Appendix 1 (as supplied by the authors): Full study protocol

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 care[6–11] and it is integral to provincial mental health strategies[12–15] 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).

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?

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 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
		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).

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.

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.

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 institutitonal 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.

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