Developing an evidence-informed model of long-term life care at home for older adults with medical, functional and/or social care needs in Ontario, Canada: a mixed methods study protocol

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ABSTRACT

Introduction The COVID-19 pandemic exacerbated existing challenges within the Canadian healthcare system and reinforced the need for long-term care (LTC) reform to prioritise building an integrated continuum of services to meet the needs of older adults. Almost all Canadians want to live, age and receive care at home, yet funding for home and community-based care and support services is limited and integration with primary care and specialised geriatric services is sparse. Optimisation of existing home and community care services would equip the healthcare system to proactively meet the needs of older Canadians and enhance capacity within the hospital and residential care sectors to facilitate access and reduce wait times for those whose needs are best served in these settings. The aim of this study is to design a model of long-term ‘life care’ at home (LTlifeC model) to sustainably meet the needs of a greater number of community-dwelling older adults.

Methods and analysis An explanatory sequential mixed methods design will be applied across three phases. In the quantitative phase, secondary data analysis will be applied to historical Ontario Home Care data to develop unique groupings of patient needs according to known predictors of residential LTC home admission, and to define unique patient vignettes using dominant care needs. In the qualitative phase, a modified eDelphi process and focus groups will engage community-based clinicians, older adults and family caregivers in the development of needs-based home care packages. The third phase involves triangulation to determine initial model feasibility.

Ethics and dissemination This study has received ethics clearance from the University of Waterloo Research Ethics Board (ORE #42182). Results of this study will be disseminated through peer-reviewed publications and local, national and international conferences. Other forms of knowledge mobilisation will include webinars, policy briefs and lay summaries to elicit support for implementation and pilot testing phases.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The novel mixed methods approach combines the power of ‘big data’ with a multiperspective understanding of the home care sector from experts by lived experience.
⇒ The model of long-term ‘life care’ at home (LTlifeC model) will reflect the spectrum of medical, functional and/or social care needs of community-dwelling older adults.
⇒ The use of prepandemic data as the basis for designing a postpandemic solution for home and community care may limit the generalisability of study findings.

INTRODUCTION

Long-standing evidence on care for older adults indicates the need to think of long-term care (LTC) as a system, not a specific sector and focus on people and communities across an integrated continuum of services and supports in a variety of care settings.1 The COVID-19 pandemic exacerbated existing challenges with older adult care across the Canadian healthcare system. Sustaining minimum care standards in home care and LTC sectors that were already underfunded and under-resourced has become more challenging;2-5 putting frail older adults and the people who care for them at risk of negative outcomes.6 7 Care deemed non-essential in acute hospital and primary care settings was reduced or harder to access.8-11 hampering limited system capacity for provision of comprehensive geriatric care.12 13 While the pandemic was a catalyst for virtual care adoption with older patients,14 15 challenges with privacy, training, change management and technology access16 led to concerns of perpetuating existing fragmented care experiences...
and poor coordination across settings. The emergence of grassroots social media groups resulted in the formation of community networks across Canada that aimed to help vulnerable Canadians get access to essential items (eg, groceries) during peak pandemic restriction periods, highlighting the longstanding gap in available community-based non-medical support services to address the social care needs of older Canadians. Family caregivers in Canada have reported increased caregiving responsibilities and concerns during the pandemic, including providing more behavioural and emotional support, finding alternative ways for social contact and connection during lockdown restrictions, facilitating access to vaccines and other public health safeguards, providing more hours of direct care to fill gaps and delays in service, experiencing fewer opportunities for respite, and having more worry about financial security. This has led to an increase in caregiver burnout, distress, isolation and loneliness, which were already major system concerns before the pandemic.

More than two-thirds of Canada’s COVID-19 deaths occurred in residential LTC homes and retirement homes during the first 6 months of the pandemic (wave 1). Putting LTC reform at the forefront of a postpandemic response to improving care for ageing Canadians. Recent emphasis has been placed on improving residential LTC home facilities, building more residential LTC beds, and improving standards of care to enhance quality of life in congregate settings. Improvements to quality of care, adequacy of medical director coverage, staffing, use of agency staff and other facility level factors have been found to be important. These efforts are essential as residential LTC home admissions continue to become more concentrated on those with the greatest needs, however, commentators project that Canada will not be able to build enough beds to sustainably serve the growing population of older Canadians in existing types of residential care facilities if current patterns of admission are maintained.

People have always preferred to live and receive care at home as they age. A survey of 498 Canadians conducted during the pandemic by the Ageing in Place Research Cluster at the University of British Columbia Okanagan indicated that 82% of respondents preferred to age in place, with 68% of respondents not changing their perspective on ageing in place as a result of their experience during the pandemic. Unfortunately, 35% of Canadians with home care needs prior to COVID-19 did not have those needs met due to inadequate availability of services. Gender-based analysis of home care recipients in Ontario revealed that men are more likely to have a distressed caregiver and be admitted to residential LTC. Most home care is short-term, task-based and reactive to address chronic disease instability through the delivery of postacute follow-up care. Moreover, the home care system is not designed to support social and mental health needs. Much of long-stay home care is supported by family caregivers, but with changes to family structures, income disparities and changes in workforce participation, caregivers may not be available or willing to continue to provide this level of care into the future. Recent data indicate that only 11% of newly admitted LTC residents in Canada could have been cared for at home with existing home care services and supports. While this suggests there is very minimal unnecessary admission to residential LTC in the current system, it also reinforces that LTC system reform efforts must prioritise and strengthen home and community-based care options in addition to improving and expanding residential LTC options to achieve a more sustainable approach to caring for a growing population of older adults with complex needs.

Although care needs vary across populations, countries including Germany, the Netherlands, Sweden and Denmark have been cited as examples of jurisdictions that focus on de-institutionalisation, rehabilitation, caregiver support and integrative services that prioritise home care to match the preferences and meet the needs of older adults. An innovative model of care for older Canadians that prioritises sustainably meeting the needs of people across the continuum of care requires action on system-wide evidence and clinical data, leveraging the expertise of community providers and applied researchers, listening and responding to the lived experiences of older adults and family caregivers, and ultimately valuing and prioritising the quality of life and preferences of people as they age.

The aim of this study is to design a new model of long-term ‘life care’ (LTLifeC model) to sustainably meet the needs of older adults at home, giving Canadians more options for where to live and receive care as they age, and reserving residential LTC home and hospital capacity for those whose needs are best served in these settings. The study will be guided by the following three objectives:

1. To build a set of unique evidence-informed patient vignettes to describe differences in the medical, functional and/or social care needs of the older adult home care population, based on known predictors of residential LTC home admission.
2. To co-design a series of unique community care packages with patients, caregivers and providers using the evidence-informed patient vignettes to match medical, functional and/or social care needs with types and frequencies of care and support services.
3. To determine LTLifeC model feasibility using the Ontario healthcare market as a test case, based on comparisons of cost, referral patterns and patient profiles to usual home care, residential LTC and other emerging care models.

METHODS AND ANALYSIS

Design
An explanatory sequential mixed methods study design will be applied across three phases (figure 1). Phase I is quantitative, involving secondary analysis of routinely
collected home care assessment data. Phase 2 is qualitative, involving a modified eDelphi process with home care clinicians and focus groups with older adults, family caregivers and community providers. Phase 3 involves secondary analysis of routinely collected LTC assessment data and care model cost data, and methodological triangulation of phase 2 data to inform key informant interviews as the final step in this phase. Triangulation will involve comparing the care packages emerging from the eDelphi survey to the thematic framework emerging from focus group analyses to develop both refined care packages and a key-informant interview script focused on operationalisation challenges and opportunities. Each phase of the study will have a rapid step and a detailed step. This multi-step design feature will allow the researchers to build an evidence-informed solution as quickly as possible, while concurrently working to refine the LTifeC model with more detailed quantitative and qualitative exploration and engagement of a wider range of participants. Quantitative and qualitative data will be given equal weight in model development and data integration will begin in the development of the qualitative data collection tools and processes.

Setting
This study will take place in Ontario, Canada. Publicly funded home care and residential LTC homes fall under the jurisdiction of the Ontario Ministry of Health and the Ministry of LTC.51 At the time of study development, there were 14 Local Health Integration Networks across the province responsible for assessing eligibility for, and coordinating access to, local home care services and residential LTC.52 In 2017–2018, more than 100 000 people received care in residential LTC homes and more than 200 000 people received long-stay home care, meaning for a period of more than 60 consecutive days.53 54 About 52% of home care recipients receive home care from only publicly funded services; the remaining recipients supplement with privately obtained care and support.57 Ninety-six per cent of long-stay home care clients in Canada have an unpaid caregiver and more than a third of these caregivers are distressed.55 56 About 54% of residential LTC homes in Canada are privately owned (with a mix of for-profit and not-for-profit homes) and 46% are publicly owned.52 In both the Ontario home care and residential LTC sectors, comprehensive, standardised clinical assessment tools have been mandated.58–62 These standardised assessment tools, including the Minimum Data Set (MDS) 2.0 and its updated version, the interRAI Long Term Care Facilities (interRAI LTCF), in LTC, and the RAI-Home Care (RAI-HC) and its updated version, the interRAI Home Care (interRAI HC), in home care, are to be used by clinicians at the point-of-care to assess the preferences, strengths and needs of individuals and to develop care plans based on the assessment outputs. These tools are part of a larger family of instruments developed by the interRAI research consortium,63 a not-for-profit, international network of over 100 clinicians, researchers and health policy experts in over 35 countries. In Canada, interRAI assessment data captured by trained assessors is aggregated by the Canadian Institute of Health Information (CIHI) at a national level into three databases: (1) the Home Care Reporting System (HCRS) that captures home care assessment data (RAI-HC); (2) the Continuing Care Reporting System (CCRS) that captures LTC assessment data (MDS 2.0); (3) the new Integrated interRAI Reporting System that brings together both LTC (interRAI LTCF) and home care (interRAI HC) assessments into a single integrated longitudinal dataset. Data available in these databases can then be used to inform organisational level activities such as quality improvement, benchmarking or resource allocation, and on a system level to analyse and compare data across regions and provinces.64–66 In previous research, the RAI-HC, MDS 2.0 and the newer interRAI instruments have been found to have strong data quality in terms of reliability, validity and completeness.67–71 The interRAI suite of assessment tools also have strong clinical utility and are intended to support care planning at the point-of-care in the settings where they are used; facilitated by the various

![Figure 1](http://bmjopen.bmj.com/) Explanatory sequential mixed-methods design. CCRS, Continuing Care Reporting System; CHRIS, Client Health and Related Information System; HCRS, Home Care Reporting System; OHSS, Ontario Health Shared Services.
outcome and risk scales and clinical assessment protocols derived from assessment data.63 72-74

**Phase 1: quantitative phase**

**Sample Size**

The rapid step will use CIHI’s 2017/2018 HCRS data to understand the demographic and clinical profile of the population of home care clients assessed with the RAI-HC in Ontario.66 The detailed step will use a dataset previously linked by Ontario Health Shared Services (OHSS) that brings together 2018–2019 home care service utilisation data from the Client Health and Related Information System and 2018/2019 interRAI HC assessment data to facilitate understanding of service levels in the current model. Cases will be included in the cohorts if they: (1) were assessed with either the RAI-HC or the interRAI HC in either hospital or community settings within the fiscal year; (2) were older than 18 years of age at time of assessment; and (3) were assessed in Ontario. Note these data are 1 year newer than the data used in the rapid step of phase 1 and phase 3, due to different data reporting schedules and availability between data sources (ie, CIHI vs. OHSS). The rapid step cohort is expected to include ~205,000 individuals and the detailed step cohort is expected to include ~115,000 individuals.53 75 These sample sizes represent the entire assessed population meeting inclusion criteria and are determined by the size of the database.

**Data collection/analysis**

The rapid step will involve secondary analysis of the HCRS data using existing and new interRAI algorithms to identify homogeneous groups of individuals who could be considered appropriate for a LTlifeC model based on known medical, functional and social predictors of admission to residential LTC, including: social frailty, caregiver distress, chronic disease, functional impairment, behaviours and cognition, medical complexity, geriatric syndromes and mental health. Descriptive statistics will be calculated for each homogeneous group to develop a unique patient vignette describing the most predominant demographic and clinical details; with emphasis on characteristics shown to be increasingly prevalent in residential LTC populations, such as: older age, rural living prior to admission, co-morbid health issues, dementia, polypharmacy, and physical, functional and cognitive impairments.29 30

The detailed step will involve bivariate analysis of the OHSS dataset to refine the patient vignettes using additional details about clinical needs linked to current service utilisation patterns. All secondary data analysis will be conducted using SAS software, V.9.4 of the SAS System for Windows.76

**Phase 2: qualitative**

**Participants/sample size**

The rapid step modified eDelphi process will involve up to 24 home care clinicians who currently work as a clinical executive, clinical manager or point-of-care provider in Ontario. Efforts will be made to stratify participants to include providers representative of existing home care service delivery models whose role could be leveraged in new ways (eg, personal support workers, nurses, occupational therapists, physiotherapists, registered dietitians, speech-language pathologists, social workers and spiritual care providers). This sample size is chosen to both ensure opinion diversity and a feasible volume of responses.77

The detailed step focus groups will involve up to 24 adult and/or older adult participants who either self-identify as: (1) an older adult care recipient of health and social care services within the past 5 years or (2) a family caregiver of an older adult care recipient. The focus groups will also involve up to 24 health or social care providers who currently work in home and community care, residential LTC, primary care or community support services in Ontario. This sample size was chosen with a goal of reaching saturation.78-80 The goal will be to conduct 4–6 focus groups with 8–12 participants in each. Groups will be heterogeneous, with efforts to include an equal distribution of providers and older adults/family caregivers in each. All phase 2 participants must self-identify as being able to read, write and understand English. Participants may be from any gender, culture, racial and/or ethnic group.

**Recruitment**

Phase 2 rapid step and detailed step recruitment will employ a convenience sampling strategy with health and social care providers identified by clinical leaders in community care and older adults and caregivers identified from a pre-existing database of interested past recipients of home and community care services in Ontario. This sampling strategy was primarily a feasibility decision due to health human resource challenges in home care and anticipation of the potential difficulty reaching older adults and caregivers with home care experiences during the ongoing COVID-19 pandemic. Social media will supplement these strategies. Potential participants will be invited by email, provide informed consent, and receive an e-gift card honorarium.

**Data collection/analysis**

In the rapid step, a modified eDelphi process will be employed to derive consensus on care packages for each of the vignettes from phase 1.81-83 There are three ‘layers’ for which consensus will be sought for each vignette, using materials that will encourage participants to think innovatively about a new model of home-based care:

1. The focus or dominant health concerns using the Pillars for Positive Health.84 85
2. The most important types of community-based care or services that could be provided to meet medical, functional and social care needs, from a list of existing community-based care/services.
3. A quantification of the dose of each type of care/service that should be provided to meet needs daily/
weekly/as needed over a 12-week period to align with residential LTC assessment timelines. The first stage of the modified eDelphi process will address the first two layers above. Each patient vignette will be developed into a case-study narrative to bring the care needs to life in a story format. The second stage will address the third layer. Each stage will have up to three rounds of self-administered participant surveys (each expected to take up to 1 hour to complete), separated by 1 week.

The surveys will be administered online using SurveyMonkey and responses will be downloaded and analysed in Microsoft Excel 2010 software, V.14.0.7268.5000 for Windows to develop preliminary research-based care packages for each vignette. Survey results from each round will inform subsequent rounds. Participants will be asked to rate priority/level of importance/dose using a seven-point Likert scale. Consensus will be considered to have been reached on items that are rated 5 or greater by 70% or more participants. Items that are rated 5 or greater by less than 50% of participants will be removed. Participants will receive an emailed report of the median, distribution and their own scoring for each item after every survey round.

In the detailed step, focus groups will help refine the care packages that emerged in the rapid step. Participants will be provided with at least one case-study narrative and corresponding care package in advance. Focus groups will begin with an icebreaker activity to help participants get to know one another. Most of the focus group discussion will involve empathy mapping, in which participants will reflect on what the characters in each case-study narrative might say, do, think and feel.

Focus groups are expected to last for 2 hours and will be conducted online using Microsoft Teams, with at least one lead and one support facilitator and will be recorded and transcribed verbatim. NVivo software, version 12 will be used to code suggested changes related to focus, type and dose of care and services. Research-based care packages will be refined based on common themes.

Phase 3: qualitative/quantitative

Participants/sample size

The rapid step will use 2017/2018 CCRS data to examine the characteristics of LTC home residents and compare with the population of individuals described in the long-stay home care data. Cases will be included in the cohort if they (1) were admitted to residential LTC in the 2017/2018 fiscal year; (2) were assessed with the MDS 2.0 in LTC in the 2017/2018 fiscal year; and (3) were older than 18 years of age at time of assessment. The cohort is expected to include ~115,000 unique individuals, which represents the entire population of assessed individuals meeting study inclusion criteria. This sample size was determined by the size of the database.

The detailed step of phase 3 will involve up to 10 adult participants who self-identify as a decision-maker currently working in home and community care, primary care, LTC, specialised geriatric services or community support services in Ontario. This sample size is adequate as the goal is to complete a referral mapping process, not necessarily to reach saturation.

All phase 3 participants must self-identify as being able to read, write and understand English. Participants may be from any gender, culture, racial and/or ethnic group.

Recruitment

Phase 3 detailed step recruitment will employ a convenience sampling strategy. Potential participants will be identified by clinical leaders in the community care sector and invited by email. All participants will be required to provide informed consent and will receive an e-gift card honorarium.

Data collection/analysis

The rapid step will involve secondary data analysis of the CCRS data to determine the prevalence of each of the six patient vignette groupings in residential LTC. This will help to estimate overlapping care needs in the two settings. All secondary data analysis will be conducted using SAS software, V.9.4 of the SAS System for Windows.

The rapid step will also involve pricing the LTLifeC model. Care and services in each of the research-based care packages will be mapped to provider disciplines in current publicly funded Ontario home care to generate preliminary per day costs. Coordination and referral time for care and services that would be delivered outside of the home environment will be included. Initial estimates will be compared with current per day costs of usual home care, residential LTC and hospital care beds in Ontario to inform feasibility of model adoption. Microsoft Excel 2010 software, V.14.0.7268.5000 for Windows will be used to organise cost data.

The detailed step will involve semistructured key-informant individual interviews with health and social care decision-makers about key characteristics of integrated health and social care packages, including identification and recruitment of patients, and coordination and engagement of patients and family caregivers.

Interviews will explore the extent to which each patient vignette reflects patients served by their organisation. To identify potential referral processes for the LTLifeC model, the Institute for Healthcare Improvement nine-step closed-looped referral process will guide questions.

Key-informant interviews conducted by a research team member are expected to last for 1 hour, will be conducted online using Microsoft Teams or by telephone and audio-recorded, and will be transcribed verbatim. Thematic analysis will be conducted using NVivo software, version 12 to identify dominant referral pattern themes.

Patient and public involvement

Patients/the public will be involved in this research through the participation of older adults, caregivers and community health and social care providers, beginning in phase 2 and through phase 3 of the study. The input,
ideas and expertise of these older adults, caregivers and community health and social care providers will be collected through eDelphi surveys, focus groups and key-informant interviews. These perspectives are not typically engaged in research or health system design, so we anticipate their involvement to enhance the likelihood of acceptability of a new LTlifeC model with end-users and increase the potential for positive system change. Patients/the public were not involved in the design of the study and will not be involved in recruitment or the conduct of the study. Study research objectives were informed by longstanding evidence of Canadians’ preferences to live, age and receive care at home; however, patients/the public were not explicitly consulted or involved in objective development. Participants will be able to indicate their interest in receiving a summary of the results of the study at time of consent, in a format of their choosing (eg, electronic or mailed). Knowledge mobilisation efforts will aim to reach a wide audience by publishing study findings in open-access journals and disseminating results through lay summaries and infographics shared using methods such as social and traditional media, webinars and conference presentations.

ETHICS AND DISSEMINATION
This study has received ethics clearance from the University of Waterloo Office of Research Ethics (ORE #2182). Results of this study will be disseminated through open-access, peer-reviewed publications and local, national and international conferences. Other forms of knowledge mobilisation will include webinars, policy briefs and lay summaries to elicit support for implementation and pilot testing phases. Target audiences will include researchers, practitioners, policy-makers and the broader public.

DISCUSSION
Unique methodological contributions
To our knowledge, this is the first mixed methods home care study to combine the power of ‘big data’ with a rich, context-specific, and multiperspective understanding of challenges and opportunities for enhancing home care from deep engagement of experts by lived experience. The methodological approach taken in this study aligns to professional and public calls for better use of routinely collected health information in health services research; specifically, HCRS data to close the knowledge to practice gap in home and community care through evidence-informed care planning and quality improvement, including the development and evaluation of new programmes and models of care.

While vignette-based data collection in qualitative research studies has been criticised in past for not adequately reflecting real-life situations, the vignettes developed in this study will be uniquely generated from the dominant characteristics and care needs of key subgroups within the existing Ontario home care population who may be at risk of residential LTC admission. This quantitative starting point will increase the likelihood for generalisability of the vignettes for use with older adult, caregiver and health and social care provider participants across the province.

Phase 3 of this study will generate evidence to support the positioning of this new model for success within a volatile postpandemic healthcare system and help to develop an evaluation framework for future implementation and pilot testing, including key outcomes aligned to the quadruple aim.

Challenges/limitations and risk mitigation
It is anticipated that there may be some data collection challenges or delays because of pandemic restrictions and competing priorities but the aim is to mitigate these challenges by using online data collection strategies, analyzing routinely collected health assessment information and including participant honoraria. While this study is being conducted in Ontario, the use of standardised patient assessment data to drive model development will allow for future feasibility assessment across Canada.

This research study may result in the identification of weaknesses in the system of publicly funded home and community care in terms of the range of care and services available, the breadth of unmet needs and the need for enhanced public or private funding. In that event, efforts to encourage uptake by researchers, policy-makers and decision-makers will require effective knowledge translation and mobilisation. Economic modelling to demonstrate potential for long-term system efficiencies will likely be needed. We will also explore opportunities for model optimisation using virtual care and technology, hub-and-spoke design, primary nursing care structure, and integrated care navigation and coordination with existing community services and volunteer programmes.

Embedded health system research scientist co-leads of this study will help with building connections to existing opportunities for health system innovation in Ontario, including Ontario Health Teams. Strong community care representation and leadership at innovation tables is essential for realising the potential of new care models such as LTlifeC.

Another potential limitation of this study is the use of prepandemic routinely collected health data as the basis for designing a postpandemic solution for home and community care. As both home care and residential LTC have become even more constrained during the pandemic, we expect that the care needs of older adults in the community will be at least as significant, if not greater, than they were prepandemic. Engagement of experts by experience through the pandemic, will ensure that the new LTlifeC model responds to essential postpandemic factors, including: personal protective equipment, virtual care, social anxiety, fear of illness, hesitancy for new people to be in one’s home environment, health human resources shortages, and community services operating at lower capacity with higher costs.
The exclusion of participants who are unable to read, write and understand English from participation in this study has the potential to introduce bias into the study findings. This study design choice was made from a feasibility perspective, but efforts will be made to explore linguistic diversity as a point of discussion in the focus groups to inform planning for future implementation and pilot testing of the model.

Potential for LTlifeC model to improve integrated LTC
Developing a new model of needs-based home care has the potential to enhance overall health system capacity to expand LTC further into the community, respond to individual ‘life care’ needs, prioritise quality of life and offer older adults more choices for how to live and receive care as they age. For example, the Geriatric Resources for Assessment and Care of Elders (GRACE) Team Care Model, an integrated geriatric care model in the United States, leveraged in-home comprehensive geriatric assessment and risk stratification based on standard criteria to guide person-centred, interdisciplinary care planning and case management and saw reductions in total institutional bed days of care.\(^{120,121}\) The LTlifeC model will similarly leverage comprehensive assessment using interRAI HC to stratify older adults into unique patient groups, each with an evidence-informed care package as a starting point for integrated care planning and customisation based on individual needs. A solution tailored to the Ontario context that meets the needs of older adults at home long-term could help preserve hospital and residential LTC home capacity for older adults whose needs are best served in these settings; thus, creating a more integrated continuum of services that match the spectrum of medical, functional and social care needs existing in the ageing population in Canada.\(^{122}\) Implementation and pilot testing of the LTlifeC model is outside of the scope of this study protocol but will be planned as a follow-up study, using the evaluation framework that will be produced in phase 3. The long-term goal of this body of work is to generate evidence that will influence and support adoption of this type of care model in Ontario to help future-proof the healthcare system, ensure individual preferences, and care needs are prioritised,\(^{123}\) and broaden conceptualisations of necessary LTC system reform beyond sector-specific solutions.\(^{124}\)

Study status
The planned duration of this study is 2.5 years, from May 2020 to December 2022. Phase 1 of the study has been completed. The rapid steps of phase 2 and phase 3 have also been completed. The detailed step of phase 2 is underway. The detailed step of phase 3 is anticipated to start in September 2022.

Contributors
JLG contributed to study design and implementation, drafted the manuscript and approved the final version. MS and PH contributed to study design and implementation, critically reviewed the manuscript and approved the final version. JPH and GAH contributed to study design, critically reviewed the manuscript and approved the final version.

Funding
The study is supported by SE Health, a Canadian not-for-profit social enterprise. MS, JPH and GAH are also supported by interRAI Canada and JLG, MS and PH are supported by SE Research Centre. GAH is supported by the Schlegel Research Chair in Geriatric Medicine at the Schlegel-UW Research Institute for Aging.

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 section for further details.

Patient consent for publication
Not applicable.

Provenance and peer review
Not commissioned; externally peer reviewed.

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