

BMJ Open Transforming primary care for older Canadians living with frailty: mixed methods study protocol for a complex primary care intervention

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ABSTRACT

Introduction Older Canadians living with frailty are high users of healthcare services; however, the healthcare system is not well designed to meet the complex needs of many older adults. Older persons look to their primary care practitioners to assess their needs and coordinate their care. They may need care from a variety of providers and services, but often this care is not well coordinated. Older adults and their family caregivers are the experts in their own needs and preferences, but often do not have a chance to participate fully in treatment decisions or care planning. As a result, older adults may have health problems that are not properly assessed, managed or treated, resulting in poorer health outcomes and higher economic and social costs. We will be implementing enhanced primary healthcare approaches for older patients, including risk screening, patient engagement and shared decision making and care coordination. These interventions will be tailored to the needs and circumstances of the primary care study sites. In this article, we describe our study protocol for implementing and testing these approaches.

Methods and analysis Nine primary care sites in three Canadian provinces will participate in a multi-phase mixed methods study. In phase 1, baseline information will be collected through questionnaires and interviews with patients and healthcare providers (HCPs). In phase 2, HCPs and patients will be consulted to tailor the evidence-based interventions to site-specific needs and circumstances. In phase 3, sites will implement the tailored care model. Evaluation of the care model will include measures of patient and provider experience, a quality of life measure, qualitative interviews and economic evaluation.

Ethics and dissemination This study has received ethics clearance from the host academic institutions: University of Calgary (REB17-0617), University of Waterloo (ORE#22446) and Université Laval (#MP-13-2019-1500 and 2017-2018-12-MP). Results will be disseminated through traditional means, including peer-reviewed publications

Strengths and limitations of this study

- This study will be conducted in nine different primary care sites across three Canadian provinces.
- The primary care sites represent diverse contexts.
- This study is conducted in team-based primary care settings, thus may not be generalisable to solo practitioner clinics.

and conferences and through an extensive network of knowledge user partners.

Trial registration number NCT03442426; Pre-results.

INTRODUCTION

Background and rationale

The Canadian population is ageing,¹ and a larger proportion of healthcare spending is now directed towards older adults.² The healthcare system, however, is not well designed to meet the needs and challenges of our ageing population, who often have numerous and complex health issues,^{3–5} or who might be considered at risk or frail. For this project, we define frailty as a state of vulnerability to stressors due to declines in multiple physiological systems.⁶ We recognise, however, that there is ongoing debate in research and clinical communities about the definition and operationalisation of this term.⁷

Many older adults require care from multiple providers across multiple settings, and find it confusing and overwhelming when trying to navigate an uncoordinated healthcare system.^{8–16} This can lead to inadequate

transfer of information,¹⁷ medication errors and other adverse events^{18 19} and poor outcomes²⁰ for a population that is already vulnerable. Older patients tend to look to their primary healthcare providers (HCPs) to assess their needs and coordinate their care, however physicians report being overwhelmed by patients with increasingly complex and chronic conditions.²¹ Too often, this leads to a break down in care resulting in high economic costs and negative social impact. Recent reviews have found that an effective primary care model for ‘high need, high cost’²² patients requires appropriate targeting (through screening) and further assessment, engagement of patients and caregivers in decision-making supported by evidence and coordination with other health and social services.²²

The identification and assessment of risk and frailty

The development of frailty can be slow and subtle and can be easily dismissed as normal signs of ageing.²³ As such, identification can be complex. Frailty is often detected only in the late stages, which limits the potential to intervene for positive outcomes, with resulting high economic and social consequences.²⁴ While there is currently no agreed on standard to screen for frailty, many studies have shown that the proactive use of screening tools in clinical practice is an efficient and effective way to identify risk, mitigate acute crises and reduce vulnerability in older adults.²⁵ Primary care is an appropriate setting for early identification of frailty and risk, which can guide appropriate treatment or intervention to potentially avoid adverse health outcomes and reduce the progression of frailty.^{23 26} For effective risk screening in primary care to be feasible on a consistent basis, screening tools are required that are straightforward and quick to use, as well as valid.²⁷

Patient engagement and shared decision-making

There is growing recognition of the importance and benefits of person-centred care approaches^{28–30} and patient engagement has been identified as a central element of patient-centred care.^{28 31–33} A more active role for patients in their healthcare can improve the quality, efficiency and outcomes of care.^{34 35} Moreover, an engaged patient is more likely to understand their health conditions, to participate in proposed treatment plans and to report greater satisfaction with their healthcare and quality of life.^{36 37} Despite being less accustomed to an active role in healthcare decision-making than younger patients, with encouragement, older adults can participate in shared decision-making and can derive health benefits from doing so.^{38–43} Despite the recognised benefits of patient-centred healthcare, there remains a lack of consensus on how this can be achieved.

Care coordination

Coordination of care has been highlighted as a defining principle of primary care⁴⁴; however, care coordination for older adults can be a labour-intensive task, particularly

for patients with multiple comorbidities. While beneficial services and programmes may exist within the community, many HCPs may not be aware of these services or may not have the time to provide referrals, particularly for those older adults who are not yet considered high risk.⁴⁵ The lack of use of technology to facilitate referrals has been identified as a key gap in the coordination of care.⁴⁶

Enabling technology

Technological changes in healthcare are being driven from multiple sectors including governments, industry, professional associations and individual consumers including older adults.^{18 42 47–49} Health information technology offers tremendous benefit for the healthcare system, particularly in the area of coordination of care. For these benefits to be realised, patients and practitioners need to be involved in the design, implementation and evaluation of these systems.^{50 51}

A primary care intervention for older adults who are at risk or living with frailty

Aligning with the review conducted by McCarthy and colleagues,²² we aim to implement evidence-informed interventions to identify, assess and support older adults who are at risk or living with frailty. This project will support consistent-risk screening, patient and family caregiver engagement, shared decision-making and stronger care coordination. This article will describe the study protocol for the tailoring, implementation and evaluation of an evidence-based primary care model for frail and at-risk older adults that aims to improve health, social and economic outcomes.

Aim and objectives

In this project, we aim to implement and test enhanced primary healthcare approaches for older patients that includes an efficient screening approach to identify older adults who may be at risk for adverse outcomes; tools to support patient and family engagement in decision-making; and a streamlined, technology-supported care coordination process. These interventions will be tailored to the needs and circumstances of the study sites. Details of the interventions are provided in the Methods and Analysis section.

Our specific objectives are to:

1. build the capacity of primary HCPs, patients and family caregivers to work as partners in decision-making and to ensure patient and family caregiver values and preferences are considered in care planning.
2. evaluate the health, social and economic impact of the interventions from the perspectives of patients, family caregivers and primary HCPs.
3. assess the feasibility and scaling of the interventions.

METHODS

The interventions

The study interventions include the following approaches:

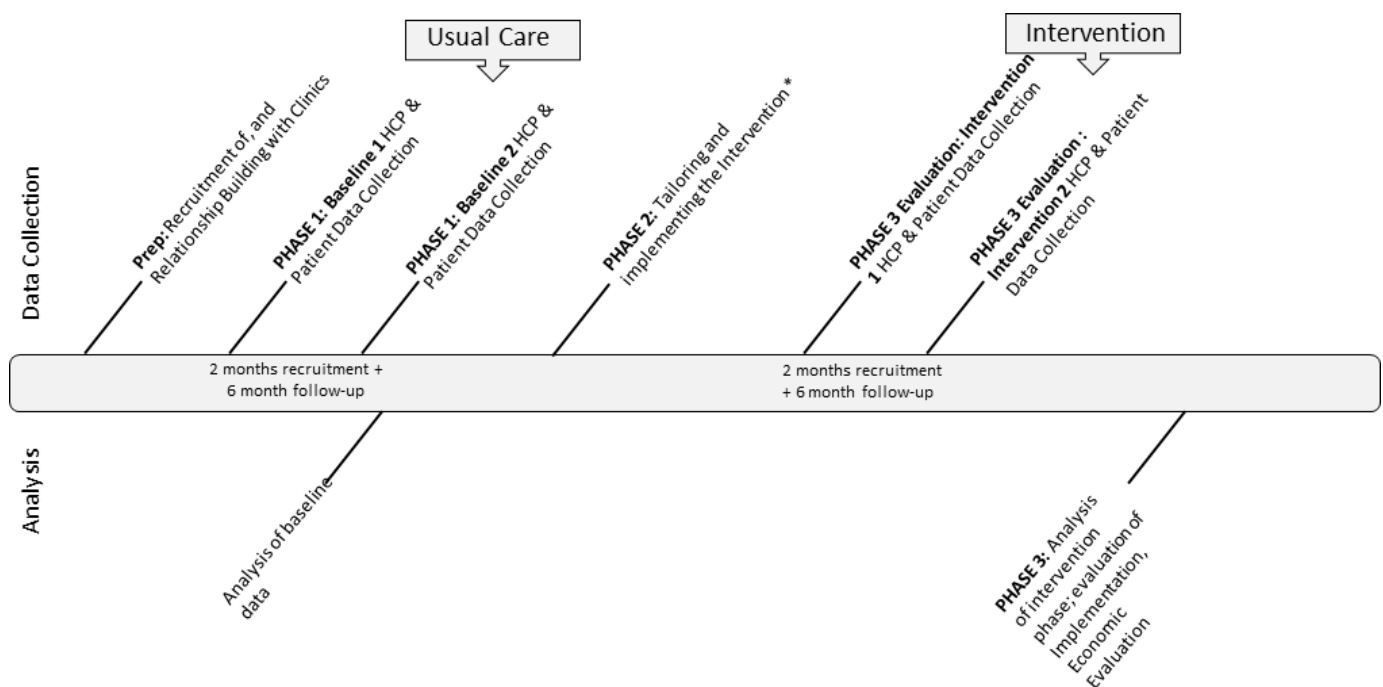
1. Risk screening: The interRAI Assessment Urgency Algorithm (AUA), is a brief (usually <1 min) validated decision-tree algorithm which classifies patients into six risk categories (1=lowrisk; 6=highestrisk).⁵² The most feasible method of administration (self or HCP completed) and format (paper, fillable PDF or electronic) will be determined at each site.
2. Patient engagement and collaborative decision-making: Providers will be trained in the CHOICE patient engagement framework^{40 42} and the use of evidence-based shared decision-making tools (Decision boxes^{53 54}) which will become part of routine care for older adults attending the clinic during the intervention. The CHOICE Framework encourages providers to understand patient and family caregiver preferences and values, and build relationships based on open communication and trust. Once relationships are established, decision boxes help guide the patient and provider through a decision-making process which is grounded in best available evidence on specific health conditions (eg, depression, cognitive impairment, malnutrition, caregiver burden, functional decline). Providers will work with patients/family caregivers to create their care plans, provide education and in partnership, discuss options for referrals to new services.
3. Coordination of care with the support of technology: HCPs will use the risk-level score from the AUA as well as any additional patient-specific information gleaned from their patient engagement strategies to determine the need for specialist and community referrals. Caredove, an online database and referral platform (www.caredove.ca), will be used for community referrals

based on the AUA score and additional information. The platform allows providers to follow-up on referrals to ensure patients are receiving the service. This platform is active in one province, but will be codeveloped for two other provinces.

Study design

This study will use a quasi-experimental comparison group design with mixed methods and pretest and post-test data collection (see figure 1). The comparison group will receive usual care; the intervention group will receive the proposed interventions as described above. For this project, usual care also takes place in the team-based primary care settings, but before introduction of the study interventions. The interventions will contain all the proposed elements but will be tailored for each site, using codesign methods, ultimately informing development of a scalable model. The usual care group will be followed for 6 months after study entry (baseline period, phase 1). Following baseline data collection, the interventions will be tailored for implementation at each study site (phase 2). Recruitment and data collection will then take place for the intervention phase (phase 3). Intervention group patients will also be followed for 6 months after study entry.

Threats to internal validity, namely bias due to selection, maturation and testing,^{55–57} will be reduced by adjusting for baseline differences between groups in the statistical analysis, and the inclusion of the comparison usual care group. External validity, the extent to which results will be generalisable to other populations and clinics,⁵⁸ will be informed by collecting demographic information on



* Note that PHASE 2, is expected to be ongoing, and may continue into PHASE 3.

Figure 1 Timeline and overview.

patients (age, sex, comorbidities) and HCPs (type of training, years of practice), and by conducting research in multiple, diverse clinics (urban/rural, three provinces).

The project will be conducted in a phased approach, following Sidani and Braden's⁵⁹ recommendations for complex health interventions. The phases are described below, and also presented in a timeline diagram (figure 1):

1. Phase 1: Baseline data collection: this will include an assessment of the 'usual care' practices at each of the nine study sites and the collection of data (baseline and at 6 months follow-up—referred to as Baseline one and Baseline two in figure 1) from patients who will form the comparison group.
2. Phase 2: Tailoring and implementation of the intervention: this will include collaboration with site staff in codesign processes to tailor the primary care intervention to each clinical and community context. This phase will also include training of site personnel and monitoring the implementation process guided by the Consolidated Framework for Implementation Research (CFIR).⁶⁰
3. Phase 3: evaluation: This will include collection of pre–post data on newly recruited patients—on recruitment and again at 6 months follow-up—referred to as Intervention 1 and Intervention 2 in figure 1. This will also include evaluation of implementation experiences as well as an economic evaluation.

Study population and recruitment

The target population for this study is older adults aged 70 or older who are rostered patients at the study clinics. Patients living in long-term care homes or who have been rostered for less than 6 months will be excluded. Patients will be approached by their HCP to participate in the study. If the patient agrees, a researcher will obtain written consent for participation.

Nine team-based primary care clinics will act as study sites within both urban and rural communities in three provinces: Quebec, Ontario and Alberta. Primary HCPs (including physicians, nursing and allied health) at each clinic will participate in all phases of the study.

Patient and public involvement

Our research team works in partnership with a group of older adults (Seniors Helping as Research Partners) who have assisted in the development of the research project and data collection materials, and will review analysed data and final reports.

Study data collection

Participant data collection

During the baseline and intervention phases, participants will be recruited and surveyed about their care experience at the clinic. Patients will complete a written survey with questions related to socio-demographic characteristics, general health information, and self-reported outcomes (eg, emergency department use).

The primary outcomes for this study are a patient experience measure—the Patient Assessment of Chronic Illness Care (PACIC) and a quality of life measure—the EQ-5D-5L:

- ▶ PACIC: The PACIC⁶¹ is a 26-item self-report survey to capture patient experience in five areas: patient activation, delivery system design, goal setting, problem solving and follow-up/coordination.⁶² Each item is scored on a five-point scale ranging from 1 (no or never) to 5 (yes or always). Participant responses for all 26 items will be combined to produce an average summary score. The PACIC will be collected at two pre–post time points during the baseline phase and two pre–post times during the intervention phase.
- ▶ EQ-5D-5L: The EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) is a self-administered questionnaire that contains five items (mobility, self-care, usual activities, pain and anxiety/depression), with five response levels per item.⁶³ The EQ-5D-5L quantifies a patient's health state using a five-digit vector based on the responses to the five questions.⁶⁴ From this five-digit score, participants will be assigned a time trade-off score from the established Canadian EQ-5D-5L value set.⁶⁴ In addition to the five-item questionnaire, participants will rate their health from 0 to 100 on the EQ Visual Analogue Scale with endpoints labelled 'the best health you can imagine' (100) and 'the worst health you can imagine' (0).⁶⁵

A purposefully drawn sample of patients representing low, moderate and high levels of frailty, using the AUA, will also participate in qualitative interviews (6–8 patients/study site). Interviews will be audio-recorded and transcribed verbatim. The interviews will consist of two parts. In part 1, open-ended questions will be used to probe patients' perspectives on current practice, care coordination processes, patient engagement and shared decision-making. In part 2, the interviewer will use directed questions to develop a Goal Attainment Scaling (GAS) Guide. GAS is an individualised goal setting and measurement approach that enables users to individualise goals to the needs, concerns and wishes of a specific patient, and also to individualise the scales on which attainment of these goals are measured.^{66–68} In the initial interview, a GAS guide will be created for each participant, based on their personalised healthcare goals for the coming 6 months. Five to 6 months after the initial interview, participants will be recontacted via telephone to follow-up on their GAS guide goals. In this brief follow-up interview, participants will be asked 'how are you doing with your health goals?' (with reminders of the original goals, as necessary).

HCP data collection

HCPs from each of the nine sites will be asked to provide both quantitative and qualitative feedback based on their current experiences in their role. A sample of providers from each site (~4–6 HCPs/site purposefully selected to include all health professions in the primary care team)

will complete a self-administered Canadian Institute of Health Information (CIHI) Attributes of Primary Health Care Provider Survey. This survey includes four sections: provider demographics, structure and organisation of the practice, team functioning and healthcare service delivery. Additionally, the organisational lead from each study site will complete the CIHI Measuring Organizational Attributes of Primary Health Care Survey to document the structure of the clinic, the healthcare services offered, as well as the organisation of services at the site.⁶⁹

At each study site, HCPs and organisational lead staff of the primary care healthcare team will be invited to participate in a semi-structured focus group interview; a separate focus group interview will be held with community providers. Focus groups (6–8 participants/group) will be led by an experienced qualitative researcher, audio recorded and transcribed verbatim. Focus group questions will probe current practices and experiences within the clinic, and from the community perspective.

The CIHI survey and individual and focus group interviews with HCPs will be conducted again in the post-intervention phase of the study.

Tailoring and implementing the intervention

The intervention will be implemented in each study clinic and will be tailored to each site, in partnership with HCPs. However, interventions at each site will include all of the components outlined above, that is, risk screening, patient engagement and collaborative decision-making and coordination of care with the support of technology.

Overall evaluation

Implementation evaluation

Following the final data collection phase an in-depth evaluation of the implementation of the intervention and its components will be conducted, to inform an assessment of its future feasibility and sustainability. Our analysis will be guided by the CFIR, which will guide our assessment of factors that influenced the implementation and performance of the intervention.⁶⁰ Data from patient interviews, HCP interviews, HCP focus groups, HCP survey data and usage data related to the intervention components (eg, number of decision boxes used, number of Caredove referrals made) will be used to understand the implementation experience and challenges encountered, as well as the consistency and conformity with which each site used these components of the intervention. This framework also allows us to monitor unanticipated influences that may impact implementation of our intervention. This could include monitoring of the COVID-19 pandemic, and the impact it may have on primary care in Canada.

Economic evaluation

To examine the potential economic impact of our proposed model of primary care, we will compare the costs and effects of the intervention with usual care. We will conduct the analysis from the perspective of the public payer, using effectiveness data (changes in PACIC)

and estimated costs associated with self-reported health service utilisation (eg, hospitalisation, emergency room visits). We will use the net benefit regression framework⁷⁰; this allows adjustment for potential confounders (eg, demographic characteristics, geographical location) and for consideration of the repeated measures aspect of the data. The output of the analysis will be the incremental net benefit of the intervention compared with usual care.

We will derive quality-adjusted life years (QALYs), using data from the EQ-5D-5L. A QALY is a preference-based utility measure of health-related quality of life as perceived by the patient and is calculated by combining health-related quality of life measures with data on health state duration. To estimate QALYs gained, we will convert EQ-5D-5L data to a utility score using a validated algorithm.⁶⁴ The secondary output of this analysis will be the incremental cost per QALY gained by the intervention compared with usual care. A cost-effectiveness acceptability curve and 95% CI will characterise the uncertainty of our findings.⁷⁰

Sample size

Because interventions are tailored to each site, we desired a sample size allowing for site-specific inferences. Our sample size calculations are based on our primary outcome measures, the PACIC and the EQ-5D-5L. To detect a clinically important mean difference of at least 0.5 SD between two independent groups ($\alpha=0.05$, 80% power), the required sample size is 63 participants per site for both the baseline (phase 1) and intervention (phase 3) phases.^{61 71} To account for missing data or attrition, we have set a target of 70/group/site. As we have nine participating sites, the total sample size for the study will be 1260 (630 participants allocated to the usual care group (phase 1) and 630 participants allocated to the intervention group (phase 3)).

Data analysis

Quantitative analysis

The quantitative outcome measures for this study will be evaluated through a change score outcome model. The change in scores for the EQ-5D-5L and PACIC administered at two time points (study entry and at 6 months) for both phases 1 (baseline) and 3 (intervention) will be evaluated using a mixed effects linear regression model with random site and subject effects. Pre–post changes in scores for items in the CIHI HCP surveys will be analysed using paired samples t-tests.

Qualitative analysis

Interview and focus group transcripts will be blinded, assigned pseudonyms and entered in NVivo V.13, a qualitative analysis software programme. All analyses will rely on team-based analysis⁷² and line by line coding.⁷³ Qualitative analysis will be informed and refined by the research team and respond to the data collected. Our approach is likely to include a blend of a priori coding (informed by the research questions and key topics of inquiry) and

emergent coding that captures important topics raised by interview and focus group (FG) participants.^{73–76} A coding tree will be created, and themes will be derived from the codes. Team discussions will happen at multiple phases throughout the analysis to help clarify the data and discuss major and minor themes that emerge. As qualitative analyses are an iterative process, further details will be provided in the resultant manuscripts. The team will reply on the Consolidated Criteria for Reporting Qualitative Studies (COREQ) guidelines⁷⁷ for reporting qualitative findings which includes providing details about participant recruitment, study setting, combination of interviews and field notes, detailed description of the coding tree, detailed description of how the themes were derived from the data and information about member checking.

Ethics and dissemination

Ethics approval from local Research Ethics Boards has been obtained from all three institutions involved in data collection and analysis (University of Waterloo (ORE# 22446), University of Calgary (REB17-0617) and Laval University (#MP-13-2019-1500 and 2017-2018-12-MP)). Multiple manuscripts will be published in peer-reviewed journals. Findings will also be shared with stakeholders through workshops, academic conference presentations, policy briefs and lay summary reports.

DISCUSSION

This research will evaluate the implementation of an evidence-based primary care model aimed at improving care for older adults who may be at risk or living with frailty. Our interventions aim to engage and support patients and family caregivers to improve their care experience as well as their overall quality of life. While based in primary care, our project will have a significant impact on health system integration, with links to community services and specialists aligned with level of risk. The proposed study is consistent with current standards for primary care interventions to improve continuity of care for seniors, namely systematic screening of risk implemented concurrently with standardised referral systems, with additional training and support for HCPs.⁵

We anticipate that the site-specific tailoring that will occur through significant input from site staff and patients will result in a more sustainable and coordinated model of care resulting in greater satisfaction for both patients and providers.

Our project aligns with the Government of Canada recommendations for ‘unleashing innovation’ to improve healthcare,⁷⁸ including patient engagement and empowerment, health systems integration and industry as an innovation catalyst (including more rapid deployment of technologies). The research will produce a scalable, sustainable model as well as knowledge mobilisation strategies and tools to facilitate future implementations in primary healthcare settings across Canada.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods and analysis section for further details.

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