Exploring the Experiences of Health Workers Recruiting for Clinical Trials in Mental Health

by

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Submitted in partial fulfilment of the requirements
for the degree of Master of Science

at

Dalhousie University
Halifax, Nova Scotia
June 2020

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Abstract

Most clinical trials fail to recruit the planned number of research participants, thus leading to underpowering of trials and sometimes outright failure of the studies. Recruitment for clinical research in mental health is often conducted by front-line mental health workers because they have direct contact with patients on a daily basis. The main objective of this study was to examine the recruitment experiences of mental health workers to identify and explore enablers and barriers to the recruitment of study participants. The secondary objective was to identify strategies for improving recruitment to mental health trials. The final objective was to identify strategies to improve mental health workers' engagement in mental health trials (in order to increase recruitment). If mental health workers are not engaged and active in recruitment activities, then recruitment may be less effective, and the trials may not be able to proceed as planned.

The participants recruited for the current study were mental health workers involved in recruitment for mental health clinical trials. An interview guide was developed to conduct semi-structured qualitative interviews. Qualitative descriptive methodology was used to guide data collection. Data from the transcribed telephone interviews were analyzed using inductive thematic analysis. Four different types of enablers and barriers to recruiting for mental health trials were produced from the data, through the process of thematic analysis: health worker-related enablers and barriers (e.g., the attitudes, beliefs, and expectancies of health workers regarding mental health trials), participant-related enablers and barriers (e.g., ease of access for participants), study design-related enablers and barriers (e.g., inclusive eligibility criteria), and collaboration-related enablers and barriers (e.g., regular visits from the research team). Enablers and barriers also vary depending on the type of research trial being recruited for (e.g., e-mental health trials vs face-to-face mental health trials). Findings aligned with previous research on enablers and barriers to recruitment that had been investigated in trials looking at interventions for a variety of physical health conditions. They revealed insights into how health workers can most effectively be involved and engaged in recruitment for mental health clinical trials.

Keywords*:* clinical trial, participant recruitment, qualitative, research methods, enablers, barriers, patient-oriented research, health workers

List of Abbreviations Used

RCT – Randomized Controlled Trial

e - mental health – electronic mental health

PI – Principal Investigator

Chapter 1: Introduction

Overview

Recruitment of research participants is a necessary but difficult task (Newington & Metcalfe, 2014), often identified as the most challenging part of health research (Patel et al., 2003). Although recruitment can be challenging in all types of research studies, researchers who conduct clinical trials (the most common of which are randomized controlled trials, or RCTs) have more difficulty recruiting participants compared to other types of research, such as observational studies or qualitative studies (Newington & Metcalfe, 2014; Patel et al., 2003). Researchers have determined that the majority of health researchers rely on health workers, such as physicians, nurses, and social workers, to help with recruitment in a variety of ways. Reliance on health workers is often necessary because they have access to potential research participants. Recruitment activities may include handing out written invitations, allowing emails to be sent to employees in hospitals/clinics, circulating electronic posters, telephone reminders, and using social media to attract participants (Furimsky et al., 2008; Liu et al., 2018; Tishler & Reiss, 2011; Treweek et al., 2013). Most of the research focused on recruitment with clinical trials has been quantitative and there is a paucity of research that has explored the personal *experiences* of those who assist in recruitment for mental health trials. Examining recruitment using qualitative, in-depth, exploratory methods may help us to better understand the experiences of recruitment for mental health clinical trials by those who work in a variety of different mental health settings.

Clinical trials are used to assess the effectiveness of mental health interventions, as well as health interventions more generally (Bucci et al., 2015), and can provide very high-quality research findings (Elliott et al., 2017; Team et al., 2018). The purpose of clinical trials in mental health is to evaluate new interventions to prevent, treat, or manage mental illnesses. Recruiting for clinical trials, particularly randomized trials (studies where people are allocated at random into an experimental group, where they get a treatment, or a control group, where they do not), is more difficult than recruitment for observational studies (non-experimental studies, e.g., case-control, cohort, and cross-sectional studies) because participants must accept that they will be assigned to either a

treatment condition or a control condition, where they won't actually be receiving the new treatment (Patel et al., 2003).

Recruitment for clinical trials in mental health is particularly difficult when compared to trials examining physical health conditions, because many mental health treatments are reasonably effective, leading to patients being doubtful about trying new therapies (Liu et al., 2018). In addition, mental health populations tend to be more vulnerable and may have poorer decision-making capacity, causing clinicians to be more apprehensive about discussing potential research participation with them at their clinical encounters (Liu et al., 2018). Furthermore, two large systematic reviews and meta-analyses (Fletcher et al., 2012; Treweek et al., 2013) found a lack of evidence-based interventions for successful recruitment to clinical trials, particularly to e-mental health (i.e., distance-delivered) interventions, and a lack of a systematic methods to choose the most effective recruitment strategies.

Since participants being recruited to participate in mental health clinical trials may be caregivers of those with mental health issues, or they may be patients themselves, clinicians need to be sensitive to the ways in which they recruit these participants. Therefore, researchers need to be mindful of the enablers and barriers to recruitment from the clinicians' perspectives. Clinician referrals and contact from clinical staff (compared to being contacted by research staff) have been found to be the most efficient and successful recruitment avenues in non-randomized mental health studies according to a recent systematic review (Liu et al., 2018), so the same finding may extend to randomized trials. My study explored the complexities of how mental health workers experience recruitment of potential participants for research studies focused on mental health trials.

My interest in recruitment to mental health trials has stemmed from my experiences with research as a student, my personal experiences as a user of mental health services, and my experiences being recruited for (and participating in) mental health research.

Literature Review (Background)

After reflecting on my own biases and motivations for pursuing this research topic, I turned to the literature. In the remainder of this chapter, I have critiqued several

key research studies on the topic of mental health recruitment, by discussing the type of study, the participants, the findings, and lastly the limitations of these studies. This highlights how my qualitative descriptive study significantly adds to the body of literature.

For example, Treweek et al. (2013) conducted a large Cochrane systematic review and meta-analysis on methods to improve recruitment to randomized controlled trials, but they only included three studies on mental health. However, they had a very large pooled sample size of over 43,000 participants. They found that including telephone reminders to patients and having open-trial designs (where both the researchers and participants know which treatment patients are receiving) may improve recruitment (Treweek et al., 2013).

In their 2016 systematic review, Briel and colleagues (2016) found that the majority (76%) of discontinued clinical trials were stopped as a result of recruitment issues, and approximately 25% of clinical trials are discontinued before completion. When trials have low recruitment rates, this leads to smaller sample sizes, reducing the quality of the evidence that the clinical trial could potentially provide and often leading to premature termination (Furimsky et al., 2008). Low sample sizes may increase type II error, concluding the intervention is not effective when in reality it is (false negative).

Enablers of recruitment. Team and colleagues (2018) did a qualitative study to investigate barriers and enablers to recruitment for a randomized controlled trial on the effectiveness of aspirin in those who have venous leg ulcers. With a qualitative design, they were able to gain a deep insight into the barriers and enablers to recruitment for randomized controlled trials (which are the most common type of clinical trial). This was a major strength of their study, as well as the fact that they suggested potential ways to improve recruitment into clinical research in the future. The main barriers to recruitment that they found were narrow/restrictive eligibility criteria, and researchers over-estimating how big their potential participant pool could be. In addition, French and Stavropoulou (2016) did a qualitative descriptive study that helped them to develop a framework of factors that influence recruitment for randomized controlled trials, specifically from the perspective of nurses. This approach helped them to understand the perceptions, attitudes, and beliefs of the health workers they were interviewing, in the

way that the participants themselves actually framed the themes/concepts (French & Stavropoulou, 2016; Sandelowski, 2000).

Enablers of recruitment can be grouped into study-related enablers (e.g., an ambitious and experienced research team, inclusive selection criteria, and trial information that is clear and simple), participant-related enablers (e.g., patient eagerness to participate, family supports), health worker-related enablers (e.g., routinization of research-related activities in the clinic), practice-related enablers (e.g., incorporating recruitment strategies into the health worker's daily routine), collaboration-related enablers (e.g., availability of research staff at the clinic and good coordination between researchers and clinicians at the recruitment locations), and health system-related enablers (e.g., having a highly-staffed clinic; Team et al., 2018).

In their narrative review examining challenges to recruitment of research participants, Patel and colleagues (2003) identified collaboration between researchers and health worker-recruiters, as well as having good interpersonal and communication skills (i.e., a health worker-related variable) as important enablers to recruitment in mental health research. They concluded their paper with several potential techniques to improve recruitment, including considering the patient's perspective, stressing to the participants and to health researchers the relevance of the research they are recruiting for, enhancing health researchers' interpersonal/communication skills, and having training and supervision for health researchers who are recruiting. A limitation of their research however is that they did not provide suggestions for mental health worker-recruiters specifically, but for health researchers more generally.

Barriers to recruitment. Barriers to recruitment fall into several groups: (1) study-related, (2) participant-related, (3) health worker-related, and (4) practice-related (Bugeja et al., 2018). Team and colleagues (2018) identified these and also found ethics-related, collaboration-related, and health system-related barriers. According to Team and colleagues (2018), study-related factors are more significant compared to the other categories of barriers.

Bugeja and colleagues (2018) did a systematic review of barriers and enablers to recruitment for randomized controlled trials in the treatment of chronic wounds. Donovan and colleagues (2014) conducted a qualitative, grounded theory study to learn about

recruitment experiences among health workers recruiting for six different randomized controlled trials. The key barriers they found were organizational challenges, less than expected eligible patients, and strong treatment preferences of patients.

Study-related barriers include too restrictive eligibility/exclusion criteria and lack of eligible participants (Patel et al., 2003), highly demanding study requirements for participants, and logistic issues (e.g., duration of research visits, involving a significant time commitment, and/or a long study duration) (Denhoff et al., 2015; Donovan et al., 2014; Team et al., 2018).

Participant-related barriers include lack of ability to fully comply with the intervention, limited cognitive abilities, limited English language proficiency, technology-usage difficulties, lack of interest, and strong treatment preferences of patients (Bugeja et al., 2018; Donovan et al., 2014; Team et al., 2018).

Health worker-related barriers include difficulty in combining their research and clinical roles, dissatisfaction with recruitment procedures, lack of knowledge or skills relating to the project, and confusion regarding the purpose of the inclusion criteria as well as the rationale for the overall trial (Team et al., 2018; Ziebland et al., 2007).

Practice-related barriers include environmental concerns such as a shortage of available clinic rooms, having a busy clinical practice, lack of availability of staff, time constraints, administrative issues such as not sending out reminder letters on time, lack of clinician incentives to participate in recruitment, and lack of integration of recruitment into daily clinical practice (Bugeja et al., 2018; Foster et al., 2015; Team et al., 2018; Treweek et al., 2013).

Ethics-related barriers include lack of privacy and ethics-enforced requirements such as strict safety procedures, excessively lengthy participant information sheets, and a slow ethics approval process delaying recruitment (Newington & Metcalfe, 2014; Team et al., 2018).

Collaboration-related barriers include lack of availability of project researchers on-site and lack of reminders about the study (Team et al., 2018). Lastly, health system-related barriers mainly involve lack of staffing at the clinics (Team et al., 2018).

Mental health researchers often rely on the ‘front-line’ mental health providers to refer patients to their studies because front line workers have direct contact with patients

who are potential research participants. Initial recruitment tends to be the step where the barriers are the greatest, which is why in the current study I chose to focus on this early contact between patient/caregiver and mental health provider, and how to optimize these encounters for recruitment.

Overall, the barriers lie in the lack of ability of clinicians and patients to engage in the research process. A variety of reasons have been found to contribute to this lack of engagement: participants and/or clinicians not understanding the research objectives and rationale of the trial (Ziebland et al., 2007), lack of incentives for health workers' efforts in recruiting, highly demanding study requirements for participants, lack of clinician training, knowledge, skills, and expertise in research, unfavorable attitudes/beliefs towards clinical trials (e.g., that they are unrealistic, unreliable, not generalizable to the 'real world', or simply irrelevant for the mental health workers' patients), and time constraints (Bucci et al., 2015; Patterson et al., 2010).

In their qualitative study of barriers and facilitators to care coordinators' (who are typically community psychiatric nurses) recruitment for a psychosis research trial (seven care coordinators were interviewed), Bucci and coworkers (2015) found four key themes: (1) Engaging the care coordinator in recruitment, (2) barriers to referring to research studies, (3) facilitators to referring to research studies, and (4) organizational constraints that affect how research findings could be transferred to routine clinical practice. They also recommended that the best strategies will vary depending on the clinical team and the research trial in question, so mental health providers and researchers need to be flexible so that they can tailor their recruitment strategy to maximize recruitment in their own population of interest (Bucci et al., 2015).

Mental health clinicians may be reluctant to refer their patients to clinical trials if they are in the beginning stages of treatment and they are trying to develop a therapeutic alliance with their patients in order to ensure they can engage their patients in the first-line treatment for their condition (Furimsky et al., 2008). Furimsky and colleagues (2008), in their sample of 43 clinical trial participants from a First Episode Psychosis Program, found that in these patients, there are additional challenges to recruitment associated with family interpersonal dynamics and communication styles. They found that collaboration-related variables (between clinicians and researchers), participant-

related variables (e.g., monetary incentives), and study-related variables (e.g., flexible scheduling) are important enablers in trials evaluating interventions for first-episode depression and first-episode psychosis patients (Furimsky et al., 2008).

Strategies to improve recruitment and engagement. In their systematic review, Fletcher and colleagues (2012) found that the most effective strategy to improve clinical trial recruitment was using qualitative methods to examine recruitment enablers/barriers, and then addressing these findings in the context of the sample from which the qualitative data were obtained. In another qualitative systematic review, Liu and colleagues (2018) also found that strategies that improved recruitment and engagement in research varied greatly depending on the clinical setting, the mental health condition in question, and the study design. Some of the strategies found to be effective (in some trials but not in others) included increasing the accessibility of information and consent materials, direct recruitment by clinical staff, and recruitment through non web-based advertisements (Liu et al., 2018).

In their cross-sectional quantitative survey study of 562 patients, family members, and mental health workers, Becker and colleagues (2016) found that minimizing wait times is important to engage patients with early intervention services in mental health, as well as providing patients with a range of treatment services that they can choose from (including e-mental health services *and* more traditional, face-to-face interventions, both in the community and in hospital settings). Encouraging collaboration between clinicians, patients, and family members also has been found to increase their engagement with early intervention mental health *services,* therefore the same finding might extend to engaging patients in mental health *research* (Becker et al., 2016). Respecting patient perspectives and preferences (Patel et al., 2003), as well as including them in the design of mental health services was also found to be important in increasing their engagement with these services (Becker et al., 2016). It is important for researchers to recognize how much patient preferences vary and account for this variability in designing interventions and services for them, to ensure that recruitment and engagement in mental health research is optimized (Becker et al., 2019). For example, some patients prefer interventions aimed to improve symptoms as opposed to improving overall functioning or quality of life. So, this group of patients likely would not benefit from a research trial testing an intervention

designed to improve their work functioning as opposed to an intervention that could improve their symptoms of depression or anxiety (Becker et al., 2019). In addition, some patients prefer more convenient interventions (such as e-mental health interventions, that can be accessed from home), as opposed to more conventional interventions (traditional, face-to-face services in clinic/hospital settings) (Becker et al., 2019).

In their qualitative systematic review that included 27 studies, Bugeja and colleagues (2018) found that broadening participant inclusion criteria, extending the recruitment period, and adding extra recruitment sites were common strategies used to improve recruitment to clinical trials. These are potentially useful strategies because they address study-related barriers (particularly restrictive inclusion criteria), which have been identified as the most significant group of barriers contributing to low recruitment rates in some studies for physical health conditions (e.g., chronic wound RCTs, Bugeja et al., 2018; chronic venous leg ulcers, Team et al., 2018). Bugeja and colleagues (2018) also found that approximately 12% of the studies that stated their target sample size actually achieved it, and most of the studies they included were randomized controlled trials.

In a qualitative study of eleven surgeons' experiences of participation in a multi-centre RCT, Ziebland and coworkers (2007) concluded that interventions providing training to health workers, including refresher sessions on the specific aims/rationale for the trial, may need to be provided on a regular basis, particularly for longer clinical trials (because clinicians may not remember the objectives/rationale of any given trial that they are asked to recruit for). These training sessions could help to reinforce the benefits of the research trial and its clinical relevance, keeping recruitment motivation and interest in the study high among health workers (Patel et al., 2003; Ziebland et al., 2007). According to Patel and colleagues (2003), interventions that train health workers to improve their generic interpersonal and communication skills may be of value to increase health workers' recruiting activities and ability to engage patients/caregivers in research.

Furthermore, knowledge of the research project, attitudes, skills, and the research experience of recruiters (in terms of their ability to use effective recruitment strategies) have been identified as significant enablers in clinical trial recruitment, however these factors are very under-researched currently, in favor of strategies that make participation

more inviting and less burdensome for patients (Newington & Metcalfe, 2014; French & Stavropoulou, 2016).

The aforementioned studies that have identified various enablers and barriers to recruitment have also identified a clear gap that this thesis research will address. There is a lack of research looking at the enablers and barriers to mental health clinical trial recruitment from the perspective of *health worker-recruiters*, instead of only considering the issue of recruitment from the perspective of participants or looking at the interests and perspectives of researchers leading the clinical trials.

Furthermore, there is a lack of research looking at recruitment enablers/barriers in the *context of mental health research*. The mental health context is unique, requiring tailored and intensive research efforts, for several reasons. Firstly, mental health patients and caregivers are very vulnerable populations with high rates of comorbidities – more research is needed to address these complex health care needs and support this highly vulnerable population. Secondly, there is not enough mental health research being performed to fully address the burden of mental illness (Ahmed & Mari, 2014). More effective recruitment and health professional engagement will lead to studies being more valid and reliable, and ultimately will lead to improved mental health outcomes (Ahmed & Mari, 2014). Improved mental health outcomes include a reduction in mental health-related fatalities (for example due to suicide), lower levels of distress, and an improved quality of life among mental health patients and caregivers. Thirdly, improving recruitment and health worker engagement in mental health research will impact society as a whole by reducing the social and economic burden of mental illness. The social and economic impact of mental illness is larger than for most physical health conditions, further highlighting the importance of improving recruitment in the mental health context.

Qualitative research is useful in answering questions of “why?”, “how”, and “what” (Neergaard et al., 2007) of a specific phenomenon (Sandelowski, 2000). A qualitative descriptive approach was chosen to address the research question as it provides a methodology to elucidate a phenomenon as directly described by the participants with this lived experience. With my chosen qualitative approach, I looked for the unique experiences of different participants because I was seeking new and deeper

understandings of what it means to recruit for mental health clinical research. Even though I looked at different experiences I was also looking for common themes across health workers' experiences. Qualitative description was used because it is the most accurate way to present participants' *descriptions* of experiences (through their own voices) and is the best way to ensure that researchers are clear and transparent when they interpret the data (Bradshaw et al., 2017; Sandelowski, 2000). It is better than other qualitative approaches when researchers' time and resources are limited, which was the case in the current study (Bradshaw et al., 2017). It is the best approach to give voice to the participants.

Rationale

The rationale for the current study was to contribute to the body of knowledge regarding enablers and barriers to recruitment of participants to mental health clinical trials from a mental health recruiter's perspective. There is a scarcity of qualitative research that has explored the experiences and perspectives of health workers who have participated in recruitment for clinical trials and I did this research to fill some of this gap. Not only did I address enablers and barriers, but I opened my exploration to further examine new ways of understanding recruitment experiences that cannot be attained through quantitative research, which tends to be more prescriptive. I also explored ideas about potential recruitment strategies with clinician recruiters that could be used in the future to improve electronic mental health (e-mental health) trial recruitment in particular, but also recruitment to mental health trials more generally (Denhoff et al., 2015).

Objectives

The overall purpose of the study was to explore the experiences of health workers recruiting for clinical trials in mental health. The main objective of this study was to examine the experiences of health workers involved in recruitment for mental health trials, so that I could identify and explore enablers and barriers to recruitment. The secondary objective was to collect health workers' suggestions to identify strategies for improving *recruitment* to mental health trials. The tertiary objective was to identify strategies to improve health worker *engagement* in mental health trials. Recruitment is the process involved in enrolling participants for a trial, whereas health workers'

engagement is defined as how much they are involved in trial-related activities and how they are able or not able to participate in research recruitment.

Chapter 2: Methodology

I used a qualitative descriptive approach (Braun & Clarke, 2019; French & Stavropoulou, 2016; Sandelowski, 1995; Sandelowski, 2000; Thorne et al., 1997; Thorne et al., 2004). Overall, I chose qualitative description because my research question pertains to human experiences (i.e., those of mental health worker recruiters) and, more specifically because the methodology of qualitative description provides a *comprehensive* way to *describe* the experiences of the participants (in my case the recruitment experiences of mental health workers) that has the potential to add more depth and understanding to the experience of recruitment (Gaughan et al., 2014).

The qualitative descriptive approach was implemented after careful consideration of all of the potential alternatives, such as phenomenology, ethnography, or grounded theory. Qualitative description offered a robust way to ensure that my *descriptions* relating to health workers' experiences of clinical trial recruitment were rigorous.

In line with this approach, my data collection involved the use of semi-structured, open-ended questions so that I could acquire a comprehensive, rich description of the "who", "what", and "where" of mental health workers' recruitment experiences in terms of successes (enablers) and challenges (barriers) that they faced (Braun & Clarke, 2006; Clarke & Braun, 2013 Sandelowski, 2000). Qualitative descriptive studies are the most appropriate in situations where researchers are seeking a straight, comprehensive, and accurate description of a phenomenon (Sandelowski, 2000). This qualitative descriptive study was conducted by telephone, in the natural setting (i.e., the work environment) of the participants (i.e., the mental health workers) who experienced the phenomenon of interest (i.e., their experiences recruiting patients) (Sandelowski, 2000).

There were several reasons for choosing qualitative descriptive methodology. Qualitative descriptive methodology was chosen because its main philosophical assumption is that it is **naturalistic** (Sandelowski, 2000), meaning that participants understand a phenomenon by giving it meaning in its natural context, which in the current study was the work environment of mental health workers. Naturalistic inquiry also means that the interviews were conducted in such a way that reinforced to participants that they were the experts in understanding their own experiences. Since my desired outcome was to thoroughly describe the participants' recruitment experiences,

this was a strong justification for the qualitative descriptive approach that I chose (Gaughan et al., 2014). The goal of qualitative descriptive research is to provide a comprehensive summary of events experienced by certain individuals.

The second philosophical assumption of qualitative descriptive research is that it is **inductive,** meaning it describes/summarizes the phenomenon it studies (i.e., recruitment experiences in the current project; Bradshaw et al., 2017; Thorne et al., 2004). In the current study, this inductive approach informed the depiction of the themes and their analysis. The main difference between qualitative description and other qualitative approaches is that it involves the least amount of interpretation, thereby increasing the data's accuracy and reducing the chance that the data could be biased. Overall, this inductive approach informed my understanding of recruitment enablers and barriers, as well as suggestions to improve recruitment and health workers' engagement in future mental health research.

The final philosophical assumption of qualitative descriptive research is that it is **subjective**, meaning each person has their own unique perspective when describing a phenomenon, including both the participants (i.e., the health workers) and the researchers. Qualitative descriptive research helps researchers to understand a phenomenon from multiple perspectives, instead of simply providing evidence for a pre-existing theory (Bradshaw et al., 2017). Qualitative descriptive research is most useful when a researcher is aiming to achieve a "straight description of a phenomenon" (Sandelowski, 2000).

Qualitative descriptive methodology was chosen because its main ontological assumption is that multiple realities exist. There is no 'one truth' (Bradshaw et al., 2017). Many truths were found by the researchers, which were influenced by time variables, contextual variables, and other individual-related and larger scale variables. For example, in my study a contextual variable would be the occupation of the participant, because experiences of recruitment were generally more positive for those health workers for which resource coordinating and recruitment constituted the entirety of their job. In other words, there was no one 'truth' about how to be the most successful recruiter, or a prescriptive formula on how to recruit mental health populations, because this is affected by so many different variables in the lives of both patients and mental health providers.

Therefore, taking all of these variables into account, I did uncover multiple truths and perspectives regarding clinicians' perceived barriers and enablers to recruitment. Even though I was uncovering multiple truths, there were some recurring topics that allowed me to extract the main themes, and all members of the research team were able to recognize when saturation had occurred (at the point where no new themes were emerging from the data).

The qualitative descriptive approach first aims for a literal understanding and then to understand human experiences through analysing and interpreting the meaning that people give to events, which in this case would be health workers' experiences of recruiting patients for mental health trials. It is important to stay close to the surface meaning of the words and events, because it must be presented as close as possible to the verbatim descriptions of their experiences. Qualitative descriptive methodology allows for the multiple perspectives (i.e., 'truths') of participants to be thoroughly described, valued, and validated as it recognizes that multiple realities exist.

An advantage of qualitative descriptive methodology is that its main epistemological assumption is **subjectivism**, positing that the researcher knows reality in his/her own way (there are multiple 'truths'). According to subjectivism, many interpretations of reality exist, and *all* knowledge is subjective. In this study, I subjectively interpreted health workers' recruitment experiences after using verbatim quotes as supporting evidence to describe the themes in my "findings" chapter. In doing this research, I also acknowledged that my subjective interpretation of reality, as a researcher, is socially constructed, based on my own experiences. This insight informed my study and made it more reflexive because it helped me to ensure that my own biases, values, and experiences as a researcher would not influence how my participants expressed their own experiences during the interviews. In addition, to ensure that my own experiences would not influence my analysis (based on my preconceived notions about this topic or any previous literature I had examined) I frequently self-reflected on my potential biases. Furthermore, it was important to recognize and accept that although descriptions and subsequent interpretations of qualitative data can vary by researcher, this does not mean that any one researcher's work and analyses are not valid – multiple realities exist in the qualitative descriptive paradigm.

In conclusion, qualitative descriptive research is naturalistic, subjective, inductive, interactive, and retains unique cases/experiences. With my chosen qualitative approach, I searched for the unique experiences of different participants because I was seeking new and deeper understandings of what it means to recruit for clinical mental health research. I chose qualitative description because it is the least interpretative method, leaving less room for researcher bias (Sandelowski, 2010). Furthermore, it is one of the most frequently applied qualitative methodologies, and it is at an appropriate difficulty level for a novice qualitative researcher or graduate student to be able to use to acquire valuable qualitative research skills.

In addition, according to Neergaard et al. (2007), qualitative description is useful for health research because it can focus on the *experiences* of patients, friends/relatives, and mental health workers. The qualitative descriptive approach doesn't need to build on pre-existing theories or develop theories as do other qualitative approaches (Sandelowski, 2000). Although qualitative description is not particularly interpretative, it still has some interpretation involved because all research data needs to be understood and processed in some way (Sandelowski, 2010).

Recruitment

The researchers identified 14 mental health workers associated with different types of organizations (e.g., working in various capacities at clinics, hospitals, or intake service agencies) who had past or current involvement in mental health clinical trial recruitment, and were able and willing to participate in a telephone interview about their recruitment experiences. Participants were recruited through Dalhousie University's Department of Psychiatry, through professional relationships with the committee supervisor and through acquaintanceship with the researcher. All participants were recruited via in an invitation sent by email. The email addresses of potential participants were found online, through the Dalhousie University website, as well as using a Strongest Families recruitment database with names, emails, and occupations of the various recruiting bodies in these research projects. For some participants, repeated emails were sent out to those who had expressed interest, in order for us to confirm their interest and find a time to conduct the telephone interview.

Participants. There were 14 participants, interviewed between July and August 2019. Table 1 shows the demographic characteristics of participants. The majority of participants (79%) were between the ages of 41 and 60 (table 1). The sample consisted of 29% males and 71% females (table 1). Psychiatrists comprised the most commonly represented occupation – 43% of the sample were psychiatrists (table 1). In addition, 67% of the sample held a doctoral degree – either an MD, PhD, or PharmD – indicating that this sample is overall highly educated (table 1). There was a diversity in the professions and specialties of the health workers who participated, and they were involved in clinical trials for a range of mental illnesses, from eating disorders to psychotic disorders to anxiety disorders to neurodevelopmental disorders. The only downfall was that there were no nurses.

Table 1. Frequencies of participants' characteristics (n=14).

	Number of participants (%)
Age	
31-40	3 (21%)
41-50	5 (36%)
51-60	6 (43%)
Gender	
Male	4 (29%)
Female	10 (71%)
Occupation	
Psychiatrist	6 (43%)
Psychologist	2 (14%)
Pharmacist	1 (7%)
Nurse	0 (0%)
Social Worker	2 (14%)
Child and Youth Worker	2 (14%)
Resource Coordinator	1 (7%)
Highest Educational Qualification	
College Diploma	2 (13%)
Bachelor's degree	3 (20%)
Master's Degree	0 (0%)
PhD	3 (20%)
MD	6 (40%)
PharmD	1 (7%)

Procedure

Ethics. Ethics approval was obtained from the IWK Research Ethics Board. All participants received information about the study, had all their questions answered, and signed an Information and Consent Form prior to participation. Participants were advised that during the data collection, transcription, and data analysis phases their data would be stored in a secure, password-protected folder with restricted access on the Centre for Research in Family Health's SharePoint account (a secure online document management and storage system). After analysis was completed, data was stored on a password protected, encrypted USB stick in a locked filing cabinet at the Centre for Research in Family Health, to be destroyed five years after the study's completion.

Question development. A semi-structured interview guide was created for the interviews. The guide was open-ended, beginning with the question 'Tell me about your involvement as a recruiter. What are your roles and activities? What has your experience been like and how do you feel about your experience?'. These broad questions were meant to encourage participants to start the interview on their own terms to describe their experiences in a way that was most meaningful to them. Probes were then used throughout the interview to ensure that the areas of interest that were extracted from past literature were addressed. These included the participants' experiences/opinions about the most frequent and significant enablers and barriers to recruitment (Bugeja et al., 2018; French & Stavropoulos, 2016; Team et al., 2018). Before data collection began, the interview questions were pilot tested with other members of the research team (at the Centre for Research in Family Health at the IWK Health Centre) in order to practice the interview structure and ensure that the flow of questions was logical.

Email contact. Potential participants were first contacted via email, providing them with some background information about the study and their potential role in it (i.e., a 45-minute phone interview). The Information and Consent Form was attached to this email, and participants were encouraged to read and sign it before the phone interview. Participants were informed that their interview would be audio recorded (this information was included in the consent form).

Phone interviews. Participants were initially asked if they had any questions related to the project from when they completed the Consent Form. Their questions were answered by the Principal Investigator (PI) before the interview began (or prior to the day of the interview, via email or telephone). Demographic information was collected, including the participants' age, gender, and occupation (table 1). A semi-structured interview lasting approximately 45 minutes was conducted by the PI and audio recorded. After completing the telephone interview, participants received a thank you email, which included their signed copy of the Information and Consent Form. They were also emailed a $20 Amazon gift card in appreciation of their time.

Data Analysis

In order to retain confidentiality, participants were identified using a unique participant ID number. The data from the transcribed phone interviews were analyzed using the method of inductive thematic analysis, where the main themes and subthemes were extracted from each interview transcript (i.e., this analysis was driven by the data) (Braun & Clarke, 2006; Clarke & Braun, 2013; Maguire & Delahunt, 2017; Sandelowski, 1995; Sandelowski, 2000 Thorne et al., 2004). The main researcher, AM, did the transcribing.

The first three transcripts were read by the PI (AM) and the researchers MA and DJ, who both have extensive experience with qualitative research. MA was mentoring the PI in qualitative methods throughout the course of the project. DJ is a research assistant at the Centre for Research in Family Health at the IWK Health Centre. The researchers discussed and came to consensus about the emerging themes/issues in the first three transcripts, as well as reflected on how their backgrounds might influence the interpretation of the data to ensure a rigorous procedure of data analysis (Bucci et al., 2015 followed a similar procedure to maximize rigor). AM then continued to analyze the remaining interviews immediately after each was conducted and transcribed.

Data collection and analysis continued simultaneously, following the steps outlined by Braun and Clarke (2006). In step 1, each transcript was read several times to get a general feel for the content. In step 2, the data were reduced into smaller chunks by looking for emerging issues within each transcript. In step 3, five preliminary themes were extracted from each transcript. In step 4, as analysis continued, the transcripts were

compared and reviewed to develop common themes and subthemes across all transcripts. This type of thematic analysis does not require the use of codes or computer software (Nowell et al., 2017).

After this inductive analysis, a deductive, top-down theoretical thematic analysis was performed to address the three research objectives and which objective each theme and subtheme was addressing (see tables 2-5; Braun & Clarke, 2006; Bucci et al., 2015). In this manner, the analysis was related back to the three research questions/objectives and the broader literature (Bucci et al., 2015).

After interviewing and analyzing the transcripts of 14 participants, saturation was achieved. Saturation occurs when no new themes are observed in the data. The supervisors PM and MA, along with AM, agreed that saturation had been reached after 14 participants, and so no additional interviews were performed.

Trustworthiness and Reflexivity

Process (field) notes and the perspective of the researchers also introduces bias which was taken into consideration during analysis and reviewed again upon the writing up of findings. Trustworthiness and reflexivity were attained through rigorous and effortful attention of the researchers to processes, personal biases, personal values, and personal experiences. Process notes (which depend on the descriptions of the participants) were kept to critically reflect on team members' observations, biases, and interpretations of the data.

The consistent manner in which the semi-structured interview guide was delivered also helped to ensure trustworthiness. Reflexivity was further strengthened because the researchers were constantly self-monitoring and self-reflecting on their own biases, values, and past experiences. For example, I self-assessed my biases through reflexive journaling practice throughout the continuation of this study. This self-contemplation helped me to become aware as to how my own biases, values, and experiences could affect this qualitative project.

Credibility (internal validity) was ensured through regular discussion at team meetings of the ongoing analysis. Transferability (how the study findings could be applicable and/or replicated in other settings) occurred through providing an extensive background for the study in the introduction and literature review, comprehensive

descriptions in the findings and discussion, in-depth interviews, and verbatim quotations. Sharing the evidence in this manner enabled a comprehensive and transparent presentation of findings transferable to clinical and research practices. Dependability (reliability) and auditability were established with careful record keeping of decisions and rationale related to the research. In addition, MA and DJ followed the same methods and processes (for the analysis of the first three transcripts) to arrive at similar conclusions as AM, in order to ensure dependability and confirmability of the findings.

Chapter 3: Findings

Eight themes regarding enablers and barriers of recruitment were identified throughout the analysis. In alignment with Qualitative Descriptive methodology, verbatim quotations are included as evidence to support each of the themes and subthemes. Brief descriptions are also included for each theme and subtheme. Describing the findings in the context of this study means presenting the evidence with one or more quotations that are representative of the majority of participants who also spoke to the theme.

Key Themes and Subthemes

Key themes and subthemes produced from the data included: 1) health worker-related enablers, (2) health worker-related barriers, (3) participant-related enablers, (4) participant-related barriers, (5) study-related enablers, (6) study-related barriers, (7) collaboration-related enablers, and (8) collaboration-related barriers (tables 2 and 3). The data were rich, and participants were open to sharing; the topic was of high interest to participants. The fact that I identified so many themes and subthemes is a sign of the high quality of data provided by the participants.

Themes one and two, health worker-related factors, have to do with intrinsic (internal) factors related to the mental health workers themselves, such as their attitudes towards research, their enthusiasm about the trial, and their beliefs/knowledge about the research (table 2). Six subthemes were produced in the analysis and included three enablers and three barriers (tables 2 and 3).

Themes three and four, participant-related factors, are those relating to the patients or caregivers who are being recruited, such as their willingness, commitment, and motivation for participation (table 2). These themes have eleven subthemes (six enablers and five barriers; tables 2 and 3).

Themes five and six, study-related factors, are those having to do with characteristics of the study design, such as realistic inclusion criteria and patient involvement in all stages of the project (Patel et al., 2003; table 2). These themes have four subthemes (one enabler and three barriers; tables 2 and 3).

Themes seven and eight, collaboration-related factors, are those relating to the relationship between the health workers and the researchers of the trial (Patel et al.,

2003), such as having a supervisor from the organization who is in regular contact with the research team and can answer questions that mental health workers have about the trial (table 2). These themes have three subthemes (two enablers and one barrier; tables 2 and 3).

The ninth theme is strategies to improve recruitment to mental health trials, and it has eleven subthemes (i.e., eleven strategies; table 4). The final theme is strategies to improve health worker engagement in mental health trials and has six subthemes (i.e., six strategies; table 5).

Table 2. Enablers to recruitment for mental health trials (Objective 1).

Health worker-related factors: • Health workers who have positive attitudes, beliefs, and expectancies regarding mental health trials. • Health workers' enthusiasm about the trial and a strong commitment to promoting it. • Health workers are often motivated to recruit because they are looking for supports and services for their clients because of a gap.
Participant-related factors: • Providing honorariums to participants. • Mentally healthy, organized, and independent participants (e.g., caregivers). • Committed, willing, and highly motivated participants (not just looking for a quick fix). • Well-educated, higher socioeconomic status participants. • Participants wanting insight (i.e., having interest in knowing more about their illness/treatment/recovery) and perceiving a personal benefit to their participation. • Ease of access for participants enables recruitment for e-mental health trials.
Study-related factors: • Inclusive eligibility criteria.
Collaboration-related factors: • Regular correspondence/feedback between researchers and health workers. • Health workers feeling that their recruitment efforts are being valued by the research team.

Table 3. Barriers to recruitment for mental health trials (Objective 1).

Health worker-related factors: • Lack of time and energy to participate in recruitment for the study. • Lack of health worker interest and financial incentives for recruitment efforts. • Health workers having difficulties balancing their clinical vs research workload.
Participant-related factors: • Transportation or mobility issues for in-person mental health trials. • Time constraints (e.g., only being able to do appointments in the evening, or not being available during the summer months or holidays due to vacation). • Lack of follow-through or interest. • Language barriers. • Participant cognitive challenges.
Study-related factors: • The intervention feeling too burdensome/lengthy for participants. • The objective of the study is only peripherally related to the participant's issues or only relevant to a narrow subset of participants. • Lack of funding.
Collaboration-related factors: • Researchers not providing a detailed enough description of the intervention to the health worker.

Theme 1: Health worker-related enablers. When the health worker-related enablers mentioned by participants were organized, three subthemes were produced (table 2).

Subtheme 1: Health workers who have positive attitudes, beliefs, and expectancies regarding mental health trials enables recruitment. The first subtheme was endorsed by the majority (eleven) participants (table 2).

Regarding the enablers for the Strongest Families research trial that she recruited for, participant 1 mentioned believing in the research project as well as the importance of the health worker-recruiter having personal interest in the project:

"I really believed in it, and I'm a big fan of telephone counseling, and counselling support, so for me it was an easy sell. It really didn't feel like I was trying to be a salesperson… it was something that I would be interested in if I was a parent as well."

Participant 2 also felt positive towards mental health trials because of how they enhance clinical knowledge.

"I think anything that can further our knowledge and understanding of mental health treatment and help us understand better the efficacy of what we're doing, is always a positive thing."

Participant 12 made a similar point, stating that it isn't external pressure that drives him to recruit; rather, it is intrinsic (i.e., internal) motivation and intellectual curiosity:

"We don't have to be recruiting patients or anything like that, so I wouldn't say I'm mandated to recruit patients in a clinical trial. That's more just a choice that I've made."

Feeling like the participants will benefit from the trial, such as for the psychotherapy trial for depression that she recruited for, was an enabler mentioned by participant 4:

"If I have a patient that I can see there would be some benefit to them for being involved in the research, then I'd look at the criteria and see if they fit."

Subtheme 2: Health workers' enthusiasm regarding the trial and a strong commitment to promoting it enables recruitment. Some participants felt that it was important for them, as health workers, to be enthusiastic and strongly committed to promoting the research trials they were recruiting for. This subtheme was also endorsed by the majority (8) participants. For example, participant 1 stated that:

"If the person on the other end of the phone from our agency, who's talking about the program, has some enthusiasm about the program, that probably added to the success."

According to participant 1, it is important to highlight the benefits of participating in the research trial to potential participants (e.g., caregivers):

"We tried to tell them the benefits that might come out of participating in the study and get parents on board. And you know, a lot of parents were very interested, because any research that they felt might benefit their child or another child in the future was enough for them."

According to participant 2, emphasizing to participants that the research trial provides the exact services that they are looking for is paramount:

"I found most people very receptive, and especially after a 45-minute conversation with them, for us to say, "by the way, there are people who doing some research around the services which are exactly what you're looking for; would you be willing to learn more?" Most people were very receptive. So, from our end it was absolutely effortless."

Subtheme 3: Health workers are often motivated to recruit because they are looking for supports and services for their clients because of a gap. The third subtheme,

health workers looking for supports and services for their clients because of a gap, was strongly endorsed by six participants. According to participant 7:

"That's why I would develop interventions, because of gaps and accessibility issues. So, we may know what's effective, but the families can't actually get that evidence-based intervention because it's not available in their community, or they're not able to do it on Monday at 2 o'clock for example."

Participant 9 mentioned that she would be more likely to refer to a clinical trial if it had no waitlist, in contrast to other mental health services that generally had long wait times:

"I felt like it was another tool in my toolbox that I could offer to families. It was another option, because at the time the clinical trial was immediate support (no waitlist), whereas some of the other programs that we could potentially offer to the families would have a long waitlist."

To attract them to the trial, participant 9 would highlight how the trial addresses gaps in the mental health system to the families that she was doing intake calls with. She wanted to ensure that participants were aware that the trial offered immediate, easily accessible, and potentially very beneficial support:

"You know "hey, there's a program we've been given some funding for that is immediate, there's no waitlist, and it's a telephone support program".

Participant 4 brought up the issue of certain interventions or psychological/psychiatric assessments being very expensive, meaning that clients who don't have insurance would have a particularly hard time accessing them:

"... A lot of patients don't have insurance, and we have long waiting lists at the clinic."

This is a big part of the reason why participant 4 was motivated to recruit for these studies.

Theme 2: Health worker-related barriers. When the health worker-related barriers mentioned by participants were organized, three subthemes were produced (table 3).

Subtheme 1: Lack of time and energy to participate in recruitment on the part of the health worker is a barrier to recruitment. This was a very significant theme for

several participants. According to participant 5, his job is very mentally taxing, so it can be hard to always keep recruitment at the forefront of his mind:

"The biggest challenge is finding physical time but also mental time to integrate [recruitment] in my day-to-day clinical practice with each patient encounter. So, making this awareness that we have this and that project going on, is that patient suitable, yes or no, like I find that just gets evacuated from my mind through the day."

According to participant 8:

"The challenges would be more on the clinician side, as well as just lack of availability, and lack of knowledge of the patients that they would even have such an opportunity to engage in research."

Subtheme 2: Lack of health worker interest and lack of financial incentives for their recruitment efforts are barriers to recruitment. This subtheme was favored by five participants. According to participant 8, lack of clinician interest is one issue along a spectrum of weak links in the process of recruitment:

"There are many weak links in the process [of recruitment], from disinterested clinicians or overly busy clinicians, to unavailable patients, disinterested patients, to some administrative roadblocks, for example that occasionally clinicians change over time and we need to recommunicate to the team what the study is about."

Furthermore, participant 8 noted that lack of financial incentives for health worker-recruiters is a significant barrier to recruitment:

"Clinical staff across the board are nearly never paid, other than some physicians, to do or support clinical research."

When clinicians are disinterested in the research trial, they are less likely to remember to bring it up when meeting with patients. According to participant 13:

"Probably the biggest factor is that [the trial] doesn't even come to [the health worker's mind] in the first place."

Subtheme 3: Health workers having difficulties balancing their clinical vs research workload is a barrier to recruitment. This was also considered a significant theme by several participants. According to participant 13, due to difficulty in maintaining a balance between their clinical and research responsibilities, many

clinicians often prioritize their clinical work and completely forget to bring up research studies with their patients.

A similar concern was brought up by participant 4, who said that clinicians, when meeting with patients, tend to inadvertently place recruitment at the bottom of their list of priorities:

"In general, I think as a member of an academic department, [research trial recruitment] is something that I like to try to do. You would think that I would think about it, but even putting up signs in my office to remind myself, it tends to drop down to the bottom of the list and sometimes you don't know if they're even still recruiting."

Difficulties for clinicians in maintaining a clinical-research balance is also something that was brought up by participant 8 as a significant barrier to recruitment. This imbalance leads to patients not always being informed about potential research studies they are eligible for.

Theme 3: Participant-related enablers. When the participant-related enablers to recruitment mentioned by participants were organized, six subthemes were produced (table 2).

Subtheme 1: Providing honorariums to participants enables recruitment.

According to participant 1, honorariums are quite helpful for recruitment:

"I definitely feel that some kind of token at the end of it is going to be really important for families, which I know in the past Strongest Families has done; a nominal amount of money, or a gift card, or something."

According to participant 2, honoraria are useful in improving recruitment rates:

"As we went along too, the IWK did have a little bit of budget for incentives (honoraria). It really did make a difference; it gave us a little bit of gear."

According to participant 3, monetary incentives could help with their motivation and engagement with the trial:

"When they get there and if they find out they're getting something from being involved I'm sure they're perfectly happy with that and it probably does help with motivation and engagement."

Subtheme 2: Mentally healthy, organized, and independent participants enable recruitment. When referring to trials involving parent training, participant 3 strongly endorsed this point, stating:

"I usually try to pick families where the parents are both mentally healthy themselves, well organized, independent in their uptake of skills…Usually the families that seem like they don't do so well are families that struggle with their own mental health issues. They also may have ADHD, their organizational skills are challenged, those kinds of things."

Subtheme 3: Committed, willing, and highly motivated participants enable recruitment. In response to what kinds of things would make it more likely for participant 1 to invite caregivers (participants) to take part in the study she was recruiting for, she stated:

"If the parents seemed very much into wanting to know about resources in the community, books that they could read, any resources that they could explore to get help for their child, to me that showed a commitment that they were interested in pursuing more than just "hi, my child is being defiant, I want them to get fixed." So, if it looked like there was an opportunity and that they were committed, and it wasn't just a quick fix that they were looking for, then I would identify that this might be a good thing to consider. That was the main criterion for me."

Participant 11 further emphasized the importance of participants being willing and committed to participating, aside from just meeting the primary inclusion criteria:

"There had to be the [primary inclusion] criteria, and also the willingness, so once I presented all of the information and they still seemed like they were wanting to participate, then I wasn't really worried about it being a burden."

Subtheme 4: Well-educated, higher socioeconomic status participants enable recruitment. For example, according to participant 3: *"[The families we send to Strongest Families] are usually more well educated, more well off, better organized."* This may be because families with higher socioeconomic status are more likely to appreciate the importance of the research, and understand its overall purpose, which then may make them more motivated and capable of participating in the intervention.

According to participant 10, she tends to recruit participants of higher socioeconomic status, who also tend to be more educated:

"The women that I tend to recruit tend to be of higher socioeconomic status."

Subtheme 5: Participants wanting insight and perceiving a personal benefit to their participation enables recruitment. According to participant 4, a significant factor making participant recruitment more successful was: *"If they have some sort of insight or interest in knowing more about themselves and their illness."*

According to participant 11, it is important for families to *want* the help and the insight that the intervention could provide them with. In other words, participants must have an understanding and appreciation of the benefits that they could get out of participating. According to participant 12, patients expecting benefit from the study is an important factor in motivating them to participate:

"Patients are usually pretty comfortable participating in studies, especially if it's something that they perceive is going to be of value for them…Some patients are more inclined to get involved if they think it's going to benefit them in some way."

When discussing the smartphone food-diary trial that he ran (for eating disorders), participant 12 said:

"If patients thought they would be able to use an app if that was something they were interested in, and most people were, then they'd probably be more inclined to want to do it, compared to say a study where they weren't necessarily getting anything of value or perceived value."

Subtheme 6: Ease of access for participants enables recruitment for e-mental health trials. This subtheme was endorsed by approximately half of the participants, in particular those who were all involved in recruitment for e-mental health trials. Participant 9 felt that it was more convenient to have an intervention over the phone than in person, but only for some caregivers:

"Some parents were totally fine with accepting that referral to the program; they found it convenient to do it over the phone, whereas other parents were like "no, I don't want it to be focusing on me I want it to be focused on my child, so I want to come in for counseling sessions.""

Participant 14 also highlighted the importance of easily accessible mental health support provided through clinical trials:

"I think it was an easy sell because it was something that was different from just an in-office service. Families could do it on their own time, they could have a conversation with their coach at a time that was convenient for them, so the program itself really made it accessible to the family."

Theme 4: Participant-related barriers. When the participant-related barriers to recruitment mentioned by participants were organized, five subthemes were produced (table 3).

Subtheme 1: Transportation or mobility issues is a barrier to recruitment for in-person mental health trials. Transportation/mobility issues were brought up as barriers for several participants. According to participant 14, the Strongest Families intervention trial was especially appropriate for those with mobility/transportation issues, given that it was an e-mental health intervention:

"It was really encouraged as well for those who may have mobility issues, or difficulty coming to an office, because if they're a single parent, or they have a lot of children, coming to an in-office appointment might be difficult."

According to participant 9, in reference to the Strongest Families intervention trial:

"It's about how you sell it to them. So, most of the time, parents were excited about it. So, they were like "oh yeah, that sounds like a great program; I don't have to get into my car, I don't have to drive; someone calls me.""

In reference to mobility issues, participant 7 emphasized that:

"We may know what's effective, but the families can't actually get that evidence-based intervention because it's not available in their community, or they're not able to do it on Monday at 2 o'clock for example."

Subtheme 2: Time constraints on the part of the participant (e.g., only being able to do appointments in the evening, or not being available during the summer months or holidays due to vacation) are a barrier to recruitment. According to participant 10, participants can get overwhelmed thinking about the time commitment involved in their participation in clinical trials: *"Some of my patients become overwhelmed with the time commitment. It's a longitudinal study over a number of years."*

On the other hand, when it comes to e-mental health trials, the timing is more flexible, because participants can schedule evening appointments if this is the only time that they have available:

"Families could do it on their own time, they could have a conversation with their coach at a time that was convenient for them" (Participant 10).

On the matter of convenience, participant 3 stated:

"Other factors that come into play in deciding whether families will go [to Strongest Families] is convenience (if families can't come to an 8:30 to 4:30 time frame of appointments, Strongest Families offers greater flexibility), so we'll refer to Strongest Families in that case."

According to participant 8, a significant time constraint is when participants are unavailable during the summer months or during other peak vacation times of the year:

"The other [challenge] was patient unavailability during holiday times in the winter around Christmas, but most importantly for 2-3 months in the summer, a lot of patient populations just aren't available…they're on vacation and so on, and that slows down research recruitment."

Subtheme 3: Lack of follow-through or interest on the part of the participants is a barrier to recruitment. This subtheme stood out quite potently for several participants. According to participant 2, for example, lack of follow-through is a central issue in patient recruitment:

"Overall, the difficulty that was encountered was more the follow-up. So, people who were no-shows, or people who declined once they got the call from your principal researcher, talking about what was entailed in the study."

Participant 12 also found that patients not interested in participating, being unmotivated to participate, or being lost to follow-up is a big issue in eating disorder clinical trials particularly (compared to intervention trials for other types of mental illnesses):

"We came to realize that [recruitment] is much slower than that, between people not wanting to participate, not being eligible, or dropping out very quickly early on in the process."

Participant 13 experienced serious issues with lack of follow-through or interested participants, which led to him having to prematurely terminate the clinical trial research that he was involved in:

"It was a longitudinal study, so I think the follow-up was 3 months, so a number of people would have chosen to drop out partway through or were lost to follow-up partway through." Sometimes this lack of interest or follow-through can be due to trial-related factors, such as participants not being fully informed about the benefits and aims of the trial.

Subtheme 4: Language can be a barrier to recruitment. This subtheme was supported by the majority of participants. For example, participant 11 said:

"If English was their second language, we would make a referral and set up an interpreter, and so that's not something we would be able to offer in this situation."

Participant 2 also was recruiting for Strongest Families just as participants 11 and 14 were:

"If I had somebody with a language barrier, I may not have sent them to the service. For example, if we had someone come into the office and complete their intake with an interpreter, I don't think that would have made sense to send that [intake form] along. That's the only barrier I can really think of."

Participant 9 also highlighted the language barrier issue – she was another resource coordinator involved in recruitment for many different trials, including Strongest Families:

"With language skills, we could not refer them [to Strongest Families] if there was an ESL issue. That was an exclusionary criterion."

Participant 10 also emphasized the barrier of language:

"My patient population is overwhelmingly English-speaking. It probably wouldn't occur to me to recruit/refer somebody who needed an interpreter."

Subtheme 5: Participant cognitive challenges is a barrier to recruitment. For example, in reference to the Strongest Families intervention that she was recruiting for, participant 3 said:

"If a parent has cognitive challenges, they're not going to be able to easily and independently absorb that material. They're not going to be able to keep pace with that standard protocol."

Participant 10 also made a similar point:

"It would definitely not occur to me to invite or to recruit someone with cognitive challenges."

Theme 5: Study-related enablers. The main study-related enabler that was found was inclusive eligibility criteria. This theme was confirmed and strongly endorsed by the majority of participants (in addition to being considered important in previous research). For example, participant 14 highlighted the importance of having inclusive eligibility criteria to improve recruitment to mental health trials, given that she found this to be helpful in increasing recruitment rates in her own recruitment experiences:

"For our purposes of the research project it was kind of if they didn't meet eligibility then we wouldn't offer it to them (but there was just a few things that didn't make them eligible), so we really offered it to whoever, as long as they met eligibility."

Participant 3 also brought up the issue of eligibility criteria in mental health research trials, which often exclude those with comorbidities, making the research findings less generalizable to real world patient populations (i.e., outside of just populations participating in mental health research trials):

"A lot of the outcomes in research don't translate to outcomes in real world practice. Partly because they don't recruit people who are as complex as we see."

In other words, having more inclusive eligibility criteria would widen the recruitment "net", meaning that there would be a larger pool of potential and actual participants; less people would be excluded due to comorbidities or other factors.

The same issue of breadth of recruitment criteria was brought up by participant 10:

"Sometimes research trials tend to have a lot of exclusion criteria, which makes the results difficult to generalize to real world populations."

Theme 6: Study-related barriers. When the study-related barriers to recruitment mentioned by participants were organized, three subthemes were produced (table 3).

Subtheme 1: The intervention itself being too burdensome or lengthy for participants is a barrier to recruitment. This subtheme was endorsed by the majority of participants. According to participant 2, interventions can sometimes be too burdensome, particularly longitudinal interventions with a lengthy follow-up period:

"Overall, the difficulty that was encountered was more the follow-up. So, people who were no-shows, or people who declined once they got the call from your principal researcher talking about what was entailed in the study."

Often the interventions feel too burdensome due to a high time commitment (for example a lengthy study duration) on the part of the participants or too much of a time commitment on the part of the health worker. This can be evidenced by participants not showing up to their initial appointments and/or not attending follow-up appointments. When referring to studies that she recruited for, participant 4 explained:

"So, sometimes I think of it, and then it seems too complicated to sort out (whether or not they'd be the right people [to participate in any given study] or who to contact). And then I just don't bother, to be honest!"

According to participant 10, some interventions can feel too burdensome for participants due to their time commitment but also due to a high psychological burden. In reference to the trials she has recruited for, participant 10 highlighted:

"I've had a fairly high number of patients refuse to participate because of the time commitment. I've had negative psychological responses from a few patients from the experience of participating."

Subtheme 2: If the objective of the study is only peripherally related to the participant's issues or only relevant to a narrow subset of patients, this is a barrier to recruitment.

According to participant 5:

"If the objective of the study is only peripherally relevant to my patient's issues or only relevant for a narrow subset of patients then that makes it even more challenging to keep that one in mind whenever I will encounter a suitable patient of that narrow subset."

Participant 13 encountered this problem in a trial that he was doing to test a specific intervention for Tardive Dyskinesia, a movement disorder caused by chronic antipsychotic use. He had a problem of availability of potential participants: a mismatch

between study requirements and the population of patients. Patients with Tardive Dyskinesia represent only a narrow subset of patients who take antipsychotic medications, so finding a large enough sample for his study proved to be impossible, leading to the premature termination of the study:

"So, because of the challenges of finding individuals who have persistent Tardive Dyskinesia, that made it difficult to reach out to psychiatrists in the Halifax area who may have been able to refer to our study… After about a year of attempting to identify participants through contacting psychiatrists that care for people with serious and persistent mental illness, we really came up with very few referrals (inpatients and outpatients). So, it really made it very clear to us that we could not do the study because of that reason."

Subtheme 3: Lack of funding is a barrier to recruitment. According to participant 12, *"It's important to always be focusing, if we can, on things that are going to make a high impact, because obviously with the few dollars there are and if we are recruiting patients we would want to look at things that are likely going to make a significant change in outcomes."* However, given that the current study involved only one eating disorder mental health worker (participant 12), and there were several important issues raised by this participant, such as lack of funding for eating disorder research, future research should further examine the issues involved in recruitment for eating disorder trials more specifically.

Theme 7: Collaboration-related enablers. When the collaboration-related enablers to recruitment mentioned by participants were organized, two subthemes were produced (table 2).

Subtheme 1: Regular correspondence between researchers and mental health workers enables recruitment. This was a very important theme which was also endorsed by the majority of participants. According to participant 11, receiving feedback about recruitment successes or failures from the research team is paramount for successful recruitment:

"Once we sent the referrals to the program, we would receive pretty regular feedback from the research department, letting us know "yes, in this month we've recruited X number, and in this month, we've recruited X number." So, that was always good to see,

and sometimes they would let you know personally "you, [participant 11] in particular were able to send X many referrals over.""

According to participant 10, sending email reminders to mental health worker-recruiters to mention study recruitment at the end of their intake calls can help to encourage them to recruit on an ongoing basis:

"I get emails every 4-6 months, and I've had 2 meetings with them over the last 2 years. So, I do feel supported [by the research team]. The reminder emails are the main reason I remember to recruit."

According to participant 10, it is also important for researchers to give regular feedback to health workers about whether their recruitment efforts are successful, and provide them with up-to-date pamphlets:

"If they agree to learn more about it then I give their name and contact information to the main research coordinator and she contacts them. And then the research coordinator lets me know whether or not the patient has decided to participate. So, I get that feedback about whether my recruitment has been successful."

According to participant 14, effective communication of health workers with researchers on the project is crucial to successful recruitment:

"They were really good with communication. We were able to contact them as needed if we had questions. They came to physically meet us at our office, multiple times. They shared input as far as their findings, even as they were going along… So, they kept us up to date as things were happening during the research project."

Having a point-person (a project or research coordinator such as a research nurse) on-site can enable recruitment. A point-person can check in with the health workers on a regular basis. According to participant 8, it is important to have a point-person who can help clinic staff with a variety of research activities, including recruitment, if the need arises:

"The clinic I work at has a full-time staff with a master's degree and research experience, who supports both the quality improvement, data evaluation, and research at the clinic. So, for any study that happens at the clinic I have in-clinic support from the research staff, including, if need be, patient recruitment."

Having a research nurse on-site to oversee recruitment (screen patients, approach them, enroll them, etc.) as their main job could make recruitment more successful and less burdensome for physicians, according to participant 4:

"Sometimes for studies there will be a research nurse or somebody who is actually at the clinic and is able to go through and see who appropriate patients would be, and approach them and enroll them and so on. I think that would be the logical way for a study that heavily relied on patients from the outpatient clinics; that would be the way to have it work, would be to have somebody who's directly related to the study, who's not a clinician otherwise, who's not carrying a caseload, who's actually there looking at the new referrals, or looking at the caseloads and looking for appropriate patients and then approaching them."

It is also important to have regular visits from the research team to (a) explain the program to the intake staff (or other health workers), and (b) talk about the progress of recruitment. Having support and good communication with the researchers on an ongoing basis, including the provision of feedback, was a part of why recruitment was so successful in the Strongest Families trials. Researchers would visit the organization and do presentations for the health workers. According to participant 11:

"Researchers were always around, always available, they would often send emails, and keep in touch with us to let us know "hey, you guys have done a great job, you've sent over X amount of referrals, if you have any questions, if you want to run something by us, this is our information. Please feel free to contact us." On a few occasions, I recall some of the team coming to visit us in our office in Ontario to have a more face-to-face discussion and provide information that way.

Participant 9 also had the same experience of being supported in-person by the research team:

"The researchers came out to talk to us once in a while, to see how things were going, how recruitment was going, were we having any hiccups, etc. The first part was explaining the program to us when they came out, and then they came back to just talk about how the recruitment was going. Our communication was mostly in person."

According to participant 10, although it is challenging, maintaining ongoing communication with the researchers could help health workers and researchers collaborate to think of innovative ways to boost recruitment:

"So, it's hard to maintain that communication [with the researchers]. I don't know if it would be more regular meetings that would be helpful, but I think when you meet with somebody regularly, you're more likely to discuss issues and come up with ideas. I think if I had that opportunity, I might be more likely to [recruit more]."

Having a director/supervisor from the organization who is in regular contact with the research team and can answer questions that mental health workers have about the trial enables recruitment. In the case of the Strongest Families trials, the supervisor was the first point of contact by the Strongest Families research team. According to participant 1:

"It wasn't actually me who was contacted, I believe it was our supervisor at the time, and I guess that the research study was proposed to her, and she said "yeah, we're happy to do that.""

According to participant 9:

"I felt supported, because if I had any questions I could talk to my supervisor, who might get in touch with the researchers if needed."

Subtheme 2: Health workers feeling that their recruitment efforts are being valued by the research team enables recruitment. It is important for mental health workers to feel that their efforts are being valued by the research team, according to participant 11:

"If I wasn't receiving that information on a regular basis, to be quite honest, if you're not feeling like the work that you're doing is being valued then it makes it a bit more difficult to take on extra tasks."

Theme 8: Collaboration-related barriers to recruitment. This theme had no subthemes, because there was only one main barrier that was brought up by the mental health workers (i.e., the participants for the current study), which was not providing a detailed enough description of the intervention to the health worker-recruiter. This theme was articulated very well by participant 3:

"One of the challenges was describing what people are going to learn. For instance, the anxiety programs are based on cognitive-behavioral therapy for anxiety in children, but we don't have very readily access to the protocols, so to describe it to families…a little more detail would be useful."

Theme 9: Strategies to improve recruitment to mental health trials. When the strategies to improve recruitment suggested by participants were organized, seven strategies were produced (table 4).

Table 4. Strategies to improve recruitment to mental health trials (objective 2).

1. More support is needed from the researchers of the study when the recruitment/enrollment procedure is complicated (for either the participant or the health worker or both).
2. Have a clear contact person to follow up with, for example if a referral gets lost (more connection with researchers is needed to know if referrals are going through).
3. Clear and simple recruitment materials for participants (e.g., handouts, brochures).
4. Mental health workers being direct and persistent in recruitment.
5. Better integration of mental health research and clinical work/services could make recruitment easier in outpatient mental health clinics.
6. Fewer exclusion criteria (including a broad spectrum of cases).
7. Use social media, and if possible, hire a social media expert for social media-based recruitment.

Strategy 1: More support is needed from the researchers of the study when the recruitment or enrollment procedure is complicated. It is important to have a supportive/collaborative research team and an easy, simple recruitment procedure for health workers to learn. It is also crucial to provide support to both the participants *and* the health worker-recruiters while they are involved in the study, particularly if the recruitment or enrollment procedure is complicated. This strategy was endorsed by seven participants (table 4) and primarily addresses collaboration-related barriers to recruitment.

According to participant 4, recruitment procedures are often too complicated/burdensome and time-consuming for mental health workers as well as for participants. In other words, the benefit to the patient does not outweigh the difficulty of signing them up. In such situations, it is important to have more support for all of the stakeholders involved in the project:

"More support is needed when the enrollment procedure is complicated (for either the patient or the physician or both). More support from the researchers of the study."

Strategy 2: Have a clear contact person to follow up with, for example if a referral gets lost (more connection with researchers is needed to know if referrals are going through). This strategy was endorsed by half of the participants, and primarily addresses collaboration-related barriers to recruitment. According to participant 3:
"I guess one thing that's been a bit problematic is that it would be nice if there was a clear contact person to follow up with if a referral is lost… maybe if there was a contact person for our manager or something like that, just to find out what happens to these referrals when they get lost."

Strategy 3: Clear and simple recruitment materials (e.g., handouts, brochures) and procedures for participants. This strategy primarily addresses study-related barriers, particularly the intervention feeling too burdensome for participants. According to participant 5, when it comes to procedures:

"We have weekly clinic meetings, and so once every month or so they would remind us at the beginning of the meeting about the study [referring to on-site studies], and who they're looking for, and then they also send us usually an email with a flyer with the inclusion criteria." This flyer, sent to the health worker-recruiters, was part of the materials that the recruiters were then able to give to patients/caregivers interested in participating.

According to participant 3, it is important to have more detailed brochures and handouts to pass along to caregivers interested in participating in mental health clinical trials:
"The brochures are pretty vague as well. So, it would almost be nice to be able to say here's a pamphlet of this particular program, this is what you're looking at…those pieces would probably be really helpful, in terms of the description process for families."

According to participant 10, she needed more detailed information to distribute to potential participants, in order to make recruitment easier, such as through pamphlets or handouts:

"If they'd given me more information or more pamphlets to give, that might make [recruitment] easier."

According to participant 2:

"If I had a way of passing along, say a PDF file, or a website, where they could go and read a little bit more about the study, that may have made a difference once it actually got to your service [the IWK]."

According to participant 7, it is important to use creative, innovative strategies to try to attract patients/caregivers to participating in mental health trials:

"In terms of the "pull", so what they see, why are they going to follow that link or actually look at it, we do lots of things there, like trying to make it more engaging, trying to use a lot of marketing strategies in a way, so really putting in the posters, or the communication… the reasons why they might want to participate. So, you're trying to attract them to the trial."

Strategy 4: Health workers being direct and persistent in recruitment. This strategy primarily addresses recruitment issues surrounding health workers. According to participant 3, being persistent and regularly following up with the participants is needed to ensure that recruitment and retention in the study is successful, and that participants are supported every step of the way (Patel et al., 2003):

"Getting the word out is always the challenge. You have to be very persistent when you're recruiting people, with your posters and your calling… you have to do a lot of follow up to really get people engaged and also to stay in the study/program…I think that's always a challenge when you're doing clinical trials like that. These are people who aren't always well, that don't always have their lives organized very well, and their motivations change (like anyone, motivations can change at the drop of a hat). So, it's that persistence in keeping on people, keeping people engaged, reminding them that you're there, reminding them of what they're doing, I think is super key."

According to participant 12, taking a direct approach to recruitment is the most effective, such as directly asking potential participants about participating:

"When a new patient is admitted, if they fit the eligibility criteria for whatever trial we've got going on, then I would approach that patient myself usually, and just directly ask them if they were interested in participating."

As part of his direct and straightforward approach, participant 12 would use blanket recruitment (which is purely based on inclusion/exclusion criteria):

"If somebody's potentially eligible we would end up just asking them, rather than using any kind of subjective criteria for deciding "this person would be good, and this person wouldn't be good." It's more just based on the inclusion/exclusion criteria."

Strategy 5: Better integration of mental health research and clinical services could make recruitment easier in outpatient mental health clinics. This strategy mainly addresses recruitment issues surrounding the collaboration between researchers and mental health workers. Participant 13 felt that if there was better integration of research and day-to-day clinical practice, then health workers would be more inclined to remember to bring up the studies they're recruiting for with patients.

According to participant 13:

"It's very easy for [pharmacists] to not prioritize research in their day-to-day clinical practice in a community pharmacy… Easy for them to forget about the study itself. So, we had a number of different boosters to help keep the study at the forefront of their mind along the way."

At an early psychosis program in Nova Scotia, mental health workers meet weekly, to *"brainstorm different methods to help clinicians not forget about bringing the options up to their patients. Even though it's a pretty research-intensive clinic, eligible patients weren't being informed about their opportunity to participate. My impression is that when clinicians are with patients, they are very focused on the clinical needs of the patients and don't prioritize the information-sharing about participating in research."*

According to participant 4:

"There's not a lot of research taking place in the outpatient services, and I think if that were integrated better then recruitment would be easier. I think for clinics like for example the mood disorder clinic or the early psychosis clinic, where research is built in along with the clinical work, it's so much easier to have the recruiting happening in the clinic."

Strategy 6: Less stringent exclusion criteria. This strategy addresses study-related barriers to recruitment. According to participant 5, exclusion criteria should be less stringent (i.e., more inclusive) so that clients with comorbidities and more complex cases can have more opportunities to participate in research trials, and so that there are enough eligible participants:

"I see mostly patients with neurodevelopmental disorders, so I do come across studies that I would be interested in, such as psychotherapy for depressed teenagers, but very often those would exclude patients with autism, or intellectual disabilities."

According to participant 6, once they broadened the inclusion criteria, they were able to improve recruitment because they could recruit youths with a wider range of anxiety disorder severity:

"So, we had challenges with…we were trying to target mild to moderate anxiety, and I forget if we had exclusion around safety (e.g., they couldn't have ever had suicidal thoughts). But this was quite restrictive: because we were finding that people who were signing up and doing the initial screening for anxiety could have moderate to severe anxiety, or they could have had suicidal thoughts in the past but not have them at present. So, we adapted, and had a safety protocol that we put in place so we wouldn't exclude youths who had (instead of just mild to moderate) more moderate to severe. So, we had more from the mild all the way to the severe. So, we had a bigger range of anxiety."

More inclusive eligibility criteria could improve recruitment to mental health trials, given that participant 14 found this to be helpful in increasing recruitment rates, by increasing the number of potentially eligible participants.

"For our purposes of the research project it was kind of if they didn't meet eligibility then we wouldn't offer it to them (but there was just a few things that didn't make them eligible), so we really offered it to whoever, as long as they met eligibility…We definitely had a lot of eligible participants for sure."

Strategy 7: Use social media, and if possible, hire a social media expert for social media-based recruitment. This strategy mainly reduces study-related barriers to recruitment by making the study information more accessible to a larger range of people. In response to what are effective recruitment tools, participant 6 stated:

"Making it national, using social media, and hiring a social media expert. As researchers, we don't know enough about social media; there's amazing things you can do with social media to extend your reach, get to the right audience."

Participant 7 also brought up the effectiveness of using social media-based recruitment:

"We have had a lot of success using social media, especially Facebook live interviews/ presentations."

Furthermore, social media is an excellent recruitment tool but is most effectively used when recruitment ads are targeted to specific populations, and a pre-screening questionnaire is used as well, according to participant 12:

"For the trials where we were recruiting outside of clinic, becoming familiar with and good at doing the social media recruitment has really been the key to our success."

In reference to social media, participant 12 also said:

"Social media recruitment, that's been very positive, just because we've really kind of learned how to tailor the ads."

Theme 10: Strategies to improve health worker engagement in mental health trials. When the strategies to improve health worker engagement in mental health trials were organized, five strategies (i.e., subthemes) were produced (table 5).

Table 5. Strategies to improve health worker engagement in mental health trials (objective 3).

1. Researchers sending out mass emails about trial information (e.g., in a PDF flyer attached to the email) and being persistent in trying to engage health workers.
2. Frequently and regularly reminding health workers of the benefits of mental health trials, such as for addressing gaps in the mental health system.
3. Providing mental health workers with a clear list of inclusion criteria, a description of the study, and keeping the information current/updated.
4. Incentives/expectations for health workers to participate in, and engage with, recruitment.
5. Provide feedback to mental health workers about the success of their recruitment efforts.

Strategy 1: Researchers sending out mass emails about trial information (e.g., in a PDF flyer attached to the email) and being persistent in trying to engage health workers. This strategy was endorsed by half of the participants, and addresses collaboration-related barriers by improving the collaboration between researchers and health worker-recruiters. In response to how she was contacted by the research team to recruit for Strongest Families research trials, participant 3 explained:

"We would get a mass email circulated to us (probably originally from someone on the Strongest Families team, but it ends up being circulated by our mental health manager or one of the team leaders from each of our 3 community mental health teams). So, it would be a mass email that often has a word document poster-like thing inside."

According to participant 4, she would be more likely to invite patients to take part in a research study if she had *just* received an email reminder from the research team: *"Honestly it's probably more likely that I'll invite people if I've just had some sort of contact from the investigator, like if I've just had an email, or just heard around, or just received a mailout."*

In response to how she was contacted by the research team for recruitment, participant 11 highlighted:
"It was all through email, and either it would be sent to our director, who oversaw the program, and then it would filter down from her to our team, or we would receive emails from the research team with updates and providing information." Participant 11's communication with the research team was *"effective and useful."*

When asked about the effectiveness of the researchers' engagement with the health worker-recruiters in her organization, participant 14 explained:
"They really provided us with a lot of information, not just on paper but they physically would come and visit us, so they made a point of coming to see us and allowing us an opportunity to ask all the questions we needed, in-person, or even like I said, via email or over the phone, so I feel like they definitely provided us with enough information." In other words, if she needed to contact the researchers for any reason, they were always easily accessible.

Strategy 2: Frequently and regularly reminding health worker recruiters of the benefits of mental health trials, such as for addressing gaps in the mental health system (e.g., accessibility gaps for Binge Eating Disorder). This strategy of frequent reminders was endorsed by approximately half of the participants and will improve the collaboration between mental health researchers and mental health workers.

According to participant 3:
"It's that persistence in keeping on people, keeping people engaged, reminding them that you're there, reminding them of what they're doing, I think is super key."

According to participant 4, even if clinicians get annoyed with frequent reminders, it is still important for researchers to be diligent in reminding them of the benefits of research:

"I'm sure it's a pain to have to keep reminding people, and people probably get annoyed by it, but it's the only way that I would really remember to think about it."

Strategy 3: Providing health worker recruiters with a clear list of inclusion criteria, a description of the study, and keeping the information current/updated. This strategy was endorsed by over half of the participants and will improve the collaboration between health workers and researchers, as well as improving study-related barriers because it advises researchers to make study information clearer and simpler. For example, when she was asked whether inclusion/exclusion criteria would be useful for mental health worker-recruiters to have, participant 4 answered:

"I kind of do, but the only thing is that it would have to be kept updated, because I feel like at one point we did try to do that when I was on Seniors Mental Health or something, and then it gets out of date so quickly. I think more valuable would be reminders from the investigators or the research associates or something."

When asked if it would be easier for her to recruit if she knew more about the study, participant 10 answered:

"Yeah. That's a good point. I have the inclusion/exclusion criteria. I think they did give me a flyer a few years ago, but I haven't received a more recent one, because when we had a meeting, they'd added a few different arms to the study. If they'd given me more information or more pamphlets to give, that might make it [recruitment] easier. If they sent me more frequent email reminders that might make my recruitment more successful."

Strategy 4: Incentives/expectations for health workers to participate in and engage with recruitment. This strategy primarily addresses health worker-related barriers, particularly the barrier of lack of health worker interest/financial incentives for recruitment efforts. According to participant 5, having more incentives for health workers to recruit for trials (of which financial incentives are only one option) could improve their engagement and the success of the trials:

"Maybe it would make sense for there to be a little more incentive or expectation to take that role on [referring to mental health workers' recruitment activities]."

When asked whether financial incentives for health worker-recruiters might be useful, participant 13 provided important insight into the issue:

"Well I defer to the success that the pharmaceutical industry has, and I think their system involves a fair amount of funding to the research team. If it's a multicenter study, each centre is provided with a substantial amount of money for running the trial, and there are different ways in which they incentivize the referral to different studies. So, some have said that if you look through your records, you'll get money for the time you put into it, and others have said you will get money with each successful referral (meaning the person was actually recruited and entered into the trial)."

Strategy 5: Provide feedback to mental health workers about the success of their recruitment efforts. This strategy primarily addresses collaboration-related factors by improving the correspondence between researchers and health workers. It is important to provide feedback to mental health workers about their recruitment in order to maintain/increase their engagement in research (Patel et al., 2003). According to participant 8:

"Any study happening in my team or clinic would involve a conversation with the clinicians in-person before they actually disseminate the materials to them. And we have mechanisms for that, so wherever I've worked, there's been regular research update meetings with clinical staff, to inform them what's happening with research, both planned research as well as approved research as well as ongoing research, and completed research. So that we close the loop with the clinicians so that they're aware whether their efforts have panned out in the sense of research results."

Participant 11 explained that feedback about her recruitment efforts was something that made her more willing to recruit more. Participant 10 also emphasized the importance of feedback to mental health workers, stating that:

"If they agree to learn more about it then I give their name and contact information to the main research coordinator and she contacts them. And then the research coordinator lets me know whether or not the patient has decided to participate. So, I get that feedback about whether my recruitment has been successful."

According to participant 14:

"So, as an agency compared to other agencies in the Ontario province, we would get feedback around how many families we were able to recruit. But also, it was weekly or

monthly that we would get that input back. We joked a lot as a team as to how well we were doing and that we were going to try and beat another agency, to get more recruits."

In summary, results from this qualitative study have shown that there are a variety of different enablers and barriers to recruiting for mental health trials, related to mental health workers, to the potential participants of these mental health trials, to the study design itself, and/or to the collaboration between researchers and mental health workers. Health worker-related factors include their attitudes towards research, their enthusiasm about the trial, and their beliefs/knowledge about the research. Participant-related factors include participant willingness, commitment, and motivation for participation. Study-related factors include realistic inclusion criteria and patient involvement in all stages of the project. An example of a collaboration-related factor is having a supervisor from the organization who is in regular contact with the research team and can answer questions that mental health workers have about the trial. Lastly, this study identified strategies to improve recruitment to mental health trials, as well as strategies to improve health worker engagement in mental health trials.

Chapter 4: Discussion

The current study found four categories of barriers and enablers (participant-related, health-worker-related, study-related, and collaboration-related) to recruitment. This study is meaningful because the rich descriptions from participants confirm previous findings on recruitment enablers/barriers and add contextual information. For example, although my research found similar themes to previous literature, it also demonstrates the need to pay attention to the diverse contexts that each mental health worker is recruiting within. It is important to understand not only the common themes, but also the unique aspects within the common themes related to recruiting within mental health. My study also demonstrates the importance of having good interpersonal/communication skills when recruiting.

Bugeja and colleagues (2018) also found the same four categories of barriers that I found in their systematic review of enablers and barriers to recruitment for chronic wound clinical trials. They found that study-related factors were the most commonly reported, especially narrow inclusion criteria (Bugeja et al., 2018), which was something that I found in the current study as well. Other study-related barriers found in my study included: the intervention itself feeling too lengthy for participants, vague study brochures, the objective of the study being only peripherally related to the participant's issues or only relevant to a narrow subset of participants, and lack of funding. Donovan and coworkers (2014) also found restrictive eligibly criteria to be a big issue in recruitment, as well as treatment preferences of patients. However, they mainly looked at barriers and facilitators to recruitment for cancer, primary care, and infection, and not mental health trials (Donovan et al., 2014).

The current study also extended the findings of Denhoff and coworkers (2015), who used a cross-sectional, web-based survey to examine facilitators and barriers to recruitment in pediatric clinical studies. They found that over one-third of the protocols were not able to be completed due to insufficient enrollment (Denhoff et al., 2015). They also mentioned that future research is needed to help us better understand how characteristics of mental health workers could influence the success of their recruitment, and how to approach patients/families for research from the perspective of the health worker-recruiters, because they didn't find that simply looking at researchers' insights

about barriers and enablers was helpful in distinguishing which studies would be successful (Denhoff et al., 2015). This is exactly the knowledge gap that my study filled, because I examined the perspectives of mental health workers (not merely researchers) regarding recruitment barriers and enablers. For example, some of the personal characteristics of mental health workers I found to influence the success of recruitment include their enthusiasm and motivation to recruit, as well as their attitudes, beliefs, and expectations regarding mental health trials, consistent with previous research in similar populations.

Denhoff and colleagues (2015), in contrast to my study, looked at attitudes and beliefs about what made recruitment difficult from the perspective of researchers, not the health providers doing the bulk of the recruiting. Furthermore, their attitudes and beliefs about barriers and facilitators to recruitment for their own protocols were assessed using a quantitative survey, which did not allow for the same depth of analysis as my qualitative study did. They also only used participants from a single hospital, which reduces the generalizability of their findings, in contrast to my study where I interviewed mental health workers from a wide array of backgrounds, occupations, and locations across Canada.

In their qualitative review of the challenges in recruitment of research participants, Patel and colleagues (2003) emphasized the importance of health researchers having good interpersonal/communication skills when recruiting, which was found in the current study to be important for the success of recruitment by mental health workers (not just health researchers).

Interpersonal skills are typically used by mental health workers to build rapport with their patients before inviting them to take part in research - having good rapport with patients before actively recruiting them is an enabler to recruitment that I found. My findings about the importance of communication, feedback, and collaboration between researchers and mental health workers are also clinically relevant, building on results from previous studies (Bucci et al., 2015; Furimsky et al., 2008; Newington et al., 2014; Patel et al., 2003; Team et al., 2018). For example, Bucci and colleagues (2015) found that researchers communicating and collaborating with care coordinators (i.e., psychiatric nurses) was important to engage these mental health workers in recruitment, which is

consistent with the results from my study as well – researchers working alongside mental health recruiters is extremely important for mental health clinical trials to be successful in recruiting and retaining enough participants so that the findings can be translated into practice as well (knowledge translation). On a practical level, both my findings and those of Bucci and colleagues (2015) stress the need for a collaborative partnership between researchers and mental health workers. In other words, there needs to be better integration of mental health research and clinical services (theme 9, subtheme six; see table 4).

Furthermore, great caution must be taken to ensure that if financial incentives for participants as well as for mental health worker-recruiters are introduced, they should be administered in the most ethical way possible, such as by giving mental health workers protected (paid) time to do research, instead of giving them an incentive per person that they recruit.

According to a scoping review performed by Apolinário-Hagen and colleagues (2017) on the public acceptability of e-mental health interventions, these interventions were overall viewed as less helpful than face-to-face mental health interventions. In my study I also found that some participants would prefer face-to-face therapeutic interactions, for example due to not being able to concentrate well on phone conversations because of distractions. For this subset of participants, the design of e-mental health trials may be a barrier to recruitment, with a face-to-face delivery being more effective instead (Apolinário-Hagen et al., 2017).

According to the findings of my study, there are important differences when it comes to enablers and barriers for face-to-face interventions compared to e-mental health interventions (Apolinário-Hagen et al., 2017; Becker et al., 2016). Lack of transportation or mobility issues are a barrier to face-to-face mental health trials but an enabler (i.e., they make patients/caregivers more likely to participate) in e-mental health trials. Another example is ease of access: since e-mental health interventions are easier to access, this would be an enabler in e-mental health trials but not necessarily for face-to-face mental health trials. However, some face-to-face mental health trials may be easier to access than others, depending on the type of intervention being offered, the location of the intervention, and the length of the intervention.

There appear to be important differences in regard to enablers and barriers of recruitment depending on the *specific disorder* that the trial is aimed to treat. Eating disorder clinical trials in this study were found to have some unique enablers and barriers to recruitment, although currently there is not much research on this topic. Bartellas (2015) did a qualitative study exploring barriers and enablers to access and care in eating disorder *services* for youth in Atlantic Canada, and found the major barriers to be a lack of accessibility to psychological services, a lack of guidance from general practitioners, a lack of eating disorder education/knowledge (particularly among family physicians), and a lack of resources. In my study, according to participant 12, lack of funding for resources in eating disorder clinical trials can reduce the number of trials that are actually implemented and carried out, which in turn affects recruitment. Other unique challenges to recruitment for eating disorder trials are the high levels of anxiety common among eating disorder patients as well as an unwillingness to participate (in part fueled by high levels of denial and anxiety present among eating disorder patients; Bartellas, 2015). According to participant 12, *"If the experience of coming into clinic is in and of itself very anxiety-provoking, then somebody is coming to them the same day that they're starting clinic and anxious and asking them if they want to participate in the study, it's just kind of overwhelming"*.

Given that the current study involved only one eating disorder mental health worker, and there were several unique issues raised by this participant, future research should further examine the issues involved in recruitment for eating disorder treatment trials (e.g., RCTs) more specifically. Although Bartellas (2015) did a qualitative study exploring the barriers and facilitators to accessing *services* for eating disorders, they did not look at the barriers to recruiting patients to eating disorder *research* specifically. Furthermore, they looked at perspectives of young patients (not adult mental health providers), so their findings might not be transferable to other mental health patient populations.

The main barriers that were brought up by the eating disorder specialist (participant 12) in my study *and* that came up in Bartella's (2015) study were: lack of funding for eating disorder resources, lack of accessibility to appropriate care, and high levels of anxiety and shame in eating disorder patients that make them less likely to seek

treatment. Other psychological barriers aside from anxiety that need to be more thoroughly explored include: early childhood trauma, depression, fear of losing control, fear of losing the eating disorder as a coping mechanism, and lack of motivation to engage in treatment (associated with the high levels of denial present in eating disorder patients).

In addition, trials that utilize subpopulations who have more rare mental health disorders appear to also face more recruitment challenges, such as the antipsychotic trials run by participant 13 (both of which were prematurely terminated due to insufficient recruitment).

Strengths, Limitations, and Future Studies

A strength of this study was the small sample size (14 participants), that enabled me to gather rich, in-depth information about the experiences of the health workers involved in recruitment for a wide range of mental health clinical trials. Qualitative research is not meant to be generalizable, which may be considered a limitation. Therefore, I would recommend that a larger quantitative study be developed to build on the findings of this qualitative study. I did, however, purposefully select health workers who occupied a variety of organizational, agency, and institutional roles, which is another strength of my study. There was a diversity in the professions and specialties of the health workers who participated, and they were involved in clinical trials for a range of mental illnesses, from eating disorders to psychotic disorders to anxiety disorders to neurodevelopmental disorders. However, it is important to note that no mental health nurses were included. Given that mental health nurses are very involved in recruitment and patient care, not having the valuable perspective of someone representing this profession could be affecting the generalizability of my results. Lastly, this study is limited by the fact that it contains no voices of patients or caregivers directly – it is exclusively focused on the voices of mental health workers involved in recruitment.

Both health worker-recruiters for e-mental health trials and recruiters for face-to-face mental health trials participated, further diversifying the sample. Some health workers recruited only for their own trials (e.g., participants 7 and 12), others recruited for trials that they were not directly involved in (e.g., participants 1, 2, and 3), and others did both.

The primary limitation of this study is that since it was a descriptive study, interpretations about gender, race, age, and abilities could not occur. Therefore, for future studies, a methodology such as feminist poststructuralism or critical theory to look at gender, race, age and recruitment abilities of mental health workers would be an excellent next step.

Future research should systematically evaluate the effectiveness of various novel clinical trial recruitment strategies in both e-mental health interventions and face-to-face interventions (Fletcher et al., 2012; Foster et al., 2015), and use a range of mental health workers (e.g., general practitioners, psychiatrists, psychologists, social workers, intake workers, peer support workers, and other health workers).

The recommendations emerging from the current study (tables 4 and 5) for increasing recruitment rates and engagement in clinical research could also be tested in other types of mental health research, such as qualitative studies involving interviews or focus groups, to see if they can increase recruitment rates in these studies as well.

Recommendations

Several key recommendations for mental health workers were generated from this study to improve recruitment to mental health clinical trials (table 4). Training interventions could focus on helping mental health workers understand the key principles and components of the randomized-controlled trial design, and to ensure that they are comfortable with communicating the key points to patients, that they are comfortable with the eligibility criteria, and that they are knowledgeable and well-versed about all arms of the intervention. Mental health workers should use gentle probing questions with patients, so that they can determine their intervention preferences and challenges/concerns that they may have about participating in the research. Training mental health workers has been found to increase the rates of recruitment in some previous clinical trials, so it is significant that the current study will be able to add to the body of research supporting recruitment-related training for mental health workers. It is crucial that mental health workers have excellent interpersonal effectiveness skills, so that they can explain the treatments and the aims of the clinical trials that they are recruiting for fairly and clearly to patients.

To improve recruitment, more support is also needed from the researchers of the study when the recruitment/enrollment procedure is complicated. In addition, recruiters should offer flexibility for appointment times once patients are recruited into a trial, as well as ensuring they have a clear contact person to follow up with, for example if a referral gets lost. More clear and simple recruitment materials for participants (e.g., handouts, brochures) are needed. Mental health workers must be direct and persistent in recruitment. There must also be better integration of mental health research and clinical work/services to make recruitment easier in outpatient mental health clinics. Fewer exclusion criteria are also needed. Lastly, using social media, and if possible, hiring a social media expert for social media-based recruitment, could also be valuable.

Several key recommendations for researchers have been generated from this study to improve health workers' engagement in mental health research (table 5). The first recommendation is that researchers should send out mass emails about trial information (e.g., in a PDF flyer attached to the email) and be persistent in trying to engage mental health workers. The second recommendation is that researchers should frequently and regularly remind mental health workers of the benefits of mental health trials, such as for addressing gaps in the mental health system. The third recommendation is that researchers should provide mental health workers with a clear list of inclusion criteria, a description of the study, and should keep the information current/updated. The fourth recommendation is that researchers (and the organizations they work for) should provide incentives for health workers to participate in, and engage with, recruitment. The fifth recommendation is that researchers should provide feedback to mental health workers about the success of their recruitment efforts.

Future research could look at the same issues around clinical trials using qualitative interpretative methodology (as opposed to the more descriptive approach I used), which is another qualitative alternative to developing knowledge in the realm of clinical mental health recruitment.

The knowledge produced in this study will be disseminated through academic presentations and publication of this work. The strategies generated from this study should be tested as interventions aimed at increasing recruitment in future mental health research for a variety of different disorders. It may be that some strategies are more

effective than others depending on the type of disorder any given study is designed to target.

Conclusion

Study recruitment is one of the most challenging aspects of health research, yet relatively little is known about the underlying reasons (commonly referred to as enablers and barriers) why patients or caregivers choose to participate. A deeper understanding of underlying factors influencing recruitment can have a significant impact on the success of mental health clinical trials not only in Canada but also in other parts of the world.

In conclusion, the findings of this study are valuable to the mental health system because they address the issue of recruitment in the context of mental health research. Results from this qualitative study have shown that there are a variety of different enablers and barriers to recruiting for mental health trials, related to mental health workers (e.g., their attitudes and opinions about mental health research and the trials they recruit for), to the potential participants of these mental health trials (e.g., organized and committed individuals), to the study design itself, and/or to the collaboration between the researchers and the mental health worker-recruiters. Furthermore, all of these variables are interrelated, influencing each other in various ways. For example, if mental health workers are well versed about the trial and its outcomes, then they are more likely to be strongly committed to the trial and enthusiastic about it, which could influence the success of recruitment (i.e., it is a health worker-related enabler to recruitment). Then they are better able to describe to participants the significance of the trial and the outcomes they could expect from it, as well as explaining to participants what they are going to learn (influencing participants' *commitment* and *willingness* to participate in research, which is a participant-related enabler to recruitment).

Findings extended previous research on enablers and barriers to recruitment for other types of health trials. Various strategies to enhance recruitment to mental health trials were identified, as well as ways to improve mental health worker engagement in mental health research. Most importantly, the voices of participants were heard in their extensive descriptions of their challenges and successes that they faced when attempting to recruit patients/caregivers for mental health clinical trials. Their comments provided me with valuable insight into how they dealt with the challenging task of recruiting for

clinical research in the field of mental health. The findings I shared have implications for mental health practitioners and recruiters, mental health patients themselves, as well as mental health caregivers. The findings could lead to next steps that improve rates of recruitment and retention in clinical mental health research, ultimately improving mental health outcomes more globally, as well as in specific research areas, such as mood disorders, anxiety disorders, eating disorders, neurodevelopmental disorders, and/or psychotic disorders.

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Appendix A

Semi-Structured Interview Guide for Researchers

Thank you for agreeing to participate in our research study. We are interested to hear about your experiences as a health worker involved in recruitment in a mental health clinical trial. This is an exploratory study and there are no right or wrong answers. We want you to feel comfortable sharing your experiences in whatever way you would like. This style of interviewing is very open and will be more like a conversation so that we can really understand your experience and explore how you engaged with the project and with parent advisors. I would like to begin with some basic demographic questions.

Demographic Questions:
What is your age?
What is your gender?
What is your ethnicity?
What is your occupation?
What is the highest level of education you have completed?

Main Questions:
This interview is about your experiences of inviting clients to take part in mental health clinical trials.
a) Tell me about your involvement as a recruiter. What are your roles and activities? What has your experience been like and how do you feel about your experience?

b) Tell me about your experience of becoming involved. How were you contacted by the research team?
Probes:
When you're seeing a patient what kinds of things make it more likely that you will invite him/her to take part in a clinical trial?
How do you feel about recruiting for this clinical trial?
How would you invite clients to take part?
Tell me about your experience of being supported, left alone, effective communication or lack of communication with the researchers?
Was study recruitment initiated by the organization or by you?
Was it required as part of your job?
Was the organization (e.g., hospital) supportive?
Were you looking for support/services for your clients because of a gap?

c) Were there challenges with recruitment and if so, what were they and how did you handle the challenges? What could have made it better or easier?

d) Were there successes with recruitment? If so, what were they and how did you handle the successes? What made success possible?
e) Have you had any previous experience with clinical trials and if so, what was your role and how long were you involved in each study?

f) How do you feel about mental health research trials generally?

g) Is there anything else you've thought of that you would like to mention?

Extra Probes if needed:

1. What kinds of barriers have you experienced relating to the *study* design?
For example:

- lack of eligible participants (too restrictive eligibility criteria)
- the intervention being burdensome for participants
- logistical issues (e.g., the study duration being too long)

2. What kinds of barriers have you experienced relating to *participants* themselves?
For example:

- study burden on participants
- treatment preferences
- comorbid conditions
- language skills
- cognitive skills
- patient lack of interest
- technology-usage difficulties

3. What kinds of barriers have you experienced relating to your role as a *health service provider*?
For example:

- your own opinions, knowledge/skills, experience of research or in general
- balancing your clinical vs research workload

4. What kinds of barriers have you experienced relating to the *operation* of your *practice*?
For example:

- relating to the nature and setting of your clinical work – how, when, where you see patients
- administrative factors
- availability of clinic rooms
- availability of staff
- time constraints
- funding constraints

5. What kinds of barriers have you experienced relating to *ethics*?
For example:

- ethics-enforced requirements (strict safety procedures, excessively lengthy participant information sheets, and a slow ethics approval process)

6. What kinds of **enablers** have you experienced relating to the *study* design?

For example:

- realistic inclusion criteria
- study trial information and recruitment materials that are clear and simple
- providing financial incentives to patients
- providing compensation for time dedicated to recruitment

7. What kinds of enablers have you experienced relating to *participants* themselves?
For example:

- participants having previous experience of participating in clinical trials
- participants being willing and enthusiastic about the study
- participants having family support to help them meet the study requirements
- participants perceiving a benefit of the research for others in their family or community
- participants perceiving a benefit for of the intervention for themselves
- the disease/condition of interest is serious, and patients are seeking alternative treatment

10. What kinds of enablers have you experienced relating to your role as a *service provider?* For example:

- making research activities a routine in your daily workload
- the value you place on research

11. What kinds of enablers have you experienced relating to the researchers you collaborate with?
For example:

- good coordination and communication with the research team
- frequent reminders about the study by project staff
- presentations/recruitment training for members of your organization

Appendix B

Consent Form

Research Title:
Exploring the Experiences of Health Professionals When Recruiting for Randomized Trials in Mental Health.

Research Team
Principal Investigator:
Athena Milios, M.Sc. in Psychiatry Research student, Dalhousie University
Supervising Investigators:
Dr. Megan Aston, School of Nursing Dalhousie University
Dr. Patrick McGrath, Centre for Research in Family Health, IWK Health Centre
Research Coordinator:
Karen Turner, Centre for Research in Family Health, IWK Health Centre

Funding
Canadian Institutes of Health Research (CIHR) - Strategy for Patient Oriented Research
IWK Health Centre, Halifax, Nova Scotia
CHILD-BRIGHT Network, Montreal, Quebec

Introduction and Purpose

You are being invited to take part in a research study as a potential recruiter for the Strongest Families research project currently underway (Strongest Families Neurodevelopmental), or because of your experience recruiting for previous Strongest Families trials (e.g. Strongest Families FASD, Fetal Alcohol Spectrum Disorder, trial), or other mental health clinical trials. Before you decide if you want to take part, it is important that you understand the purpose of the study, the risks and benefits, and what you will be asked to do.

You do not have to take part in this study. Taking part is entirely voluntary (your choice).

You may decide not to take part or you may leave the study at any time. **This will not in any way affect your role in research trials you are involved in.**

Purpose: There is currently a lack of evidence-based interventions for successful recruitment to randomized controlled trials (RCTs), particularly in mental health. RCTs measure the effectiveness of mental health interventions. The current study will examine what challenges and successes are involved in recruitment for mental health RCTs, as

well as potential recruitment strategies that could be used in the future to improve mental health trial recruitment.

How will the researchers do the study?
Researchers will perform phone interviews with 10 health care professionals to explore challenges and successes to referring potential participants to mental health clinical trials. As a participant in this study, you would be asked to complete a one-hour telephone interview where we will ask you certain questions about your experiences recruiting for mental health clinical trials. By participating in this study, you will help us to develop potential new strategies that could be used in the future to improve mental health trial recruitment.
Interviews will be recorded and the common themes that come up by the participants will be carefully examined by the researchers (e.g., the principal investigator, the supervisors, and the research assistant).

What will I be asked to do?
As a participant in this study, you would be asked to complete a 1-hour telephone interview where we will ask you certain questions about your experiences recruiting for mental health clinical trials. By participating in this study, you will help us to develop potential new strategies that could be used in the future to improve mental health trial recruitment.
Interviews will be recorded and the common themes that come up by the participants will be carefully examined. You will be asked to answer a few open-ended questions about your recruitment experiences in mental health research, lasting about 60 minutes in total; your conversation with the interviewer will be recorded.

What are the burdens, harms, and potential harms?
We do not anticipate that you will experience any potential harm. However, if you do become emotionally or psychologically upset while answering any questions, we would suggest you contact the principal investigator or one of the supervisors, to discuss follow-up options with a health care provider with whom you are comfortable speaking to discuss this issue. If you require assistance finding a health care provider, we will provide you with a list of local options.

What are the possible benefits?
There are no direct benefits to you from participating, but we hope the experience will be enjoyable and your ideas will benefit future research projects.

Can I withdraw from the study?
You can withdraw from the study at any time. All of your contact and demographic information and, if applicable, any recording or transcript of the interview will be destroyed. Withdrawal from the study will not affect your work position or your recruitment activities.

Will the study cost me anything and, if so, how will I be reimbursed?
The study will not cost you anything. We will send to you a $20 Amazon gift card as a thank-you for your participation.

What about possible profit from commercialization of the study results?
The research team will not profit from any commercialization of the results of the research. We will openly and freely share research results and send you a copy of the final report if you want a copy.

Are there any conflicts of interest?
There are no actual, perceived or potential conflicts of interest (including financial conflicts) on the part of the researchers and/or the institutions.

How will my privacy be protected?
Recorded Interviews:
Interviews will be conducted over the phone by the Principal Investigator from a private location off-site from the IWK Health Centre and recorded on a password-protected computer. Calls will be uploaded immediately after the interview to a secure password-protected folder with restricted access on the Centre for Research in Family Health's SharePoint account hosted by the IWK Health Centre and the original recording will be deleted from the computer. Only individuals authorized to work on the research project and IT administrators will have access to the interviews on SharePoint.

Transcription and Data Analysis:
During interview transcription and data analysis, all files will be accessed from and stored on SharePoint. Files will not be saved to individual computers. Files will be removed from SharePoint after data analysis has been completed.
All names and identifying information will be removed from written transcripts. Participants' names will be replaced with a random number for each individual (but pseudonyms may also be used in the final write-up). De-identified (names and contact information removed) written transcripts will be used for analysis. All research team members will sign a confidentiality form. No identifiable information will be included in any publications or presentations. Depending on the information that you provide (and because of the small group size), there may be a risk that someone known to you will be able to identify you if they have knowledge of your personal history (e.g. co-workers may be able to identify you based on their previous knowledge).

Storage: Consent forms and audio recordings will be stored on a secure password-protected and encrypted flash drive in a locked cabinet with restricted access in the Centre for Research in Family Health until 5 years after publication of results. Only the Principal Investigator, the supervising investigators, and authorized research staff will have access to the original audio recordings.

The IWK REB Audit committee may have access to study records for audit purposes.

What if I have study questions or problems?
If you have any questions or concerns please contact Athena Milios (principal investigator), Department of Psychiatry, Dalhousie University at at254917@dal.ca or 1-877-341-8309, extension 4.

What are my Research Rights?
Participating in the interview indicates that you have agreed to take part in this research and for your responses to be used. In no way does this waive your legal rights nor release the investigator(s), sponsors, or involved institution(s) from their legal and professional responsibilities. If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-8520, Monday to Friday between 9am. and 5pm.

How will I be informed of study results?
If you would like a copy of the final research report, sign the consent form indicating you would like an electronic copy emailed to you.

Study Title: Exploring the Experiences of Health Professionals When Recruiting for Randomized Trials in Mental Health.

Participant Consent Form:

□ I have read or had read to me this Information and Consent Form and have had the chance to ask questions which have been answered to my satisfaction before deciding whether to take part.
□ I understand the nature of the study and I understand the potential risks.
□ I understand that the study involves a 1-hour phone interview.
□ I understand that I have the right to withdraw from the study at any time without any effects to my job position or my involvement in recruiting for the research projects I am involved in.
□ I agree to have my words from the interview used in reports, publications, and conferences.

I give my consent for recording to be taken of my entire session
□YES □NO

Please keep a completed copy of the Information and Consent Form for future reference.

By providing your name and signature you freely agree to take part in the study according to the terms outlined in this Consent Form.

Name

_____
___
First name **Last name**

Signature: _____ **Date:** _____
E-mail: _____
Verify Email Address:
_____
Telephone (with area code): _____

□YES □NO I agree to be contacted for future studies by Dr. McGrath's staff.
□YES □NO I would like to receive a study results letter (via email).

You have the option of allowing your study data to be re-used by approved researchers. Any of your personal information (i.e. your name, email address, telephone number) that can identify you will be removed before files are shared with other researchers. Researchers that wish to use study data must 1) have their new study approved by an

ethics board; 2) sign an agreement ensuring your confidentiality and restricting use to only the approved study.

I agree for my study data to be used for future research. I understand that my study data may be made available to other researchers, but my identity will be protected, and my confidentiality will be preserved.

□YES □NO

Appendix C

Recruitment Flyer

SEEKING HEALTH PROFESSIONALS INVOLVED IN RECRUITMENT FOR MENTAL HEALTH TRIALS:

What are challenges and successes to recruitment for you?

The barriers and facilitating factors in recruitment for research are not well understood. We hope to interview health professionals who have experience recruiting for mental health trials.

Clinical trials are research studies that assign participants to either an intervention or a control group to help researchers understand if the intervention/treatment is more effective than the control group.

We want to interview health professionals to explore challenges and successes to referring participants to mental health trials.

You will be asked to complete a ***30-minute telephone interview*** about your experiences recruiting for mental health trials.

Your participation is **entirely voluntary.** By participating in this study, you will also help us to develop potential *new* recruitment strategies that could be used in the future to improve mental health trials.

In appreciation for your time, you will receive a $20 Amazon gift card.

To learn more about this study, or to participate in this study,

please contact:

Principal Investigator:

Athena Milios, M.Sc. in Psychiatry Research student, Dalhousie University

at254917@dal.ca

This study is supervised by Dr. Patrick McGrath and Dr. Megan Aston (co-principal investigators).

This study has been reviewed by the IWK Research Ethics Board.