic analysis, an iterative, flexible, approach which combines the principles of Braun and Clarke's (2006) thematic analysis with the use of deductive a priori codes informed by research questions and theoretical frameworks toward the formation of research themes (Swain, 2018; Xu & Zammit, 2020). The CFIR domains (e.g., Innovation; Outer Setting; Inner Setting; Individuals; and Process), as well as determinants (e.g., Barrier, Facilitator), functioned as a priori deductive codes. Inductive codes were applied a posteriori using holistic and in vivo coding strategies (Saldaña, 2021; Swain, 2018). ATLAS.ti Mac (Version 9.1.3) was used to organize and code the data. AK independently coded all transcripts and created a preliminary codebook consisting of inductive and deductive codes. Using the codebook, JSF independently coded all transcripts. First-cycle coding produced code groups which were synthesized into five overarching themes and grouped according to corresponding CFIR domain (Inner Setting, Outer Setting, Innovation). Following preliminary thematic development, AK, RF, JSF, AM, and CL began to convene for tri-weekly debriefing sessions to collaboratively refine study themes.

Findings

We present our thematic findings narratively, contextualized by inner setting, outer setting, and innovation domain-specific constructs outlined in the updated CFIR (Damschroder et al., 2022a), which emerged as most salient in our data. Study themes with additional illustrative quotations are presented in Table 3.

Outer Setting Domain

The Adolescent Mental Health Crisis in the COVID-19 Context

We identified two distinct, yet intertwined *critical incidents* (Damschroder et al., 2022a) situated within the outer setting: The COVID-19 pandemic and the emerging youth mental health crisis. In line with nationally observed trends (AAP/AACAP/CHA, 2021; OSG, 2021) respondents from all four health systems described increased mental health disorders among their adolescent patients, and noted increased levels of depressive and anxiety symptoms, and suicidal ideation. These trends affected adolescents' motivation/interest in participating in P2P, and served as a limiting factor due to interactions with eligibility criteria. Across sites, respondents discussed worsening adolescent mental health in the context of the COVID-19 pandemic.

> Especially post-COVID, our patients are scoring too high [on the PHQ-9]. We're seeing a crisis in mental health … getting them in that at-risk time, it feels like that window is gone a little bit. I think they're getting the P2P handouts and they're excited but then they … score too high to participate. (Provider, HS 1)

Additionally, the increase in mental health disorders impacted adolescents' desire to participate. Respondents observed that among adolescents eligible for P2P, many declined to participate in favor of active treatment interventions (versus prevention programs) if those services were immediately accessible within their health systems or community. This resulted in some hesitation from providers to offer the P2P trial as an option to eligible adolescents if other mental health support (e.g., individual

Table 3
Study Themes and Illustrative Quotes

Theme	Illustrative quotes
The Adolescent Mental Health Crisis in the COVID-19 Context	People seem to have progressed really rapidly from one or two years ago when I saw them, and they were, "Oh, sometime I get a little down," talking about more minor traumas in their lives … to where we're starting SSRIs, and I'm trying to find them counseling support (Provider, HS 1).
	I think COVID has really shifted things … they are coming in with more tenacious issues. I know it's a good intervention, but they aren't open to the usual things. They are really shut down. Not just, "I'm a little nervous, I'm worried about starting high school". It's really beyond what I normally would see (Support staff, HS 2).
Community Context: Poverty and Racism in the Community	The fact that its free for the patients who would usually be struggling with a barrier to treatment because they wouldn't be able to pay for mental health visits, I think that's the biggest thing—its easily accessible (Provider/ Administrator, HS 2)
	Racism is everywhere, but it's on fire here. It's so raw and real … in a way that is different than other parts of the country. I think that makes people less trustful of an online program. Like, "Who is my kid going to talk to?" They are terrified of someone being racist toward their child (Provider, HS 4).
Stigma, Misconceptions, and the Need for Psychoeducation	Some parents will try to do the PHQ-9 for their child. They don't want us to think there is something wrong with their child (Provider, HS 3)
	I'm sure I catch [parents] off guard. They're like, "My kid is crazy?" I'm like, "No, no, no!" I do get that [response]. I explain … the research, that their child filled out a PHQ-9 form, that [all patients] fill out. I don't want them to think they're being singled out (Support staff, HS 4).
Stakeholder Buy-In and Motivation for Recruitment Activities	I love this program, I think it's definitely needed. We have plenty of teens who you can imagine are going to have depression laterin life. But just because it's needed, doesn't mean its easy to get people enrolled (Administrator, HS 3)
	[We've] been working hard on this study … we realize the importance of it because it is helpful for our teens. That's what helped motivate us to get the information out there to those who qualify. But it has been time-consuming … we get emails of thanks from [program admin] but we don't think it's enough… (Support staff, HS 2).
Research Parameters: Issues with Participant Eligibility, Screening, and Assessment	So many of our patients don't meet the criteria. They had super high PHQ-9 scores, they were on medication, or they had been hospitalized for [suicidal ideation or attempt] (Provider, HS 2)
	The PHQ scores were sometimes a barrier for me to referring patients. When I'd either forget what the level was, or if they were one point off, or just sometimes I feel like, "Oh this kid would be a really good fit. Today he is feeling a little more sad." PHQ is not always the best measure of that. That was a barrier to me (Provider, HS 1)

psychotherapy, psychiatry) was available. However, waitlists for psychiatry or psychotherapy services for low-income families with public insurance (over half of participants) commonly exceeded 6 months, particularly in urban settings. In these settings, adolescents sometimes decided to enroll in P2P for mental health support while they waited to access "active" interventions—which was viewed as a recruitment facilitator.

Community Context: Poverty and Racism in the Community

Community context impacted recruitment by affecting adolescents' and families' openness to hearing about the prevention programs as well as respondents' prioritization of recruitment. On one hand, respondents expressed enthusiasm for P2P as a high quality, "free," easily accessible mental health program, available regardless of insurance status. However, within some settings, and particularly within HS 4, the acuity of the patient population and addressing urgent health needs overshadowed prioritization of recruitment, interacting with the inner setting construct of *relative priority*.

> I have a 20-minute visit, and our kids are so sick because they are impoverished, and they are living in trauma. I'm trying to get their water turned back on, I'm putting out fires that there is no way I can get to a prevention program…. I don't have time for that. (Provider, HS 4)

Also salient within HS 4 were concerns regarding racism in the community (and by extension—in healthcare settings), where advocacy efforts in the wake of Breonna Taylor's death (Callamachi, 2020) had led to increased community awareness of structural and institutional racism. Respondents noted that families seemed more aware of the extent of racial injustices within their communities, and this increased awareness sometimes translated into a reluctance to trust in institutionally-sponsored research studies, or a desire to pursue increasingly available community-based alternatives, including programs that intentionally emphasized cultural sensitivity and provider representation.

Stigma, Misconceptions, and the Need for Psychoeducation

Misconceptions and stigma concerning adolescent depression, particularly among parents/caregivers, was a barrier most salient in rural and suburban clinics in IL and KY, where respondents were more likely to perceive community members' attitudes toward mental health as dismissive or stigmatizing.

> The culture around mental health is different here. Mental health is, "Suck it up. Deal with it. Stop being a bad kid." That's how parents deal with mental illnesses, so kids have … grown up to think that. When it comes to talking to counselors, doing PHQ-9s … there is significant resistance. (Administrator, HS 3)

Respondents across all four health systems also reported that caregivers worried about the implications of PHQ depression screens. For example, respondents reported that parents sometimes became concerned when they learned that their child qualified for P2P, leading to a greater interest in the meaning of the PHQ score, versus learning about the prevention program. This dynamic was particularly challenging for non-clinical staff recruiters with limited ability to discuss implications of positive depression screens.

Relatedly, parent–child communication difficulties around mental health topics were also perceived as barriers to recruitment. Although respondents understood the requirement for parental consent, some believed more adolescents would enroll if parental consent was *not* required. Conversely, others noted that parents occasionally expressed interest in P2P, but their adolescents lacked interest, or would refuse to engage in discussions with providers about their mental health.

> It's hard [talking about mental health], depending on the teen's relationship with the parent … the provider can be a nice liaison for the teen if they can convince them to get their parents back in the room. I can ask things like, "Have you noticed that your son is not his normal self?" Parents are invariably like, "Yes, I've been so worried." You're like, "Okay, so let's get this process started…." (Provider, HS 1)

Across sites, providers emphasized the role of rapport-building and psychoeducation with families as a key component of destigmatizing adolescent mental health concerns. While stigma and misinformation about adolescent depression were perceived as a barrier to recruitment, providing psychoeducation to address stigma was viewed as a facilitator.

Inner Setting Domain

Stakeholder Buy-In and Motivation for Recruitment Activities

At the conceptual level, P2P was widely supported by respondents, and regarded as an appropriate program that was well-aligned with the goals and values of implementing health systems. Overall, respondents spoke about P2P enthusiastically and were appreciative of having a needed mental health resource to offer adolescents.

> I think the study is great. I've been happy to present this to families. The fact that they've not been in a deep, dark depression, they're just in that little place that needs a little help … we're really trying to [communicate to families], "let's catch this before things get worse." (Support staff, HS 2)

Enthusiasm for the program and recognition of need among the patient population, particularly in the context of COVID-19 and the youth mental health crisis, fueled recruitment efforts. Administrative and physician stakeholders less directly involved with the day-to-day implementation of recruitment activities spoke especially highly of the perceived merits of the P2P trial, and encouraged their "on-the-ground" staff to actively recruit in their clinics.

> I didn't have any concerns [about implementing the trial]. Actually, my thoughts were really always, "How do we make this something that as many people can take advantage of as possible?" I thought it was a beautiful [opportunity] for our patients … I thought it was a perfect project. (Administrator, HS 1)

Alternatively, for some respondents in smaller, lower-resourced clinic sites, organizational demands led to diminished enthusiasm for P2P over time, and recruitment activities were increasingly viewed as burdensome. The rising demand for adolescent mental health services put increased strain on already overburdened employees tasked with recruitment duties as well as multiple other responsibilities within their clinical settings. Time constraints were compounded by pandemic-associated staff shortages, which burdened staff tasked to manage numerous competing responsibilities.

> It's difficult because [we] aren't always available to speak with the family who are interested in the study, because we have our own providers to work with … other responsibilities in the clinic to take care of. (Support staff, HS 2)

In this context, some staff expressed the perception that their recruitment efforts for P2P went unnoticed/unappreciated. Relatedly, support staff from two of the four health systems expressed the desire for additional monetary compensation for their recruitment activities.

Innovation Domain

Research Parameters: Issues With Participant Eligibility, Screening, and Assessment

Across sites, respondent's alluded to barriers concerning P2P's multi-stage screening and eligibility determination process—which some perceived to be limiting and/or inflexible, corresponding to the CFIR construct, *innovation adaptability*. As a prevention study, P2P aims to enroll adolescents at-risk for depression, as measured by the PHQ screening and subsequent behavioral health assessment by a trained behavioral health clinician (via phone). Based on enrollment metrics, over one-third of adolescents are ineligible at screening, and another third are ineligible following baseline assessment. Reasons for ineligibility after assessment include a diagnosis of a mood disorder, a history of suicide attempt or inpatient psychiatric hospitalization, or current suicidal ideation. While respondents acknowledged the rationale for a multi-step eligibility determination process in the context of a depression prevention trial, the complexity and uncertainty associated with that process were often experienced as a recruitment barrier.

> Sometimes when I've put in the referrals, one of the things I've found is that they may not qualify [after baseline assessment]. Because it's a research project, right? That's been a big barrier, because people are like, "So you're saying that they might not take me?" there's this like fear of rejection. With mental health, the last thing people need is rejection. As providers, we don't want to refer people to something that's a possibility, for mental health. That feels dangerous. A couple of times, I have had patients who didn't qualify. Then they're like, "They didn't even take me." (Provider, HS 4)

Adolescents found ineligible due to acute mental health concerns (e.g., suicidal ideation) needed to be referred to treatment or other supportive services, per research protocol. In response, staff needed to quickly pivot to connect those adolescents and families with support and resources within the health system or the surrounding community. While staff and providers recognized the necessity of facilitating linkage to needed services, the volume and urgent nature of referrals to behavioral health specialists or other clinical providers were often difficult to coordinate in the context of health systems already overwhelmed with staff shortages and an escalating demand for adolescent behavioral health providers and programs. Connecting adolescents and families with behavioral health in a timely manner often became a complex process, requiring considerable effort and unplanned time expenditure for staff.

Discussion

In this qualitative study of the P2P adolescent depression prevention trial, we conducted semi-structured interviews with diverse staff and providers representing 24 primary care clinics within four health systems in two states to gain a preliminary understanding of barriers and facilitators affecting implementation of screening and recruitment activities. Our analysis revealed dynamic and interacting determinants across the Outer Setting, Inner Setting, and Innovation domains of the CFIR (Damschroder et al., 2022a). Our findings support a preliminary understanding of internal, external, and innovation level determinants and the ways in which these factors may operate to influence implementation efforts. The updated CFIR provides descriptive language helpful for elucidating the domains in which barriers are situated, and how they may interact with other contextual domains. For example, two separate, yet entwined *critical incidents* (Damschroder et al., 2022a) emerged as Outer Setting determinants that affected recruitment across all health systems and clinics. The interaction of the pandemic with widespread declining adolescent mental health nationwide was an overarching influence threaded throughout all health systems and contexts. Notwithstanding, the convergence of these critical incidents with other site-specific determinants resulted in health system-level (or clinic-level) differences.

Community context, or *local conditions*, influenced recruitment in all settings, but emerged as particularly salient within HS 4 in Kentucky. In urban clinics serving adolescents with high medical and social needs, conditions within the wider community influenced the inner setting construct *relative priority*, affecting providers' motivation to offer the study to their patients. The view of P2P as depression *prevention* (versus active treatment), and its status as a research trial, may have contributed to provider de-prioritization of screening and other recruitment efforts in some settings. While respondents did not object to P2P, and regarded it as "conceptually good," recruitment was sometimes viewed as less important than addressing health needs perceived as more urgent, especially in the context of an ongoing pandemic.

Health inequities during the pandemic have disproportionately impacted children from ethnic and racial minorities (AAP/AACAP/CHA, 2021; OSG, 2021). In Kentucky, families' exposure to and increased awareness

of interpersonal and institutional racism at the community level were perceived to affect trust and enthusiasm for a research study where adolescents would engage with 'unknown' staff and (in the group therapy condition) providers. Increased availability of community-based resources promoting inclusive, culturally sensitive, and representative care for people of color in the Kentucky area were appealing to youth and families in this context, and some respondents expressed an inclination towards those community-based resources (versus P2P programs) when available.

The impact of *local attitudes*, inclusive of community-level stigma, misconceptions, and/or a need for psychoeducation about adolescent depression, was experienced on some level at all sites, but most palpably within HS 3, servicing rural Illinois, where staff and providers experienced difficulty with being able to get families to consent to depression screening—or subsequent assessment and programming—for their adolescents. In addition to annual screening, the AAP recommends that primary care clinicians provide education concerning the causes and symptoms of adolescent depression and treatment options to families (Zuckerbrot et al., 2018). Across clinic sites, respondents endorsed the importance of cultivating trusting, culturally sensitive family-provider relationships toward facilitating these discussions. Nevertheless, clinical providers were not always readily available to engage with families. In HS 3, system-level efforts to reduce stigma via the delivery of intentional psychoeducation and collaborative treatment and prevention planning for adolescent depression had been initiated prior to the pandemic (e.g., reframing of "mental health" as "brain health"). Yet, these systematic efforts were perceived to have dwindled throughout the pandemic given competing demands.

At P2P's inception, organizational decision-makers were enthusiastic about the adoption of the trial into their health systems. The pandemic and associated increase of youth mental health problems further strengthened support for depression prevention efforts. Respondents in diverse organizational roles expressed enthusiasm about P2P—an integral component for integrating and implementing an innovation into an organization (Weiner et al., 2009). Yet, *maintaining* buy-in throughout the course of the study is essential for achieving successful outcomes (Macauda et al., 2018).

While the pandemic and associated youth mental health crisis facilitated mission alignment within the inner setting to support initiatives toward improving adolescent mental health, these crises also introduced competing demands on staff and providers. Staffing shortages, particularly in rural and lower-volume clinics (Anaraki et al., 2022), and high demand for mental health resources greatly impacted operations within the inner setting, including available staff for recruitment, perceptions concerning the relative priority of P2P, and concerns about availability of alternative mental health support for those found ineligible. While exacerbated by COVID, these findings are aligned with previously identified barriers to implementing recruitment activities for mental health trials in healthcare settings, such as staff/provider workload (Jones & Cipriani, 2019) and concerns about vulnerability of pediatric populations (Kilicel et al., 2023).

Site champions may be uniquely positioned to address inner setting challenges toward re-invigoration of buy-in, such as facilitating collaborative planning discussions, and repeated assessment of the provider and staff goals, interests, and priorities (Hickey et al., 2018; Powell et al., 2015). While all health systems in the P2P trial had at least one site champion, role and organizational position varied, and not all health systems could maintain an active site champion. According to one clinical administrator, internal communication barriers, high staff turnover rate, and the lack of an "on-site" champion initially led to an inadequate understanding of screening and recruitment, as well as the trial purpose overall—another known recruitment barrier for adolescent mental health trials (Kilicel et al., 2023).

At the innovation level, study eligibility criteria, initially determined prior to the onset of the pandemic, limited advancement in the recruitment process for many interested adolescents due to rising depression screening scores, mood disorder diagnoses, and suicidal ideation. Notably, the study team responded to implementer feedback through initiating a process to expand the PHQ eligibility range. Notwithstanding, a complex eligibility determination process—inherent in most behavioral health trials—continued to result in frequent ineligible determinations. Potential participant ineligibility frustrated some providers and staff and may have affected motivation for presenting the trial to families as an option (Kilicel et al., 2023). Our findings emphasize the need for intentional ongoing assessment at regular intervals, to understand and respond to emerging needs, re-evaluate buy-in, and provide resources and support for issues identified at both the health system and clinic level.

Implications

In the context of the ongoing youth mental health crisis, it is imperative that youth have access to quality and affordable mental healthcare "available in primary care practices, schools, and community-based settings" (OSG, 2021, p. 12). Early identification of emerging mental health problems, including the implementation of mental health screening and prevention-focused efforts, are particularly important for promoting the mental health and well-being of youth (OSG, 2021). The integration of DMHIs into healthcare, such as primary care, may increase access to needed mental health support for youth (Stiles-Shields et al., 2023) but more evidence is needed to support their effective utilization within health settings (Lattie et al., 2022; Stiles-Shields et al., 2023).

Presently, the United States health system is ill equipped to support the urgent mental health needs of our youth, and structural change is needed (OSG, 2021). Despite considerable enthusiasm by respondents in diverse organizational roles expressed for P2P, findings from this study suggest that primary care providers will continue to face numerous challenges and extra burden when asked to implement additional, often perceived as less essential tasks, such as needed mental health trials/prevention efforts until substantial resources are invested to relieve the mindset of scarcity and build community trust (Mullainathan & Shafir, 2013; Stiles-Shields et al., 2023). Although the COVID-19 pandemic, and the associated increase in the prevalence and severity of youth mental health problems may have seemingly strengthened implementer support for adolescent mental health prevention and operated as a recruitment facilitator, the overwhelming scarcity of personnel power, time allotted per patient according to pre-pandemic standards, and mental health resources constrained recruitment efforts.

Limitations

Our study has several limitations that should be noted. First, given the status of P2P as a clinical research trial, the findings from our study may be more applicable to the research side of the research-practice continuum. Second, it is difficult to disentangle the systemic impact of COVID-19 (and the associated transitions in workflow and responsibilities) from the respondents' perspectives on the implementation of recruitment for P2P, specifically. Additionally, we were not able to interview an implementer who worked "on-site" at every individual clinic site in HS 3 and HS 4. To maintain confidentiality, certain characteristic information about respondents (e.g., years of experience in role/clinic) was not collected, which may have provided additional nuance to our findings. Finally, the interview context was focused on recruitment for a specific clinical trial at a specific time point (i.e., pre-enrollment) and may not be representative of perspectives at other time points in the research cycle.

Conclusion

Clinical trials are needed to determine the effectiveness of DMHIs for adolescents, as well as inform best practices for their implementation in diverse primary care settings. Careful attention to the dynamic interrelationships between the inner and outer settings (and their interaction with innovation-specific factors) in the planning and implementation of innovations can promote sustainability within and beyond the trial period (Legnick-Hall et al., 2020). The updated CFIR is a useful framework for identifying barriers and facilitators to the implementation of recruitment for adolescent mental health trials, as well as predicting challenges to the future implementation and integration of adolescent mental health programming within diverse health settings. Outer setting constructs such as *critical incidents*, *local attitudes*, and *local conditions*, and their interaction with inner setting constructs such as *mission alignment*, *relative priority*, and *available resources*, may be especially relevant for assessing implementation determinants during times of rapid inner and outer setting change, such as those brought on by the COVID-19 pandemic, youth mental health crisis, and the corresponding exacerbation of resource strain within healthcare settings.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Research reported in this article was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (HIS-2017C3-9333). The views in this article are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Institute, its Board of Governors or the Methodology Committee.

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