

Figure 1. Topics explored in interviews

- First impressions of the study
- Beliefs about research and randomization
- Perceptions of collaborative care model components
 - in general
 - as applied in PARTNERS
- Factors influencing motivation to refer
- Factors influencing actual completion of referral
- Organizational culture
 - social networks
 - climate
 - leadership
- Implementation processes
 - planning
 - engaging (e.g. marketing or training)
 - leading or championing
 - reflecting

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Table 1. Characteristics of qualitative study participants

Characteristics	Percent (Number, out of 23)
Geographic location of practice	
Urban	61% (14)
Rural	39% (9)
Health discipline	
Family physician	52% (12)
Nurse practitioner	22% (5)
Executive Director	13% (3)
Social worker	9% (2)
Registered nurse	4% (1)
Type of practice	
Family Health Team	57% (13)
Community Health Centre	26% (6)
Other group practice*	13% (3)
Solo practitioner	4% (1)
Previous participation in research	
Yes	78.2% (18)
No	21.7% (5)
<i>Of 18 who said yes, role in past research:</i>	
Referring provider	44% (8)
Study participant	22% (4)
Collaborator	5% (1)
Investigator	5% (1)
More than 1 role in research	22% (4)
Number of years in practice	
Mean (SD)	14.0 (12.7)
Median (Range)	9 (2-51)

Table 2. Qualitative study participants by referral stratum

Geographical setting	Practice referral rate	Individual PCP referral rate	Number of PCPs eligible	PCPs interviewed	Site Liaisons Interviewed ¹
Urban	High referral rate (n=4)	High referral rate	27	6	1
		Low referral rate	18	1	
		No referrals	20	1	
	Low referral rate (n=4)	High referral rate	3	1	2
		Low referral rate	15	2	
		No referrals	40	1	1
Rural	High referral rate (n=4)	High referral rate	11	0	
		Low referral rate	4	1	
		No referrals	7	0	
	Low referral rate (n=2)	High referral rate	4	3	
		Low referral rate	9	0	
		No referrals	15	3	
TOTAL			175	19	4

¹ There was one site liaison per study site (n=14) and one liaison for a study site that withdrew from PARTNERS early in the study; we contacted all of them.

Table 3. Perceived strengths and weaknesses of collaborative care in PARTNERS

Collaborative care element - Definition and examples	How manifested in PARTNERS (for intervention patients)	Participant perspectives
<p>Support for patient self-management</p> <p>Coaching, problem solving, or psychoeducation or skills-focused psychotherapy to increase ability to manage symptoms and effectively participate in care and decision making.</p>	<p>Lay provider (“Mental Health Technician”, MHT) provided telephone monitoring and self-management support, and later relapse prevention support; phone calls were typically weekly x 3 months, then monthly x 3 months or potentially longer to a maximum of one year</p> <p>MHT supervised weekly by study psychiatrist</p>	<ul style="list-style-type: none"> • Seen as a unique and valuable resource for patients (in a broader climate of limited access) • Strongly anticipated to be of benefit to many patients • Telephone thought to vary in appeal and feasibility for patients • Trusted that MHTs were qualified, some wanted more familiarity with them • Would have liked greater integration of MHT into their setting, more frequent and bi-directional communication to share their knowledge of the patient and their past treatments, or co-location to enable warm handoffs
<p>Use of clinical information systems for timely data</p> <p>Facilitated flow of patient- or population-level data to clinicians, e.g., via reports of patient results, case registries, reminder systems</p>	<p>Patient’s FP or NP received individual patient data monthly x 3 months (while MHT followed patient weekly), then quarterly (while MHT followed patient monthly) for a maximum of one year</p> <p>Reports included: PHQ-9 score and other questionnaire scores as appropriate to the patient, a brief summary of care with MHT, and any recommendations from the study psychiatrist</p>	<ul style="list-style-type: none"> • Theoretically useful but some had difficulty recalling what they received, and blinded patient randomization also made their opinions difficult to interpret • Could validate PCP impression, provide information not known to the PCP, or discuss referrals that were seen by the PCP as redundant or previously tried • Telephone contact between MHT and PCP initiated by MHT was rare and greatly appreciated when it occurred; very rarely (if ever) initiated by PCP • Rarely identified any changes to their practice as a result of receiving these reports or knowing about MHT involvement (perhaps because of practice habits and small number of their patients involved with PARTNERS intervention)
<p>Delivery system redesign</p> <p>Team-based care (versus physician-only care) to provide education, self-management support, information flow, and overall proactive rather than reactive care</p>	<p>Addition of MHT and study psychiatrist at a distance</p>	<ul style="list-style-type: none"> • Embraced the concept of team-based primary care for people with common mental disorders e.g., depression, anxiety; ; typically identified other conditions (e.g. bipolar, PTSD) as appropriate for follow up in specialty care • Many didn’t see the MHT care manager as an integrated member of the care team or a resource to the primary care setting
<p>Decision support for healthcare providers</p>	<p>Based on discussion with MHT</p>	<ul style="list-style-type: none"> • Appreciated study psychiatrist recommendations though did

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<p>On-site or distal psychiatrist consultation to PCPs, or provision of simplified clinical practice guidelines supported by clinician champions.</p>	<p>and an algorithm, study psychiatrist provided recommendations for optimizing treatment in the abovementioned reports</p>	<p>not necessarily act on them any sooner than the next scheduled patient appointment</p>
<p>Linkage to community resources Referrals to external resources to support clinical and nonclinical needs (e.g. peer support, exercise, home care)</p>	<p>Not formally a component of the PARTNERS intervention</p>	<ul style="list-style-type: none"> • Mixed perspectives on whether these may be best identified, introduced, and referred to by the local primary care team versus the distal collaborative care team
<p>Support for healthcare organizations Leadership, training, staffing, informatics, and other tangible resources to support adoption and implementation of collaborative care goals and practices</p>	<p>Not formally a component of the PARTNERS intervention (although PARTNERS team did provide an optional initial on-site orientation to the study for local primary care teams)</p>	<ul style="list-style-type: none"> • Identified as a major gap • Leadership support for participation in PARTNERS varied greatly and influenced adoption and implementation • Lack of training and ongoing support resulted in difficulty knowing how to introduce the study to patients, whether the study was ongoing and continuing to accept new referrals, etc. • Interprofessional staff involvement (i.e., beyond physicians) would be required to facilitate more proactive care • Staffing turnover was common and created discontinuity in knowledge of, and engagement with, the study • Some informatics capabilities could assist with proactive care (e.g., searches or flags in the EHR to facilitate identification of eligible patients); again, would require interprofessional staff involvement

Table 4: Primary care providers' perspectives on patient and study characteristics that influenced referrals to PARTNERS

PATIENT CHARACTERISTICS:

	<i>Mental health diagnosis congruent with phone-based support</i>	<i>Stage of mental illness</i>	<i>Socio-demographic characteristics</i>	<i>PCP perceptions of patient preferences</i>
<p>10 Increased likelihood of referral</p>	<p><u>ANXIETY DISORDERS:</u> "I think for anxiety, I think it was really helpful as well actually by phone call initially because a lot of my patients did have struggles getting to any appointment because they're too anxious to leave the house, they're too anxious to do just anything...they'll answer the call, and they actually like talking with somebody from the safety of their own home... for anxiety, I think it was really helpful to do it that way" (1002)</p>	<p><u>NEW ONSET OF DEPRESSION/ANXIETY:</u> "I certainly have a lot of patients with depression and anxiety that I didn't refer, [for referrals] it tends to be people that are walking in with a new symptom... I think for people that I've been following for a long time, it's just not in my algorithm" (1004)</p>	<p><u>PATIENT CHARACTERISTICS INFLUENCING MOTIVATION AND PERCEIVED CAPACITY TO SELF-MANAGE:</u> "I have kind of more of the working, younger, healthier, a better mixed population...which probably also is why I had more referrals than others – because my patients are more motivated to be self-managed and seek access to a dietician, access to a social worker, that kind of stuff. And I have an easier time getting my patients to do that than they do at the other sites [that have] ... a sicker, older population" (15002)</p>	<p><u>TIMELY RESPONSE TO A PATIENT NEED:</u> "Typically what would happen is a patient would come in in crisis, in need. Although we do have a social worker, they needed something more... And so offering them this as an interim, knowing that they would still get to the psychiatrist, seemed to alleviate some of that anxiety about, okay, when am I going to have that appointment and how come I can't get in tomorrow? And so having that sort of stepping stone, sometimes it worked extremely well and I know that some patients thought it was great" (12001)</p>
<p>28 Decreased likelihood of referral</p>	<p><u>CO-MORBID SUBSTANCE USE & ALCOHOL USE:</u> "I think addiction care over the phone might be kind of hard, personally. And I didn't refer any of my clients in particular related to like alcohol use... because I've never had a patient who was like willing to cut down drinking or was interested in getting support for cutting down drinking that would be willing to do it by phone" (15001)</p>	<p><u>ACUTE/CRISES:</u> "It was mostly if we felt that a client was a little bit more acute and not so much in a more stable environment for that phase in regards to their depression or anxiety. Then we would focus more on getting that client the needs met in regards to the counselling that they needed or being seen by a psychiatrist. So not so much being followed and screened but more intervention... Once we felt that they were a little bit more stable... And a lot of them did actually go through the</p>	<p><u>LANGUAGE BARRIERS:</u> "Language barrier was one that we took into consideration as well... we do have a really high Francophone community. So that was one of the barriers that we encountered quite a bit. So we have a big elderly population as well. So they do deal with depression, especially during the wintertime as well. So it would have been a great resource for them because it doesn't require them to come out of their home. So it reduces the risks of falls and all that. But I</p>	<p><u>PATIENT PREFERENCES FOR EMBEDDED / LOCAL SERVICE:</u> "We have...at our family health team, we have a social worker who does counselling. So when I bring these things up, I sort of put the option for counselling that we have on the table. And most of my other currently depressed people are a little more in that 40, 50 year old range, and they were quite happy to just do regular counselling. So it wasn't that I intentionally didn't refer, it was that they were happy with the resources at</p>

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		PARTNERS study afterwards” (15003)	wasn’t able to utilize the PARTNERS study for them because they only speak or understand French” (15003)	<p>the site” (5001)</p> <p>“I have some patients that just have had a bad experience with <the hospital> and they won't have anything to do with it. So I’ve had that a couple of times” (1004)</p> <p><u>RELATIONSHIP WITH PCP:</u> “I wouldn't refer people who are really busy or involved in a lot... Or I felt like we need to work on the therapeutic alliance a little bit more” (1001)</p>
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	<i>Eligibility Criteria</i>	<i>Randomization</i>	<i>Anticipated Benefits for Patients</i>	<i>Anticipated Benefits for Providers</i>
<p>Increased likelihood of referral</p>	<p><u>HOPE TO LINK PATIENT WITH SUPPORT THROUGH STUDY:</u> “There were a couple of people that I referred that had trauma that I still hoped that they would get in, and they were not eligible. So I still referred some people even though they met your exclusion criteria just in hopes that they might get some extra support” (15001)</p>	<p><u>RANDOMIZATION NECESSARY TO EVALUATE INTERVENTION:</u> “I think it's [Randomization] part of the research beast. Like if you want a good study, you probably have to do some sort of randomization. And so I understand that from a research principle. So it doesn't particularly affect me negatively” (5001)</p> <p><u>HOPE TO LINK PATIENT WITH SUPPORT THROUGH STUDY:</u> “No, I never considered whether they would get the help or not. I just knew that this is something we could offer them... And I hope that those people that needed the help got it ... it [randomization] didn't stop me from doing it (12001)</p>	<p><u>INTERVENTION ACCESSIBILITY:</u> “Access to counselling here is a problem. And so just hoping to increase services is helpful. Lots of patients here have difficulty with access in terms of driving, being able to actually go somewhere to see a counsellor. So the fact that, you know, its phone contact was helpful. Not every person is super comfortable talking to somebody in person. And so phone sometimes helps sort of initiate or get things moving. So lack of general access, phone access versus one-on-one, transportation issues” (12002)</p> <p><u>WITNESSING PATIENT BENEFITS:</u> “And until we actually made our first</p>	<p><u>STUDY AS A RESOURCE AUGMENTING USUAL CARE (VS. STUDY AS 'RESEARCH')</u> “It’s a research study about these two different interventions. It’s not a psychiatrist necessarily taking over my patient, saying here, we’re going to see this patient and assess them fully, and then we’ll do all this diagnosis and may start medications, and then we’ll send them back to you, and then work together...It’s actually more of me looking after the patient but with these additional options... an add-on to my usual care. It’s not replacing it... I just want them to be randomized and it doesn’t matter because I’m going to be doing the usual care anyways. This is an add-on that could help them”</p>

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			<p>referral, understood the ramifications for the patients and actually saw some feedback, it didn't really connect with us" (12001)</p>	<p>(11001) "I don't have the time in my schedule to actually make like just a monitoring phone call appointment every week. Maybe on a monthly basis or so then yeah, that's more feasible. But the PARTNERS study actually allowed me to give a little bit... Like step back a bit and I knew that they were being monitored. And if there was a real concern then it would be brought to my attention. So it was opening up my schedule..." (15003)</p>
<p>Decreased likelihood of referral</p>	<p><u>HIGH PREVALENCE OF CO-MORBID DISORDERS IN PRACTICE:</u> "A huge portion of my practice, it's high rates of substance abuse, high rates of PTSD and high rates of bipolar. So to come across somebody with just depression or anxiety is pretty rare." (15002)</p>	<p><u>NEED FOR IMMEDIATE SUPPORT AND CHANCE OF NOT RECEIVING INTERVENTION DUE TO RANDOMIZATION:</u> "I was kind of concerned if someone needed more of that regular support and kind of symptom check-in and psychoeducation. You know, I wouldn't be confident that they would necessarily get that from PARTNERS. So I'd prefer to actually either see them regularly, like fairly regularly myself or refer to our social worker if needed for that. So I would say for patients who were maybe more severe for which I felt like that more frequent monitoring was necessary, I chose not to refer because that risk of randomization was there" (1003) "Some people will be randomized and won't be able to access it. So like if they really, really need the support,</p>		<p><u>LACK OF KNOWLEDGE ABOUT INTERVENTION:</u> "I don't think I knew enough about it or was comfortable enough about it during that time" (13001) "I'm assuming it's a knowledge gap, a deficit in education as to exactly how either the mental health technicians or nurses can help the patient. Sometimes I think there's a stigma attached to an intervention that has the word research study attached to it" (13002) <u>REDUNDANCY OF SERVICE:</u> "It was introduced as something that could be helpful. But I guess maybe it just didn't take off, you know, due to all the factors - of some of the social workers seeing it as maybe threatening their service, other patients seeing it as a duplication"</p>

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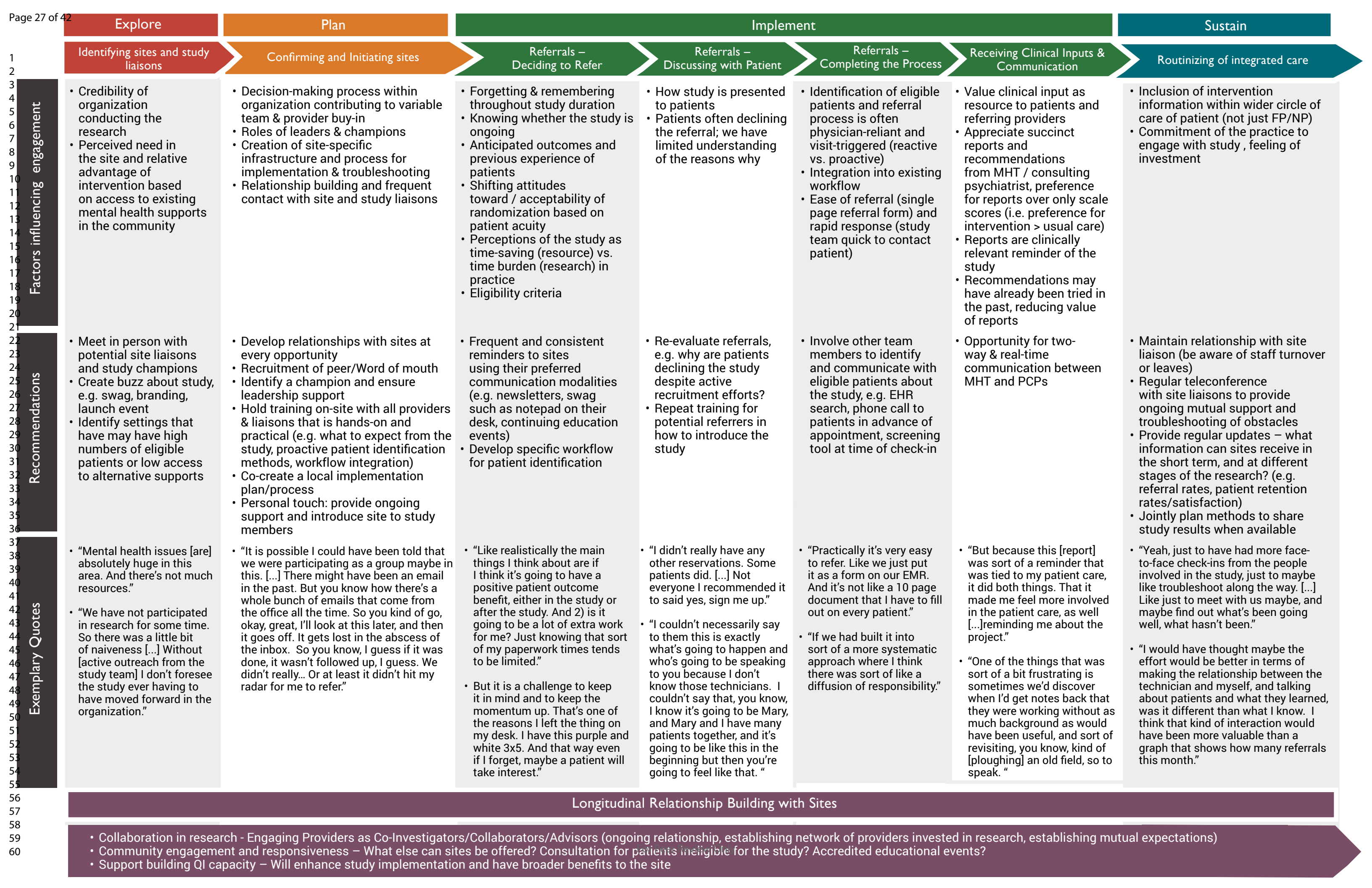
	<p>like we might not refer in because we want 100% for them to get the support. So that thing of being randomized out would be one” (1005)</p> <p>“Enhanced usual care, I mean you actually do get some sort of feedback from...you know, at a time when you wouldn't have seen patients, can be somewhat useful. But from a patient perspective, I don't think it's particularly different from what they would have had anyway...I think with any study, that's kind of the harder point – that you might get it but you might not” (1004)</p> <p>“When you try to talk to your patients about it, knowing that there's a chance that they could end up in the control group and have much...like more spaced out or infrequent assessments, I would say is kind of a down side. Knowing that, you know, just statistically maybe half your patients may end up in that group. In which case, there's less of that support there. And I think that's just something we all had to kind of keep in mind” (1003)</p>		<p>(18001)</p> <p>“Maybe I'm referring to our local psychiatric referral resource... So you may not see it [referrals to PARTNERS] because... it's hard to work with <the hospital> when I have a local resource” (11001)</p>
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Figure 2. Barriers and enablers to adoption and implementation of PARTNERs at different stages of implementation

* see separate file

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Challenges in Integrated Mental Health Care Research: Understanding Primary Care Providers' Participation in the PARTNERS Study

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Background

Most Canadians who receive mental health care do so in primary care settings.¹⁻⁵ Collaborative Care is one of the most empirically supported approaches to achieving good outcomes in primary mental health care⁶⁻¹¹ and it is integral to provincial mental health strategies¹²⁻¹⁵ and Canada's vision for primary care.¹ However, well-studied effective models of care have not been implemented in Ontario, and other unstudied models have been implemented with limited evaluation.^{16,17} Ongoing research aims to explore the effectiveness of variations on the Collaborative Care model (i.e. integrated care) that may have advantages for widespread implementation (e.g. feasibility to be delivered at a distance).

Appendix 1: Full Study Protocol

Specifically, the PARTNERS study is a pragmatic randomized controlled trial (RCT) to assess the implementation and effectiveness of an integrated care model vs. enhanced usual care for people experiencing depression, anxiety, and/or alcohol use disorders. The study aims to improve treatment initiation by the primary care provider (PCP), symptom severity, and quality of life or functioning (as measured at 4, 8, and 12-month follow up). The intervention introduces a new role of Mental Health Technician (MHT) providing telephone-based, computer-aided care management (i.e. symptom monitoring and self-management support); specialized decision support software for primary care providers to guide pharmacotherapy and psychotherapy prescribing, and; facilitated access to specialty services when needed.

Experience to date in the PARTNERS study suggests PCP reluctance to refer patients for reasons that are poorly understood and that may relate to integrated care delivery models/components and/or the RCT study design and methods.¹⁸ Referral rates have been much lower than expected based on epidemiological data, requiring expansion to numerous additional primary care sites to meet recruitment objectives. Possible factors identified by the research team include: a) lack of perceived need for the intervention, i.e. perceived adequacy of usual care, b) low value placed on receiving patient/practice data provided to participating PCPs by the study, c) low acceptability of randomization, and d) under-identification and mis-identification of both target conditions and exclusionary conditions. It is vital to understand PCPs' experience of the PARTNERS integrated care intervention and research study, to understand barriers and facilitators to integrated care research, implementation and dissemination, and to inform the design of future research.

Potential implications for uptake of integrated care in clinical practice

The proposed study aims to understand factors influencing participation in integrated care delivery (e.g. uptake of specialist treatment recommendations provided by the study) and factors influencing participation in integrated care empirical research (i.e. referrals to the PARTNERS RCT). The former may shed light on barriers and facilitators to widespread uptake of integrated care models beyond research settings and will be important to consider in the development of integrated care models that are likely to be adopted and sustained. Poor healthcare provider uptake of evidence-based models of integrated care is a public health concern that perpetuates problems with access to appropriate mental health care and the population health burden of common mental disorders.

Study Objectives and Research Questions

This study aims to explore PCPs perspectives, experiences and opinions of the PARTNERS study and understand referral patterns. We ask the following questions:

1. ***Perceptions and preferences regarding integrated care models.*** How do PCPs perceive the role for, and the advantages and disadvantages of, integrated care model components in the PARTNERS study, including measurement-based care, population-based care (e.g. practice-level data), care management, and specialist decision support? What are their preferences regarding such components?

Appendix 1: Full Study Protocol

2. **Implementation and uptake of the care model.** What aspects of the integrated care model and its implementation enabled or hindered PCP participation in the provision of integrated care (e.g. including uptake of specialist treatment recommendations)? What features of integrated care interventions could increase PCP uptake?
3. **Participation in the research (referrals to the study).** What provider, practice, intervention, and/or study factors influenced the referral rate to the study? What provider and practice factors influenced variations between different PCPs' referral behaviour? How did PCPs decide who to refer and when to refer?
4. **Future research.** What features of integrated care study design and processes (e.g. inclusion/exclusion criteria, recruitment methods, communication modes), could increase PCP uptake of future research studies on integrated care models? What are PCPs' opinions of the research team's prototypes for future integrated care research studies?

Methodology

Theoretical frameworks

Implementation consists of the constellation of processes undertaken to adopt an innovation in a particular situation and it is influenced by specific features of the innovation; the broader context and organizational setting in which implementation takes place; characteristics of the individuals involved; and the activities of planning, engaging, executing and reflecting / evaluating.¹⁹ Guided by this implementation science perspective and drawing upon the Consolidated Framework for Implementation Research (CFIR), the proposed study will qualitatively explore how PCPs responded to the integrated care intervention and RCT, and provide a contextualized understanding of the issues, challenges and processes associated with participation in the study.^{19,20}

In this study, we are particularly interested in PCPs' attitudes, beliefs and intentions that shaped their behaviour in care delivery and in the RCT. Because we plan to conduct further research of integrated care we are also seeking to identify opportunities to influence PCPs' behaviour to more thoroughly participate in subsequent studies. Thus, this research will also be guided by the Theory of Planned Behavior (TPB), which holds that intentions are shaped by a combination of:

- a) beliefs about, and valuations of, likely outcomes,
- b) perceptions of group norms and motivation to adhere to group norms, and
- c) perceptions of control, and of barriers and enablers of performance.^{21,22}

According to the TPB, intentions are then translated into action (mediated by actual control).

These two theoretical frameworks will inform all stages of the research, including study conceptualization, data collection, data analysis, and interpretation and dissemination of findings, including recommendations for future research.

Preliminary quantitative phase

Quantitative and qualitative methods often play complementary roles in mixed methods implementation research.^{23,24} This study will use a modest quantitative strand preceding the major qualitative strand (quan → QUAL). The quantitative strand will consist of descriptive statistical analysis

Appendix 1: Full Study Protocol

of referral patterns, and individual- and practice-level characteristics of PCPs who were high or low recruiters to the PARTNERS study. This analysis will be used to:

- a) complement the qualitative analysis in answering the research questions outlined above, emphasizing breadth in describing all PCPs in the study versus depth gained through interviews with a subset of PCPs,
- b) provide a basic description of variations in referral behavior, which the qualitative strand will then seek to expand upon and explain, and
- c) guide sampling for the qualitative strand (as described below).

For the quantitative phase, no new data will be collected. The research team will review existing data that tracked referral source for each patient in the PARTNERS study. Any identifying patient information will be removed prior to the analysis of referral patterns. Identifying information for the referral sources will be retained in this analysis since the results of the analysis will inform the selection of target interviewees for the subsequent qualitative phase. For each PCP and practice we will compute: a) referral rate (i.e. number of referrals per unit of time in the study), b) rate of successful referrals (i.e. proportion of referrals that were accepted into the study), c) types of referrals (i.e. by eligible diagnosis and number of diagnoses), and d) severity of referrals (i.e. median and interquartile range of initial PHQ-9 scores for their patients entering the PARTNERS study). We will also note whether the PCP is located in an urban, suburban, or rural location.

Qualitative interview sampling and recruitment

This type of study requires detailed descriptions from participants. We will conduct in-depth qualitative interviews with individual PCPs to develop an understanding of their perspectives and experiences with the PARTNERS study. Eligible participants will be PCPs at primary care practices (e.g. Family Health Teams, nurse practitioner led clinics, etc.) that participated in the PARTNERS study. We will use stratified purposive sampling to identify and engage information-rich cases that shed light on the questions under study.^{23,25} The strata will encompass major variations in PCP participation (e.g. referral rates) in the study, as well as variations in practice settings and practice participation. This is consistent with the CFIR and TPB frameworks' emphases on practice settings/context and provider characteristics. We will use descriptive statistics regarding recruitment/referral patterns for the study to guide the sampling framework by determining the nature of the variations (see Table 1). We will additionally use criterion sampling to interview individuals who had a particular role to play in the primary care setting but who were not themselves referring PCPs, for example, social workers or other individuals who were identified by PCPs as in a liaison role to the study.

Table 1. Proposed stratified purposive sampling framework for PARTNERS qualitative study

Setting	Practice Level Referral Pattern	Provider Level Referral Pattern
Urban	High referral rate	High referral rate
		Low referral rate
	Low referral rate	High referral rate

Appendix 1: Full Study Protocol

		Low referral rate
Suburban	High referral rate	High referral rate
		Low referral rate
	Low referral rate	High referral rate
		Low referral rate
Rural	High referral rate	High referral rate
		Low referral rate
	Low referral rate	High referral rate
		Low referral rate

A Research Coordinator (RC) will contact PCPs by telephone or email (see Appendix E for invitation script) and invite them to participate in an interview. The RC will use the contact information that PCPs previously provided to the PARTNERS study and/or their publicly available contact information at the website of the College of Physicians and Surgeons of Ontario. The RC will provide a letter of information as an email attachment (see Appendix D for letter of information). Potential participants will be advised they can contact the Principal Investigator if they have questions about the research study and/or contact the RC if they agree to participate. If they agree, the RC will schedule the telephone interview at a time convenient for the interviewee. Prior to the start of the interview the RC will review the consent process with participants (see Appendix F for oral consent script). Scheduling and participating in an interview will constitute implied consent. All interviews will be conducted by telephone and will be approximately 60 minutes in length. Upon completion of the interview PCPs will be provided a \$200 honorarium. Interviews will be audio-recorded, transcribed, and retained until the end of the study.

Data collection

The interviews will follow a semi-structured interview guide informed by the CFIR (which addresses characteristics of the intervention, outer and inner settings, individuals, and implementation processes) and the TPB (which addresses perceptions and beliefs that influence intentions, and in turn behavior) (see Appendix B for interview guide).^{19–22} For example, interviews will explore PCP perceptions of the evidence for, and relative advantage of adopting, the integrated care intervention; PCP beliefs, self-efficacy and motivation; the primary care organization's relationship to other organizations and to external sources of pressure; the organization's culture, social networks, climate and leadership (see Appendix C for Collaborative Chronic Care Model Core Elements table, which will be sent attached to the email with confirmation of interview), and; the processes of planning, engaging (e.g. marketing or training), leading or championing, and reflecting. Data collection and analysis will be concurrent, and we will continue data collection until reaching saturation (i.e. an understanding of the data in relation to the major components of the CFIR and TPB, and no new emerging themes). In qualitative research, it is not possible to predetermine the sample size at which saturation will be reached.²⁶ Some authors have recommended at least 3 participants per subgroup in a stratified purposive sample (n=36 for the proposed study).²⁵ For the criterion sampling of study liaisons, as few as 6 interviews may suffice.²⁷ As part of the telephone interview participants will also be asked for basic demographic information that will be used to describe the study sample (See Appendix H for demographic questionnaire).

Appendix 1: Full Study Protocol

Data analysis

The data analysis will also draw upon the CFIR and TPB frameworks. We will conduct a grounded theory analysis to develop a mid-level theory of why PCPs behaved as they did in the PARTNERS study.²⁸ Our analysis will explore PCPs' and liaisons' experiences of the PARTNERS intervention and study; factors influencing intentions, adoption and implementation of the care model and study (e.g. with respect to referrals and with respect to implementing treatment recommendations), and; opinions and recommendations for the design and 'packaging' of future interventions and studies (e.g. based on perceived utility, acceptability, feasibility, and likelihood of uptake). The dataset for qualitative analysis will consist of the interview transcripts, as well as any field notes, diagrams, and memos that are created by the research team through the process of data collection and analysis.

Grounded theory analysis uses the constant comparative method to "code" data and develop theory.^{28,29} Initially, at least two research team members (NS and the RC) will independently read several transcripts and generate "codes" (categories of incidents in the data), and while coding each incident they will compare it with other incidents coded in the same category, and in so doing generate properties of each category or code. NS and the RC will meet and compare codes to develop an initial codebook, then use the codebook to code each remaining transcript, meeting regularly and add, revise, merge or delete codes as needed. Transcripts and codes will be organized using NVivo10 software. We will then explore convergent and divergent themes across different strata/groups of PCPs, including by examining frequency of codes for each stratum, looking for patterns, building explanations iteratively, and considering rival explanations.^{28,29} As data analysis will be concurrent with data collection there will be opportunities for additional interviews as needed to saturate certain codes and/or check the developing theory by seeking confirming or disconfirming cases (estimate up to 8 supplemental interviews).²³

We will use non-leading interviews, triangulation of multiple data sources and types, and a team approach to data analysis to ensure diverse perspectives emerge, and we will use a research audit trail to provide transparency about the research team's choices.^{30,31} These steps will increase the rigor and trustworthiness of the findings.

Ethical Considerations*The consent process*

At the time of recruitment, the RC will provide the letter of information, including detailed information about the project, the purpose of the interview, confidentiality of the interview, data storage and security processes, and study contact information. Participants will be informed that participation in the study and offering their feedback will in no way affect their employment or their eligibility to participate in future research, but will be used to inform the development of future research studies on integrated care. They will be notified that they can decline to participate, and that contacting the RC to schedule and participate in an interview will be considered implied consent. At the outset of each telephone interview the RC will review key information, answer any questions, and obtain oral consent from the participant, prior to proceeding with the interview questions.

Appendix 1: Full Study Protocol

Risks

The anticipated risks associated with the study are minimal. Research risk, defined as the invasiveness of the procedures, is low for this research study, as is the risk of psychological or emotional distress. There is some social risk associated with interview participants' disclosure of perceptions, beliefs and preferences to the research team. This will be mitigated by: a) ensuring participants are aware they may decline to answer any question, b) reporting participants' data outside the research team only in aggregate de-identified form, and c) informing participants they may withdraw from the study for up to two days after their interview, in which case their data will be excluded from the analysis. There is a small risk of unintentional release of information; participants will be advised of this risk, and the study team will make every effort to protect confidential information using the methods described below.

Compensation and other benefits

Participants will be provided with a \$200 cash honorarium in appreciation for their participation in the interview. Findings from this study will inform future clinical trials of integrated care interventions and will also contribute to the research literature on ways to implement and evaluate Collaborative Care.

Appendix 1: Full Study Protocol

Privacy and confidentiality

All study data, including information used for the preliminary quantitative phase, as well as information obtained during the interviews, will be confidential. The initial quantitative analysis will be done in a password protected Excel file separate from other study data. In the qualitative phase each audio-file and transcript will be assigned a numbered code. A master linking log that links participant names and numbered codes will be stored as a password protected file separate from the study data (see Appendix G for master linking log). All study data, including the master linking log, will be retained five years after study completion in accordance with St. Michael's Hospital institutional policy. In presentations and publications, there will be no identifying information provided or linked to any particular opinions. Demographic information will be reported in aggregate form only.

Data Management

Only the investigators and research staff will have access to the data. Upon transcription of the audio-files, the transcription accuracy and completeness will be verified and the audio files will then be destroyed. Audio-files will be stored until verified as password-protected computer files on a secure server at St. Michael's Hospital. The file containing the quantitative analysis of referral rates and types; transcripts, and; a file summarizing participants' demographic data will also be stored as password-protected computer files on a secure server at St. Michael's Hospital. It is possible that some data collection and analysis will be conducted off-site (based on the geographic locations where research staff may be working); in this case, password-protected files may be stored on St. Michael's Hospital-encrypted USB portable storage devices. Any hard copies will be stored in a locked filing cabinet at St. Michael's Hospital.

Significance

Local contextual factors have significant influence on the implementation, impact, and scalability of complex interventions, yet are often under-recognized and under-reported in the literature.³³⁻³⁶ In order for the field of integrated care research to progress toward widespread adoption and sustainability of these care models, understanding factors that influence uptake is crucial. Notably, at least one major study that failed to achieve the intended outcomes of scaling and spreading integrated care also failed to produce learnings on the implementation, a significant lost opportunity.³⁷ Our study will deliver a rare understanding of the implementation challenges encountered in a large pragmatic RCT of integrated care, as well as critical guidance to improve uptake in future studies.

Dissemination and Impact

The primary impact of this research will be in shaping future research trials of integrated care led by Dr. Mulsant and others. Additionally, we will disseminate our findings in a manuscript for publication in a peer-reviewed journal, and at the following conferences: Institute for Psychiatric Services, Collaborative Family Healthcare Association, and the North American Primary Care Research Group (NAPCRG). Upon request, participants in the study will be provided with a summary of results at the completion of the project; the summary will include details on how they may optionally request copies of any additional reports and publications.

Appendix 1: Full Study Protocol

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Confidential

Challenges in Integrated Mental Health Care Research: Understanding Primary Care Providers' Participation in the PARTNERS Study

In this study we are interested in understanding your experience of the PARTNERS randomized controlled trial of an integrated care model for management of depression, anxiety and alcohol use disorders in primary care settings. We're interested in your perspective on the clinical intervention under study, as well as your perspective on participating in a randomized controlled trial.

General / Early Impressions

How did you first hear about the PARTNERS study? Probes: written or oral material; from study personnel or from someone at your site? How useful was the information you received in deciding whether you wanted to be involved? Is this type of information more persuasive if it comes from a peer?

How did you decide whether to participate in the study? What appealed to you at the outset? What did you hope that you and your patients would get out of participating? Was there anything that didn't appeal to you or that you had reservations about? Did you discuss the study with anyone else (e.g. in your practice setting) and if so how did that influence you?

Have you participated in randomized controlled trials or other clinical research previously? (As an investigator, collaborator, study participant, or referring provider?) How was your experience of PARTNERS similar to or different from other research experiences? Please explain.

Integrated Care Interventions

You may remember the PARTNERS study involved multiple components that are typically bundled and referred to as "integrated care". I'd like to hear your opinions about each component. I'll describe each component and how it was enacted in the PARTNERS study. I'd like to know your perspective on how it was provided in PARTNERS and how it could be provided in future studies.

Patient support for self-management is a key component of integrated care and focuses on coaching and problem-solving approaches that aim to help patients better manage their symptoms and care. In general, what do you think about this type of support for patients? How important is it? Who do you think should provide it and how? In the PARTNERS study patients randomized to the integrated care intervention received 3 months of weekly telephone monitoring followed by 3 months of maintenance monthly telephone monitoring, with no additional monitoring when they had few or no symptoms. The MHT helped them monitor symptoms, adhere to treatment, and provided education and support. What do you think about this way of delivering patient support for self-management?

Providing timely clinical information to patient's health care providers is also a core element of integrated care. This typically involves providing the results of patient report symptom rating scales to their clinical team, and can involve providing individual patient-level data and/or practice-level data. In PARTNERS, you received information (such as findings and recommendations) from the MHT following the baseline assessment and ongoing on an "as needed" basis.

Appendix 2 – Interview Guide

1
2
3 Was this data useful to you? Please explain. E.g. did it inform the care you provide?
4

5 Did you receive you any other information about the study at all during your participation? E.g.
6 newsletter or other correspondence from the study coordinators?
7

8 Are there any ways you think the data / reports could be improved? (e.g. frequency, type of
9 information, ability to further communicate)
10

11
12 **Expert input** was a component that provided guidance to primary care providers. It could be done a
13 number of ways, e.g. providing clinical practice guidelines or care pathways, or providing individual case-
14 based consultation on-site or at a distance, ‘on the fly’ or at a pre-scheduled time. In PARTNERS this was
15 provided by receiving evidence-based treatment recommendations by the MHT and the project
16 psychiatrist, and by receiving treatment updates and progress reports from the MHT, as required. How
17 did you receive the input? What did you do with the information/input you received? Were there things
18 about the input or about your practice or work week that made it easier or harder to implement the
19 recommendations, i.e. that made it more or less likely that you would do so?
20
21

22
23 Probes: integration into PCP workflow, value of / trust in the suggestions, perception of them being
24 suggestions versus expectations i.e. retaining or relinquishing control, perception of feasibility, comfort
25 level with implementing the recommendations.)
26

27
28 What do you think about the role for expert input and the different ways it could be provided? What are
29 your preferences for how this guidance could/should be provided and by whom?
30

31 Interaction with MHT or psychiatrist? Seen as resource?
32

33 Probes: preference for expert-generalist (FP) or expert-specialist (psychiatrist), frequency and mode of
34 communication, level of detail, organization of information, etc.
35
36

37 **Delivery system redesign** refers to redefining roles and responsibilities in care delivery, for example
38 having other clinical providers who aren’t physicians provide self-management support, symptom
39 monitoring, and clinical information management. In PARTNERS this again refers to the Mental Health
40 Technician and the study providing the symptom monitoring and feeding data back to you. What was it
41 like for you to have responsibilities divvied up in this way? Who do you think should provide the
42 different aspects of, say, depression care? Who do you think should provide the different aspects of,
43 say, addictions care? Please explain.
44
45

46
47 **Links to community resources** outside the primary care team may be a part of integrated care
48 interventions but were not featured in the PARTNERS study. During our interviews we’ve heard different
49 perspectives on whether identifying community resources is something that should be done by the MHT
50 versus by the local primary care team. In your opinion, how important is this component to achieving
51 good outcomes for your patients? Probe: What types of community resources are relevant / important
52 to you? (e.g. housing support, employment, exercise groups, peer support) How important would it be
53 for future integrated care initiatives to provide information about community resources? Please explain.
54
55
56
57

Appendix 2 – Interview Guide

1
2
3 **Leadership support and/or staff training** to implement integrated care can also be a core component of
4 integrated care. Did you encounter this while participating in the PARTNERS study? What form did it
5 take? How important is leadership support and/or staff training for implementing integrated care
6 initiatives? Please explain. (Probe: If they endorse a role for this, get them to describe specifically what
7 they think is needed. E.g. if leadership, clinical or administrative leadership or both? What leadership
8 activities? If training, what topics, what format, what frequency?)
9

10
11 This next question is not specific to the PARTNERS study. Thinking about all of the components of
12 integrated care that we've been talking about, i.e., support for self-management, clinical information
13 flow, decision support, redistribution of roles, links to community resources, and leadership and staff
14 training, do you have any opinions about the bundling or combination of the difference components?
15 Anything that seems particularly important? Complementary? Redundant? Unnecessary? Contradictory?
16 Please explain.
17
18

19
20 In your opinion, does integrated care make it more likely that patients will recover from their mental
21 health conditions? Please explain.
22

23
24 The endpoints that were measured in the study were rate of remission or recovery for patients with
25 clinical depression, generalized anxiety disorder, panic disorder, and/or alcohol misuse. The study
26 measured a number of outcomes throughout the intervention related to these disorders, in addition to
27 measures for cognition; pain; mental health treatment; patient satisfaction; and, mental, physical,
28 social, and vocational functioning. Are any of these outcomes meaningful from your perspective? Are
29 there other outcomes that matter a great deal to you as a primary care provider for your patients?
30
31

32 Referrals

33
34 Tell me about the types of patients you referred to PARTNERS and the reasons why you referred them.
35

36
37 Can you walk me through how you referred someone, e.g. how you explained the study to people
38 (menu that they can choose from, not an "either or")?
39

40
41 Were there other patients with depression, anxiety and alcohol use disorders that you chose not to
42 refer? What influenced you to refer or not to refer? Probes: clinical workflow / time / remembering,
43 likelihood of patient acceptance to participate, likelihood of patient being deemed eligible for the study,
44 perceived need for / utility / relevance of the intervention, anticipated workload
45

46
47 During our interviews we've often heard that remembering/forgetting can be a challenge. What kind of
48 reminders to refer to the study do you think are effective? (or What kind of reminders would you prefer
49 to receive?)
50

51
52 We also heard that sometimes patients were offered the study but declined it. Can you think of any
53 reasons why your patients might have declined a referral to the study?
54

55
56 Thinking of a time when you referred someone to the study, can you walk me through their care? How
57 were you caring for them before the study? At what point did you decide to refer? (Probe for the exact
58
59
60

Appendix 2 – Interview Guide

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3 moment when it crossed their mind and/or when they decided, what cued them?) What steps did you
4 need to take to refer them? Was there anything that made it easier to refer them? Was there anything
5 that hindered you or posed a barrier that you needed to overcome in order to refer them?
6
7

8 In this study, patients with depression, anxiety disorders, and/or alcohol use disorders were eligible, and
9 patients with other mental illnesses such as bipolar disorder, PTSD, or substance use disorders were
10 ineligible. Did these criteria influence your perspective on the study? Please explain. What types of
11 patients would you want to see integrated care interventions for in the future? Please explain.
12
13

14 Compared to other primary care providers who participated including providers at your practice, you
15 tended to refer to the PARTNERS study more frequently/less frequently. Does that surprise you or is that
16 what you would have guessed? Why do you think you might have referred more frequently/less
17 frequently compared with other primary care providers?
18
19

20 Compared to other primary care **practices** that participated, your **practice** tended to refer to the
21 PARTNERS study more frequently/less frequently. Were there things about the leadership,
22 communication, workflow, patients, clinical or administrative team, opportunities for training and/or for
23 reflection on practice, culture of the organization, or other factors that may have contributed to the
24 practice's referral patterns?
25
26

27 **Randomized controlled trials / intervention studies**

28
29 As you know, in a RCT patients are randomly allocated – in this case either to receive the integrated care
30 intervention (i.e. connection with a MHT and the other components) or to receive symptom
31 assessments every 4 months with the results of those assessments fed back to you. What was it like for
32 you to refer patients knowing they would be randomized? How did that influence your decision to refer
33 or not to refer, or whom to refer, to the study?
34
35

36 **Future Interventions and Studies**

37
38 Would it have been helpful for the research team to meet with you or to have visited your site at the
39 outset and/or on a regular basis to support implementation? Would it have been helpful for either the
40 study team or someone at your site to proactively help you identify suitable patients? E.g. pre-clinic
41 chart review, query of your EMR, identifying people who are known to your team who are eligible?
42
43

44 How would you feel about the study team inviting your patients once you've agreed to their suitability?
45 How would this work in your setting (Not concerned about mechanics but more your reaction to pre-
46 screening and inviting patients)?
47
48

49 This interview and others like it will shape future integrated care interventions and studies. What, if
50 anything, would you like to tell the researchers about what you'd want to see in future integrated care
51 models? What, if anything should be kept similar to PARTNERS? What would you change? Probe for
52 reasoning: estimated likelihood of benefit to patients? Benefits / convenience to primary care
53 providers? Feasibility of implementation?
54
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