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ASSESSING CARE MODELS IMPLEMENTED IN PRIMARY HEALTH CARE FOR PERSONS WITH DEMENTIA: A MIXED METHODS STUDY

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ABSTRACT

Introduction: Dementia is on the rise in Canada and globally. Ensuring accessibility to diagnosis, treatment and management throughout the course of the disease is a very significant problem worldwide. In order to provide comprehensive care to patients and their caregivers, enhancing primary care-based dementia care is seen as the way forward. In many Canadian provinces various collaborative care models and innovative interventions anchored in primary care to improve dementia care have been developed and implemented. The overall objective of our research program is to identify key factors for good quality of dementia care and successful collaborative care model implementation, and to facilitate dissemination and scale up of dementia best practices.

Methods and Analysis: We will use a convergent mixed methods design. An observational study using chart review and surveys and a qualitative descriptive study using interviews, focus groups and documentation will be conducted in parallel and further integrated using a matrix representing sites and findings. An integrated knowledge exchange strategy will ensure uptake by principal stakeholders throughout the research.

Ethics and Dissemination: Our study has been approved by all relevant ethics committees. We will follow an integrated knowledge transfer strategy using provincial, national, and international councils. Our research will be the first provincial and cross jurisdictional evaluation of primary care models for patients living with dementia, providing evidence on the ongoing debate on the respective role of clinicians in primary care and specialists in caring for patients with dementia.

Trial registration: Not applicable

KEYWORDS

Primary Health Care; dementia; mixed-methods design

STRENGTHS AND LIMITATIONS

- Our program is the first to examine multiple models for patients living with dementia in the primary care setting across different jurisdictions and by doing so we will identify key components of dementia care and successful implementation of collaborative care models for dementia.

- We will look at models with different maturity and in different jurisdictions, which will make the comparison of the models challenging; however, we will rely on a descriptive qualitative study to inform stakeholders and given the breadth of the data collection and the triangulation of data, we will be able to obtain a good portrait of the implementation processes.

- By understanding how the collaborative care models were developed, implemented, and evolved over time, our research will provide insight and guidance on successful implementation of collaborative care models for dementia in Canada and internationally to facilitate dissemination and scale-up of dementia best practices.

- Our cross-sectional, observational study design without a control group will allow us to assess association, not causality between quality of care and key components of the collCM but will reflect a more pragmatic, real-world evaluation.

- By using a mixed-methods design, we will understand the link between implementation strategies, characteristics of the models of care, and quality of dementia follow-up while considering multi-level factors, from the patients, to the clinicians, to the primary care organizations levels

INTRODUCTION

Dementia, such as Alzheimer's disease and other major neurocognitive disorders, is a significant concern(1, 2). The World Health Organization reports that dementia is perhaps the 21st century's most serious health challenge(2). Lack of accessibility to dementia evaluation, treatment and management throughout the course of the disease is a significant problem resulting in long waiting lists, delayed diagnosis, and late intervention(1). In turn, this leads to patient and caregiver uncertainty, inadequate support, and increased burden on caregivers(1). Timely diagnosis at the appropriate level in the healthcare system is increasingly important. In order to provide comprehensive care to patients and their caregivers, collaboration between physicians, nurses, other allied healthcare professionals and various community partners is essential(3).

To deal with this issue in Canada, four Canadian Consensus Conferences on the Diagnosis and Treatment of Dementia (CCCDTD)(4) between 1989 and 2012 have recommended that prevention-promotion, detection, diagnosis, treatment and care of such patients should be primarily the responsibility of the primary healthcare.

However, primary healthcare is not yet fully prepared to deal with patients with dementia(5). It is thus essential to increase the capacity of primary healthcare clinicians to care for this population and to better coordinate care between primary healthcare, memory clinics and community organizations (e.g. the Alzheimer Society, home-based nursing services and home care services).

In response, several Canadian provinces have made considerable efforts to develop and implement Collaborative Care models (collCM) and innovative interventions in primary care to improve accessibility and care for persons with dementia and their caregivers(6-8). These interventions have been implemented in Family Medicine Groups (FMG) in Canada such as dementia strategies and local initiatives(9-11) increasing awareness and training of primary care physicians.

These primary care-based collCM share the same visions and objectives. They aim to provide timely, patient-centered, comprehensive, and continuous inter-professional care for persons with dementia, including prevention-promotion, detection-diagnosis-treatment, and disease management-coordination of care throughout the course of the disease using standardized clinical tools. This could be achieved through collaboration between family physicians, nurses and other healthcare professionals working in FMG/FHT along with their community partners and specialists as needed. Primary healthcare is becoming the hub of integrated care, where specialized services support primary care professionals in managing this complex population. However, the characteristics of these models, such as the processes and activities performed for persons with dementia and their caregivers, varies from one FMG/FHT to another. These interventions have shown promising results in terms of feasibility, clinician participation, and satisfaction(6-8).

While many countries have developed dementia strategies(12), very few have been evaluated(13). To our knowledge, only France(14) and England(15) have an evaluation plan as part of their strategy, which are focused on speciality care. The implementation of collCM in Canada represent natural experiments, offering opportunities to evaluate innovative approaches and to identify determinants of better quality of care for patients with dementia.

The overall objective of our research program is to identify key factors for good quality care and successful collCM implementation, and to facilitate dissemination and scale-up of dementia best practices. Our program will be the first provincial and cross jurisdictional evaluation of primary care models for patients living with dementia,

The specific objectives are:

1. To determine the association between potential key factors (organizational characteristics and clinician characteristics) and outcomes of successful dementia management in primary care: quality of dementia follow-up, continuity of care, and medications management
2. To examine how collCM have been developed and implemented and have evolved over time to improve care of patients with dementia and their caregivers in in Canada
3. To understand the link between implementation strategies, characteristics of models of care and quality of dementia follow-up

METHODS

To reach our objectives, we will use a convergent mixed methods design(16): A quantitative (observational study using chart review and surveys to answer objective 1) and a qualitative descriptive study (using interviews, focus groups and documentation to answer objective 2) will be conducted in parallel and further integrated (objective 3). We have used the SPIRIT guidelines(18) to present our research protocol (Supplemental file 1).

Patient and Public Involvement

Our research program will employ an integrated knowledge exchange strategy(17), with decision-makers/managers, clinicians, and patients/caregivers representatives throughout the entire study (Figure 1). We will engage patients, caregivers, clinicians, researchers, managers and decision-makers, and provincial and Canadian Alzheimer societies heavily throughout the research process. These stakeholders (clinicians, patients, caregivers, and managers) were involved in defining the research questions and study design via a series of meetings. They will further be involved in interpretation of results and dissemination of study results.

OBSERVATIONAL STUDY

Main objective

To determine the association between potential key factors (organizational characteristics and clinician characteristics) and outcomes of successful dementia management in primary care: quality of dementia follow-up, continuity of care and medications management.

Site selection

To identify FMGs/FHTs who have implemented collCM, we will use several strategies: we will draw from the list of sites from the Ministry of Health and we will contact researchers, clinicians, and decision-makers in gerontology, geriatrics and primary care at the provincial and federal levels through our professional contact lists and during national conferences. From this comprehensive list, we will include a total of 28 sites in Ontario, Quebec, and New Brunswick. Sites will be selected based on the type of collCM and level of its implementation. This rich variability across sites will allow us to determine which factors best contribute to the successful management of patients with dementia.

Design

This will be an observational study with a cross-sectional design using a chart review and questionnaires. A chart review will be conducted for patients 75 years old and older with a diagnosis of dementia. One retrospective chart review will be conducted in each site. The study period will be 9 months, from October 1st, 2015 to July 1st, 2016. The target population is all patients 75 years old and older with a diagnosis of dementia who had at least one visit to the site during the study period.

Questionnaires will be sent to the medical directors and clinicians from each site and will collect information on the organizational characteristics and knowledge, attitudes and practices (19) of clinicians.

Chart review

Outcomes

The primary outcome for the observational study is the quality of dementia follow-up. Because no such measure exists, we developed our own **Quality of Dementia Follow-Up Score** based on the recommendations from a number of expert groups, such as ACOVE-3(20, 21), CCCDTD(4), and others sources(9, 22). This score is comprised of 10 indicators of quality of follow-up for dementia and has been further validated in a pilot study (Table 1)(23). These indicators were selected by our researchers and experts in dementia based on their concordance with Canadian clinical recommendations(4) and their feasibility to be measured through a chart review. Patient's eligibility for each indicator will be assessed over the patient's entire medical chart. Based on the validated ACOVE approach, a score will be calculated for each patient by summing the number of indicators performed during the study period by the FMG/FHT divided by the number of eligible indicators for that patient.

Table 1 Summary of variables included in the analyses for the observational study with data source

Type	Variable	Description	Chart review	Organizational questionnaire	Clinicians' questionnaire
Primary outcome	Quality of dementia follow-up	10 ACOVE indicators: Cognitive testing Functional status, Behavioral and psychological symptoms of dementia Weight Caregiver needs Driving status Home care needs Community service needs (e.g., Alzheimer Society) Absence of anticholinergic medication and management of dementia medications	X		
Secondary outcomes	Continuity of primary care	Number of visits to the FMG/FHT; the number of notes, whether or not they were related to dementia, recorded in the charts by the FMG/FHT health professionals; the proportion of patients who have at least two visits to any clinician in the same FMG/FHT during the time period	X		
	Medications management	Proportion of patients with dementia who are treated with dementia medication such as cholinesterase inhibitors or Memantine; the proportion of new dementia medications prescribed or initiated; the proportion of new dementia medications	X		

		initiated by family physician; the proportion of new dementia medications initiated by specialists; and the proportion of patients who are treated with anti-psychotics during the period			
Explanatory variables	Dementia Care Implementation Score	See Appendix A		X	
	Index of Conformity to an Ideal Type of primary care setting	See Levesque et al. (28)		X	
	Clinician KAP Scores	Clinicians knowledge, attitudes and practices: physicians' and nurses' perceived competency and knowledge related to dementia; the physicians' and nurses' attitudes toward dementia; the physicians' practices in terms of cognitive evaluation; the physicians' attitude toward their collaboration with other FMGs/FHT healthcare professionals; and the nurses' satisfaction with the support from secondary and tertiary care services and the physicians' and nurses' attitudes toward the collCM			X
Confounders	Patients' characteristics	Age, sex, co-morbidities (Chronic disease score)	X		

	FMG/FHT demographic information	Rural/urban, number of registered patients, public/private, proximity to memory clinic, university affiliation, socio-economic area based on the FMG/FHT postal code, province, percentage of older patients		X	

We will also examine two secondary outcomes: a) **continuity of primary care** for patients with dementia (including the number of visits to the FMG/FHT; the number of notes, whether or not they were related to dementia, recorded in the charts by the FMG/FHT health professionals; the proportion of patients who have at least two visits to any clinician in the same FMG/FHT during the study period); and b) **medications management** (including proportion of patients with dementia treated with dementia medications such as cholinesterase inhibitors or Memantine; proportion of new dementia medications prescribed or initiated; proportion of new dementia medications initiated by family physician; proportion of new dementia medications initiated by specialists; and proportion of patients treated with anti-psychotics during the study period).

Patient characteristics

The age, sex, type of dementia, living status and comorbidities of each patient will be collected through the chart review. Comorbidities will be derived from the medication list and scored using the Chronic Disease Score(24).

Data collection procedure

Patient charts will be randomly selected among a list of registered patients 75 years and older with a dementia diagnosis. Data will be collected by research assistants from patients' charts in a

customized and secure, web-based database. An instruction manual for assessing each indicator that need to be collected through the chart review has already been prepared and tested. To further ensure the quality of the data collection, all the research assistants who will review patient charts will be trained by a single supervisor, a research nurse, who will answer any questions that may arise throughout the chart review process.

Organizational questionnaire

Our organizational questionnaire has two parts. The first part will assess the various components of dementia care implemented in each site. We adapted a questionnaire developed to assess the implementation of chronic care model in the US patient centered medical home, the PCMH-A questionnaire(25), to the Canadian context using the Canadian recommendations on dementia(26). An overall score, called the **Dementia Care Implementation Score** ranging from 1 to 10 will be derived from the questions, where a higher score signifies better implementation of the recommendations (Supplemental File 2).

The second part of the questionnaire will assess site demographic information (Table 1) and primary care organizational site characteristics. We adapted a validated questionnaire developed by the Institut national de santé publique du Québec(27) to the Canadian context. From this questionnaire, we will derive a score called the **Index of Conformity to an Ideal Type of primary care setting (ICIT)**, where a higher score indicates a better organized primary care setting (e.g. higher ETP physicians, access to electronic medical records, after-hours care, etc.)(27).

Content validity of our organizational questionnaire has been conducted with eight experts and 11 medical directors across the three provinces. Our questionnaire was developed in French and later translated into English and back translated into French to ensure equivalency between the two

versions. Our organizational questionnaire will be mailed in 2017-2018 to the medical directors at each site, along with two copies of the consent forms and a pre-stamped envelope. Multiple reminders will be made to increase the completion rate. Data will be entered by a research assistant and 10% of questionnaires will be checked for reliability of data entry.

Clinicians' questionnaires

Two clinicians' questionnaires, one for the physicians/nurse practitioners and one for the nurses and other healthcare professionals working in the participating FMG/FHT, will be used to assess their knowledge, attitudes and practices(19) toward dementia care and toward the collCM (Supplemental File 3). Both questionnaires have 83 questions, including demographic questions. From these questionnaires, nine **Clinician KAP Scores** will be calculated: the physicians/NPs' and nurses' perceived competency and knowledge related to dementia; their attitudes toward dementia care and their attitudes toward the collCM; the physicians' practices in terms of cognitive evaluation; the physicians' attitude toward their collaboration with other FMG/FHT healthcare professionals; and the nurses' satisfaction with the support from secondary and tertiary care services.

The content and construct validity of the questionnaires have been conducted with 12 researchers and 29 clinicians. Both questionnaires were developed in French and later translated into English and back translated into French. The questionnaires will be distributed to every family physician, nurse practitioner and nurse practicing at participating sites in 2017-2018. Multiple reminders will be made to increase the completion rate. Data will be entered by a research assistant and 10% of questionnaires will be checked for reliability of data entry.

Explanatory variables

Explanatory variables in this study will be the scores derived from the organizational and clinician questionnaires; specifically, the Dementia Care Implementation Score, ICIT score and Clinician KAP scores.

Analysis

Descriptive analyses

A descriptive summary of all study variables (outcomes, explanatory variables, patient and site characteristics) will be conducted overall and by site. For continuous variables, means and standard deviations will be used for normally distributed variables; medians and interquartile ranges will be used for skewed variables. For binary or categorical variables, proportions will be reported.

Statistical modelling

Modelling for primary outcome -Quality of Dementia Follow-Up Score

To determine the association between the organizational and clinician scores and the quality of dementia follow-up, we will construct a linear mixed effects model using the data collected through the chart review, organizational and clinician questionnaires, and site demographic information. The unit of analysis will be the patient. The site ID will be treated as random effect in the model, which will account for the clustering of patients within FMG/FHT. All other independent variables will be treated as fixed effects. Independent variables will include the explanatory variables (Dementia Care Implementation Score, ICIT score and Clinician KAP scores). The model will also adjust for potential confounding variables including patient characteristics (age, sex, chronic disease score) and FMG/FHT demographic characteristics (rural/urban, number of registered patients, public/private, proximity to memory clinic, university

affiliation, socio-economic area based on the FMG/FHT postal code, province, percentage of older patients). See Table 1 for a summary of the variables.

Modelling for secondary outcomes

Similar models will be constructed to explore the association between the explanatory variables (Dementia Care Implementation Score, ICIT score and Clinician KAP scores) and the secondary outcomes (continuity of care and medications management) from the chart review while controlling for the same site-level and patient-level characteristics.

Sample Size and Power Determination

We based the sample size and power calculation for this study on the primary outcome of quality of dementia follow-up. As the study was not powered on the secondary outcomes, analyses for secondary outcomes will be considered exploratory in nature. Statistically significant findings for secondary outcomes will be interpreted as hypothesis generating.

To maximize our effective sample size, we strove to maximize the number of FMG/FHT that could be included in the study based on time and budget constraints while also ensuring that an adequate effect size for the statistical models could be detected. With these constraints in mind, we determined that we would be able to include 28 sites in the study. Using an estimated Intraclass Correlation Coefficient (ICC) of 0.16 based on our pilot data, we established that 30 patients from each site would allow us to detect a small effect (Cohen's $f^2 = 0.05$) due to a single factor, with 80% power. This effect size corresponds to an $R^2 = .038$, meaning that we could detect explanatory variables that account for at least 3.8% of the variability in the dementia follow-up scores. Thus, the number of patients required for this study was calculated to be 28 sites x 30 charts = 840 patients.

IMPLEMENTATION STUDY

Main objective

To examine how collCM have been developed, implemented, and evolved over time to improve care of patients with dementia and their caregivers in Canada.

Design

We will use a qualitative descriptive design(28). A qualitative descriptive design is appropriate when the aim is to provide an in-depth description of a phenomenon, and when the phenomenon is of particular relevance to clinicians and policy-makers(28).

Sites selection

From the 28 sites selected in the observational study, 22 sites will be sampled according to a purposeful maximum variation sampling method based on the type of collCM and rural/urban location.

Data sources and target populations

Two sources of data will be used on different target populations.

Organizational questionnaire

The data collected from the organizational questionnaire will provide descriptive information about each primary care site including the patient population, human resources, and funding model, thus providing important contextual information (see observational study above).

Interviews

In-depth semi-structured interviews(29) will provide the primary source of data for the implementation study.

Interviews will be conducted in 2017 and 2019 with three clinicians (one family physician, one nurse, and one other health professional) involved in delivering care and with one leader who implemented the collCM within each site. In addition, interviews will be conducted in both 2017 and 2019 with at least one representative from each provincial Ministry of Health including project managers. In 2018, interviews with two patients from each FHT/FMG will be conducted. Physicians will identify patients who are capable to participate in an interview, and for whom participation in an interview would not be detrimental to the patient. If the patient prefers, interviews can be conducted together with their family/friend caregiver. Patients and caregivers will be asked about their experiences with the collCM in their FHT/FMG (i.e., what have they enjoyed/found helpful about their experience, what they have not enjoyed/not found helpful, and how their experience could be improved). We will interview a convenient sample of physicians, nurses and other professionals involved in the day-to-day work. Interviewing this broad range of individuals will enable all aspects of the models to be examined and ensure that all components of the specific objectives will be addressed.

Overall, there will be a total of 201 interviews conducted. Interview guides have been developed based on previous work conducted by our team (not yet published). The interviews will be conducted mainly by phone for the clinicians, managers and government representatives, and in person (e.g., at home) for patients. All the interview guides will be pilot tested for refinement and validation.

Analysis

Interviews will be transcribed and entered into NVivo12. Responses to open-ended questions from the organizational questionnaire will also be entered into NVivo12 to allow for analysis of all of the qualitative data. Data will be analyzed using conventional content analysis(30, 31). Interview

transcripts will be independently coded by two team researchers, who will compare codes to agree on a codebook for the remaining transcripts. Codes will be collapsed into meaningful themes.

Using the theoretical framework of co-creation of innovation in healthcare(3) we will assess:

1) The theoretical basis for the model (objectives, vision, mechanisms of action, target population, etc.) and its components presently implemented (actions; material, financial and human resources; organizational structure; clinical interventions; timeline; frequency of the actions);

2) Components of the collCM already in place and those still to be implemented; factors at the provincial, organizational, clinical team and community levels that can explain variations in the extent of implementation;

3) *Barriers/Facilitators to Scale-up*: Factors that will be considered in this part of the analysis will include strategy of change management, resource mobilization, training, leadership and the role of champions. Data from interviews will be used in this part of the analysis.

Results from this analysis will not only reveal the common processes through which collCM are co-created but will also explain how models have been tailored to meet the needs of the local partners and contexts.

Strategies to Enhance Rigor

Several strategies will be used to enhance rigor. First, an audit trail of analytical decisions will be kept using 'memoing' in NVivo10. Second, triangulation of data sources and researchers will be carried out.

Integration of the implementation and the observational studies

To understand the link between implementation strategies, characteristics of models of care and quality of dementia follow-up (objective 3), the data and results from both studies will be integrated, which will provide a rich portrait at the site level(16). We will merge qualitative and quantitative data to compare them. We will develop a full data profile for each site, allowing the joint review of both data types by creating a new dataset(32). First, for the quantitative data, a table of variables for each FMG/FHT will be developed and compared with the overall results across sites. Second, for the qualitative data, summaries of facilitators and barriers for the successful implementation of collCM will be developed for each FMG/FHT. Third, these data will be integrated using a matrix(16), whereby the columns will represent sites and rows will represent findings. This will allow us to draw conclusions on the link between implementation strategies, characteristics of models of care and quality of dementia follow-up.

ETHICS AND DISSEMINATION

This study will be conducted using the principles of integrated knowledge transfer(33). Much of this work will be completed through three active councils: a Provincial Council with partners in the three provinces where we collect data, a Canadian Council with stakeholders across all provinces, and an International Council with researchers from many middle and high income countries (the Netherlands, the United-States of America, Mexico, the United Kingdom, France, Israel, China, Japan and Pan American Health Organization/World Health Organization). We will engage patients, caregivers, clinicians, researchers, managers and decision-makers (deputy ministers), provincial and Canadian Alzheimer societies heavily throughout the research process. For instance, stakeholders (clinicians, patients, caregivers and managers) were involved in defining the research questions and study design via a series of meetings. They will further be

involved in interpretation of results and dissemination of study results. We will also use the following steps. First, we will present clinical sites with their individual results. Second, we will present results to our councils in order to understand the successful elements that build capacity in primary care to support the care of persons with dementia, to allow the different provinces to share successful elements of their Alzheimer plans and strategies, and finally to ensure dissemination and implementation of best practices across Canada and internationally.

Our results will also be disseminated through peer-reviewed journals, conference presentations, and social, broadcast, and print media. Authorship will be determined based on the International Committee of Medical Journal Editors recommendations.

This multicentre study has received Research Ethics Board (REB) approval from the Centre Intégré Universitaire de Santé et de Service Social (CIUSSS) du Centre-Ouest-de-l'île-de-Montréal and from each Centre Intégré de Santé et de Service Social (CISSS) or CIUSSS involved in Quebec; from the REB at the University of Waterloo; and the REB from Université de Moncton and both regional health boards in New Brunswick. Amendments to the protocol will be communicated to all the REB involved and to all regional sites. In addition, each site will give their approval to participate in the study. The director of each site will grant our team permission to access patients' charts. All individuals completing the questionnaires and individual face-to-face interviews will sign a consent form prior to participating (Supplemental File 4). The patients' capacity to consent will be evaluated by the clinicians and research team. Personal information for the patient's charts (file number) will be collected but will not be shared to the research team and will be kept 10 years at the sites. Names of clinicians and medical directors from the sites will be collected to ensure high completion rate but will be kept separately from the dataset.

DISCUSSION

Ensuring accessibility to diagnosis, treatment and management throughout the course of dementia is a very significant problem worldwide. In order to provide comprehensive care to patients and their caregivers, enhancing primary care-based dementia care is the way forward.

Our program is the first to examine multiple models for patients living with dementia in the primary care setting across different jurisdictions. It will allow us to identify key factors for good quality of care and successful collCM implementation strategies.

Our study program will provide valuable information for other jurisdictions interested in implementing a collCM. It will provide important and actionable results to provide transformative change both at the local and national levels. The results will be used to support the dissemination and scale up of best dementia primary care practices. This study will produce timely and rigorous measures of quality of care in primary dementia care and its determinants. The results of this study will be used to refine the development of the National Strategy for Alzheimer's Disease and Other Dementias Act in Canada(34). We will work closely with the Canadian Academy of Health Science, who was mandated by the Minister of Health of Canada through the Public Health Agency of Canada, to provide an evidence-informed assessment on the state of knowledge to help develop the national strategy(35).

DECLARATIONS

Consent for publication

Not applicable.

Availability of data and materials

Dataset will be accessible to the investigators of the study and will not be made public. Access to full protocol and statistical code will remain accessible to the investigators of the study only and may be available upon request by contacting the principal investigator (Dr. Isabelle Vedel). Vancouver authorship eligibility guidelines will be used throughout the study.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

IV, CM, YC, SP, GAL, NS, CGS, RS and HB made substantial contributions to the conception or design of the study and drafting the manuscript. All other authors revised the manuscript critically for important intellectual content.

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Figure Legend

Figure 1: Flowchart representing the research program design.

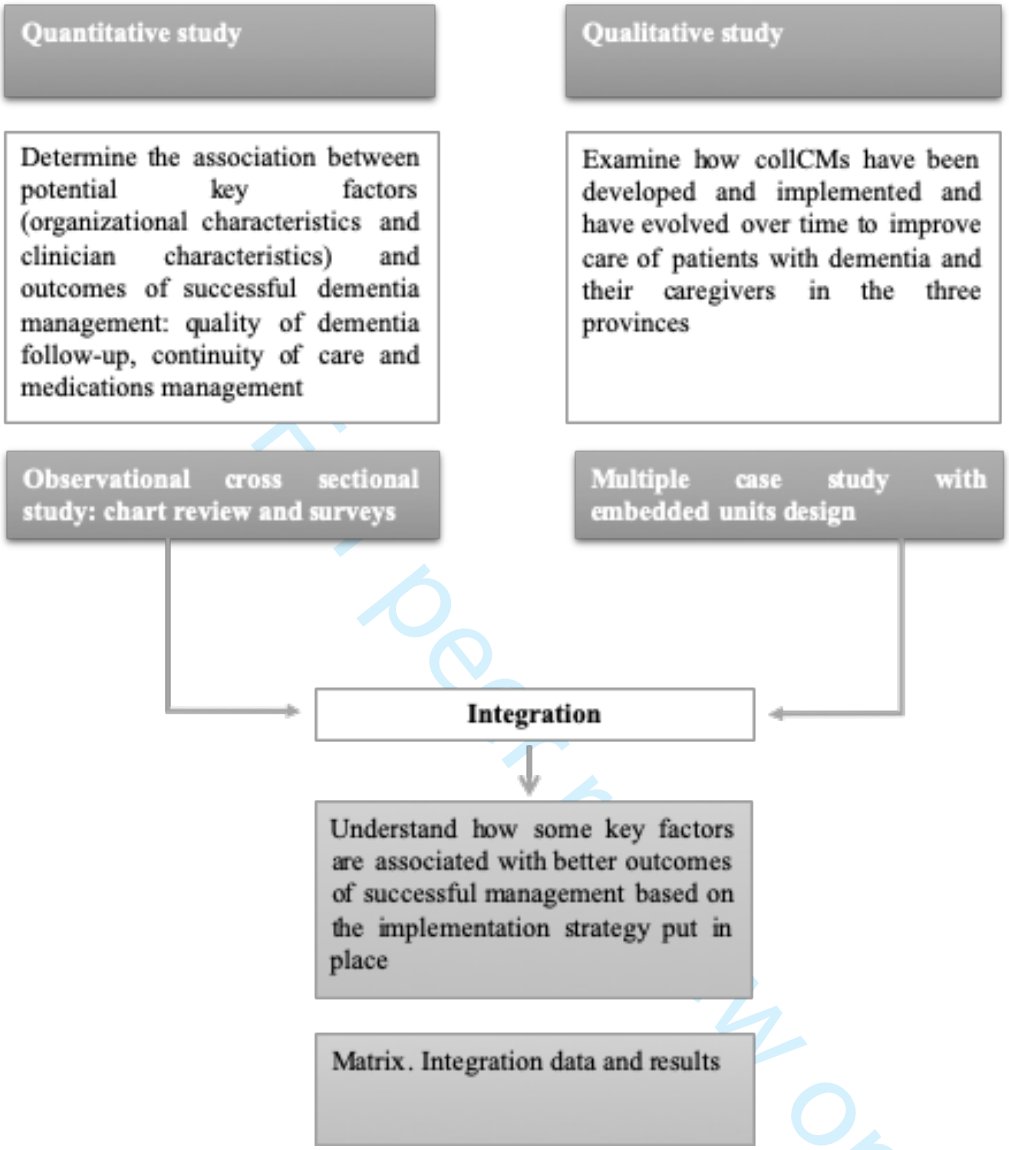

Figure 1: Research program design

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Supplemental File 2: Example of questions included in the organizational questionnaire – part A Dementia Care Practices

To what extent is there clinical leadership within your FHT regarding the care of patients with dementia?

To what extent is there leadership from external specialized resources in cognition to help your FHT to improve the care provided to patients with dementia?

How much financial support specific to the care of patients with dementia does your FHT receive from health authorities for improving dementia care?

How much financial support specific to the training of clinicians about dementia does your FHT receive from health authorities for the care of patients with dementia?

To what degree does your FHT use clinical guidelines for the care of patients with dementia?

How much regular training in dementia care do physicians practicing in your FHT receive?

How much regular training in dementia care do nurse practitioners practicing in your FHT receive?

How much regular training in dementia care do nurses practicing in your FHT receive?

How much regular training in dementia care do other allied health professionals practicing in your FHT receive?

How easy is it to generate a list of patients with dementia in your FHT?

How often are patient care plans developed by your FHT for patients with dementia?

How often do the patient's regular physicians/nurse practitioners/nurses/other allied professionals within your FHT have formal designated meetings to coordinate care for patients with dementia?

How often do the patient's regular physicians/nurse practitioners/nurses/other allied professionals within your FHT have informal discussions to coordinate care for patients with dementia?

How often does your FHT plan regular follow-up visits for patients with dementia?

How often are patients with dementia linked to a healthcare professional within your FHT who plays the role of case manager, navigator or coordinator?

How often is the burden of the caregivers or family members of patients with dementia within your FHT assessed?

How often are standardized tools used to assess the burden of the caregivers or family members of patients with dementia within your FHT?

How often is a formal care plan developed for the caregiver by your FHT?

To what extent are the caregivers of patients with dementia within your FHT involved in developing the care plan for the patient with dementia?

To what extent are the caregivers of patients with dementia within your FHT educated for their role in the patient's care plan?

To what extent do the patients in your FHT have access to external resources for caregiver support in your local community?

Supplemental File 3: NURSE AND OTHER HEALTH PROFESSIONAL QUESTIONNAIRE

A. General questions

In your current clinical practice, do you see patients 65 years old and over?

- ☐ Yes
- ☐ No **(IF NO, STOP HERE AND GIVE THE QUESTIONNAIRE BACK TO THE PERSON IN CHARGE)**

How many years of clinical experience do you have? _____

In what settings have you accumulated most of your clinical experience? (check one box only)

- ☐ Hospital
- ☐ A community-based practice
- ☐ Residential and long-term care

How many years have you been practising in your current practice setting? _____

How many of your patients are 65 years of age or older (check one box only)?

- ☐ 0-25%
- ☐ 26-50%
- ☐ 51-75%
- ☐ 76-100%
- ☐ DK (don't know)

How many of your patients have dementia (check one box only)? ___

- ☐ 0-25%
- ☐ 26-50%
- ☐ 51-75%
- ☐ 76-100%
- ☐ DK (don't know)

Do you have access in your community to specialized medical services for the elderly, such as memory clinics, geriatricians, etc.?

- ☐ Yes
- ☐ No
- ☐ DK

Were you recruited as part of a provincial initiative on aging or dementia?

- ☐ Yes
- ☐ No

Are you responsible for coordinating services for the elderly in your clinic?

- ☐ Yes
- ☐ No

What languages do you use most often in your practice setting? (check all that apply)

- ☐ French
- ☐ English
- ☐ Other (specify :_____)

Your practice setting is mainly:

- ☐ Rural
- ☐ Urban

You are a:

- ☐ Man
- ☐ Woman

Your professional background is: (check one box only)

- ☐ Nurse
- ☐ Social worker
- ☐ Other (specify):_____

What is your level of education? (check one box only)

- ☐ College diploma
- ☐ Bachelors degree
- ☐ Masters degree
- ☐ Masters degree plus a post-graduate degree (advanced practice nurse, nurse practitioner or RN-EC)
- ☐ Other (please specify):_____

B. Attitude, knowledge, and practice

You typically perform cognitive tests (check only one box)**:**

- ☐ Independently or autonomously
- ☐ In close collaboration/consultation with a physician
- ☐ Only when a physician requests it **(IF SO, SKIP TO QUESTION 2)**

Please indicate the extent to which you agree or disagree with each of the following statements concerning your ambulatory patients aged 65 years or older by circling the appropriate number:

	Disagree	Somewhat disagree	Somewhat agree	Agree	Don't know	Not applicable
I believe that I have the skills to...						
… identify cognitive impairment.	1	2	3	4	DK	N/A
… develop an appropriate care plan for patients with dementia.	1	2	3	4	DK	N/A
… give information about dementia to patients and their families.	1	2	3	4	DK	N/A
… follow up appropriately with patients with cognitive impairment.	1	2	3	4	DK	N/A
… involve the informal caregiver in the *assessment*.	1	2	3	4	DK	N/A
… involve the informal caregiver in *implementing care plans*.	1	2	3	4	DK	N/A
In my clinical environment, I have access to…						
… home-based care services (regional health and social services center) for patients with dementia.	1	2	3	4	DK	N/A
… resources in the community (such as Alzheimer Society meals on wheels, disability transportation, etc.…).	1	2	3	4	DK	N/A
In my day-to-day work…						
I think that several things can be done to improve the quality of life of a *patient living with dementia*.	1	2	3	4	DK	N/A

	Disagree	Somewhat disagree	Somewhat agree	Agree	Don't know	Not applicable
I think that several things that can be done to improve the quality of life of *informal caregivers*.	1	2	3	4	DK	N/A
I feel comfortable caring for patients with dementia.	1	2	3	4	DK	N/A
I think that the families of patients with dementia prefer being involved in the patient's care management.	1	2	3	4	DK	N/A
I think that the family and friends of patients have a key role to play in the management of dementia.	1	2	3	4	DK	N/A
I regularly keep up-to-date with dementia care guidelines.	1	2	3	4	DK	N/A

Please answer the following questions referring to your opinion on the Alzheimer Plan proposed by the Ministry of Health. (Circle one answer)

I understand the vision and values of Alzheimer Plan.

□ check here if not applicable

Understand not at all				Somewhat understand					Understand very well
1	2	3	4	5	6	7	8	9	10

I think that the changes proposed by the Alzheimer Plan will benefit me: they will help me do my work better.

□ check here if not applicable

Not at all beneficial				Somewhat beneficial					Very beneficial
1	2	3	4	5	6	7	8	9	10

I have received sufficient coaching/training around Alzheimer Plan.

□ check here if not applicable

Not at all sufficient				Somewhat sufficient					Very sufficient
1	2	3	4	5	6	7	8	9	10

I feel that the changes proposed by the Alzheimer Plan give me the liberty needed to adapt my practice to patients with dementia.

☐ check here if not applicable

No liberty at all				Some liberty					Very large liberty
1	2	3	4	5	6	7	8	9	10

Thank you!

Please return the questionnaire to «responsable_distribution».

Supplemental File 4: Patients' consent form for Quebec

Consent form
Patients and family caregivers' interview

Version 4, May 23rd, 2017

Title: Assessing care models implemented in primary health care for persons with Alzheimer's disease and related disorders

Investigator

This study is headed by Dr. Isabelle Vedel, from Montreal Jewish General Hospital's Lady Davis Institute. This interview is supervised by Dr. Yves Couturier (Ph.D.), Professor, Health and Social Services Centre — University Institute of Geriatrics of Sherbrooke.

Before you agree to take part in this study, it is important that you read and understand the information in this consent form. Ask as many questions as you need to understand what is expected of you. You have no obligation to participate if you do not want to participate.

Purpose of the study

The Ministry of Health has recently implemented an intervention in the Quebec Family Medicine Groups (FMG). The purpose of this intervention is to improve the quality of care given to patients with cognitive impairments. In this study, we want to see how this intervention was implemented in the FMG and what its effects are on the quality of the care you receive.

This study was sponsored by the Canadian Institutes for Health Research (CIHR).

What is expected of you

If you agree to participate, we will ask you to do an interview, which will last a maximum of 60 minutes. We will ask you about your experience at the FMG and on the care you receive. Specifically, we will ask you about what you enjoy, what you find helpful about your experience, what you do not enjoy, what you do not find helpful, and how your experience could be improved.

Possible risks associated with participation

During the interview, we will ask you about the care you receive, your diagnosis, how it was given to you and your experience in general. Some questions may remind you of painful memories or stressful moments and trigger negative reactions.

Benefits associated with participation and compensation

Participating in this project gives you a chance to talk to a neutral outsider about your experience. It gives you a chance to think back on the good and not-so-good aspects of the care you are given and to take stock.

You will also receive a 20$ gift-card to compensate for the time you have given this project.

Voluntary participation and right to withdraw

You have no obligation to participate. If you refuse, it will not have any consequences on your care and your refusal to participate will be kept confidential. Even if you agree to participate, you can decide not to do so at any time, without consequences or judgment. You do not even have to tell us your reasons. You can also choose not to answer some of the questions during the interview.

Confidentiality and data management

To make sure that your identity will not be discovered by anyone outside our team, we have taken those steps:

- We will give you a personal identification number (PIN) as soon as you will be enrolled. It will be composed of random numbers. That way, your real name will never appear in our reports;
- We will use your PIN for all of our documents. The researcher is the only one who will have access to the list that links your name and your PIN;
- A member of our team will transcribe your interview;
- We will always present results on groups, never on specific individuals;
- The material we will use for the project (recordings, retranscriptions, researcher's notes…) will be kept on the research network of Sherbrooke University's Research Center on Aging, where Dr Couturier works. To get access to the data, we need a computer linked to the server. Every linked computer is protected by a password;
- Our team might participate in another project on the same subject. If so, your data may be re-used, but only the PIN protected data will be used, protecting your identity;
- All paper documents with your name (consent forms, …) will be kept in a locked file cabinet, inside a locked suite, in McGill University's Department of Family Medicine. Only the principal investigators and their assistants will have access to these documents;
- Other paper data will be kept at all time in a locked drawer in room 2444 (which is also locked) in the Research Center on Aging. Only Yves Couturier (researcher in charge of the interviews) and his assistants will have access to it.
- We will present the results of our project in scientific journals and in different conferences, but it will not be possible to identify you specifically or to recognize you. The results will be presented in a general manner, with no link to your FMG or to your identity. We might, however, use a couple of quotes from your interviews. If so, we will use an alias;
- We will send a short summary of our results to interested participants. If you want to receive one, write down your postal or email address in the Signatures section;
- All data will be safely and permanently destroyed by November 2029, at the latest: the paper data will be shredded and we will ask the IT services to permanently delete the data on our computers and our servers. All your personal data will be destroyed;

For surveillance and monitoring purposes, your research file might be consulted by someone mandated by the West-Central Montreal Health's Research Ethics Committee, the establishment, or by someone mandated by authorized public bodies. Each of those persons and bodies are trained to make sure your identity is kept confidential.

For safety purposes, notably to enable us to communicate with you quickly, your name and surname, your contact information and the dates of the beginning and the end of your participation to the study will be kept for a year after the end of the study in a separate repertory maintained by the investigator in charge of the study.

Additional information

If you have any questions about the study or your participation, please contact the principal investigator, Dr. Isabelle Vedel, at: 514-399-9107, or the email address: isabelle.vedel@mcgill.ca.

You can also contact Yves Couturier, who is in charge of the interviews, at: (819) 780-2220 ext. 45143, or email address: yves.couturier@usherbrooke.ca

If you have any complaints or critics about the study, you can contact the Service Quality and Complaints Commissioner of the Montréal West Island IUHSSC at rsteinberg@jgh.mcgill.ca.

If you feel like you need more information and resources on dementia, you can ask your pivot nurse and/or contact the Alzheimer Society at: 514-369-7891, 1-888-636-6473 (41), or by email: info@alzheimerquebec.ca. You can also visit their website: http://www.alzheimer.ca/en/federationquebecoise.

If you feel isolated or if you want to talk about your situation, you can call the helpline Tel-Aînés at: 514-353-2463.

If you are in a situation of abuse, neglect or mistreatment, you can call your clinic's ombudsman and/or call the helpline Ligne Aide Abus Aînés (1-888-489-2287).

Acknowledgments
Your collaboration is precious and will enable us to successfully conduct this study. Thank you for taking the time to participate despite your heavy schedule.

Signatures

I, _____, freely consent to participate in the study named: « Assessing care models implemented in primary health care for persons with Alzheimer's disease and related disorders».

I have read the above information and I have understood the purpose, nature, benefits, risks and discomforts associated with this study. I am satisfied with the explanations and answers the investigator has given me, if needed, regarding my participation in this project.

_____ _____

Participant's signature Date

A small summary of the results will be sent to the participants who will have written the address where they wish the document to be delivered. **The results won't be available until May 2019. If the address were to change before this date, feel free to give the new address to the investigator.**

_____

Address (postal or electronic) where you want the summary to be sent.

I have explained to the participant the nature, benefits, risks and discomforts associated with the project. I have answered to the best of my knowledge the questions asked by the participant and I have made sure that he/she understood.

_____ _____

Investigator's signature Date

Other consent forms are available upon request by contacting the principal investigator (Dr. Isabelle Vedel) directly

BMJ Open

Assessing care models implemented in primary health care for persons with dementia : a mixed methods study protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-035916.R1
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ASSESSING CARE MODELS IMPLEMENTED IN PRIMARY HEALTH CARE FOR PERSONS WITH DEMENTIA: A MIXED METHODS STUDY PROTOCOL

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ABSTRACT

Introduction: Dementia is on the rise in Canada and globally. Ensuring accessibility to diagnosis, treatment and management throughout the course of the disease is a very significant problem worldwide. In order to provide comprehensive care to patients and their caregivers, enhancing primary care-based dementia care is seen as the way forward. In many Canadian provinces various collaborative care models anchored in primary care to improve dementia care have been developed and implemented. The overall objective of our research program is to identify key factors for the successful implementation of collaborative care models, and to facilitate dissemination and scale up of dementia best practices.

Methods and Analysis: We will use a convergent mixed methods design. An observational study using chart review (2014-2016) and questionnaires (2014-2018; repeated in 2020) will measure application of guidelines and implementation of collaborative care models. This study will be complemented with a qualitative descriptive study using interviews (2017-2020) conducted in parallel. Quantitative and qualitative results will be further integrated using a matrix representing sites and findings. An integrated knowledge exchange strategy will ensure uptake by principal stakeholders throughout the research.

Ethics and Dissemination: Our study has been approved by all relevant ethics committees. Our dissemination plan follows an integrated knowledge transfer strategy using provincial, national, and international councils. We will present the results individually to the clinical sites and then to these councils. Our research will be the first provincial and cross jurisdictional evaluation of primary care models for patients living with dementia, providing evidence on the ongoing debate on the respective role of clinicians in primary care and specialists in caring for patients with dementia.

Trial registration: Not applicable

KEYWORDS

Primary Health Care; dementia; mixed-methods design; health policy

STRENGTHS AND LIMITATIONS

- Our program is the first to examine multiple models for patients living with dementia in the primary care setting across different jurisdictions and by doing so we will identify key components of dementia care and successful implementation of collaborative care models (collCM) for dementia.

- We will look at collCM with different maturity and in different jurisdictions, which will make the comparison of the models challenging; however, we will rely on a descriptive qualitative study to inform stakeholders and given the breadth of the data collection and the triangulation of data, we will be able to obtain a good portrait of the implementation processes.

- By understanding how the collCM were developed, implemented, and evolved over time, our research will provide insight and guidance on successful implementation of collaborative care models for dementia in Canada and internationally to facilitate dissemination and scale-up of dementia best practices.

- Our cross-sectional, observational study design without a control group will allow us to assess association, not causality between quality of care and key components of the collCM but will reflect a more pragmatic, real-world evaluation.

- By using a mixed-methods design, we will understand the link between implementation strategies, characteristics of the models of care, and quality of dementia care while considering multi-level factors, from the patients, to the clinicians, to the primary care organizations levels

INTRODUCTION

The World Health Organization reports that dementia, such as Alzheimer's disease and other major neurocognitive disorders(1, 2), is perhaps the 21st century's most serious health challenge(2). Lack of accessibility to dementia evaluation, treatment and management throughout the course of the disease is a significant problem resulting in long waiting lists, delayed diagnosis, and late intervention(1). In turn, this leads to patient and caregiver uncertainty, inadequate support, and increased burden on caregivers(1). Timely diagnosis at the appropriate level in the healthcare system is increasingly important. In order to provide comprehensive care to patients and their caregivers, collaboration between physicians, nurses, other allied healthcare professionals and various community partners is essential(3).

To deal with this issue in Canada, four Canadian Consensus Conferences on the Diagnosis and Treatment of Dementia (CCCDTD)(4) between 1989 and 2012 have made a series of recommendations and guidelines that promote detection, diagnosis, treatment, management and coordination of care of patients living with dementia should be primarily the responsibility of the primary healthcare.

However, primary healthcare is not yet fully prepared to deal with patients with dementia(5). It is thus essential to increase the capacity of primary healthcare clinicians to care for this population

and to better coordinate care between primary healthcare, memory clinics and community organizations (e.g. the Alzheimer Society, home-based nursing services and home care services).

To this end, several Canadian provinces have made considerable efforts to develop and implement Collaborative Care Models (collCM) leveraging on the existence of interdisciplinary primary care teams(6-11). CollCM specific to dementia care have been implemented at different levels across Canadian jurisdictions.

These primary care-based collCM share the same visions and objectives, which are described in Supplemental File 1. Overall, they aim to provide timely, patient-centered, comprehensive, and continuous inter-professional care for persons with dementia, including health promotion, detection, diagnosis, treatment, management and coordination of care throughout the course of the disease using standardized clinical tools. This could be achieved through collaboration between family physicians, nurses and other healthcare professionals working in Family Medicine Groups or Family Health Teams (FMG/FHT) along with their community partners and specialists as needed. Primary healthcare teams are becoming the hub of integrated care, where specialized services support primary care professionals in managing this complex population. However, the characteristics of these models, such as the processes and activities performed for persons with dementia and their caregivers, varies from one FMG/FHT to another. These interventions have shown promising results in terms of feasibility, clinician participation, and satisfaction(6-8).

The implementation of collCM in Canada represent natural experiments, offering opportunities to evaluate innovative approaches and to identify determinants of better quality of care for patients with dementia.

The overall objective of our research program is to identify key factors for the application of recommendations for dementia care and successful collCM implementation, and to facilitate dissemination and scale-up of dementia best practices. Our program will be the first provincial and cross jurisdictional evaluation of primary care collCM for patients living with dementia,

The specific objectives are:

1. To determine the association between potential key factors (organizational characteristics and clinician characteristics) and outcomes of successful dementia management in primary care: quality of care, continuity of care, and medications management
2. To examine how collCM have been developed and implemented and have evolved over time to improve care of patients with dementia and their caregivers
3. To understand the link between implementation strategies, characteristics of collCM and quality of dementia care

METHODS

To reach our objectives, we will use a convergent mixed methods design(12): A quantitative observational study using chart review and questionnaires to answer objective 1, and a qualitative descriptive study using interviews to answer objective 2. The results from both studies will be conducted in parallel and further integrated to answer objective 3.

Patient and Public Involvement

Our research program employs an integrated knowledge exchange strategy(13), with decision-makers/managers, clinicians, and patients/caregivers representatives throughout the entire study (Figure 1). These stakeholders were involved in defining the research questions and study design

via a series of meetings using an organizational participatory approach(14). They will further be involved in interpretation of results and dissemination of study results.

OBSERVATIONAL STUDY

Main objective

To determine the association between potential key factors (organizational characteristics and clinician characteristics) and outcomes of successful dementia management in primary care: quality of dementia care, continuity of care and medications management.

Site selection

To purposively identify FMGs/FHTs who have implemented collCM, we contacted researchers, clinicians, and decision-makers in gerontology, geriatrics and primary care at the provincial and federal levels through our professional contact lists and during national conferences. We selected sites from three provinces (Ontario, Quebec, and New Brunswick), with various collCM and levels of implementation to maximize the diversity of collCM characteristics.

Design

This is an observational study with a cross-sectional design using a chart review and questionnaires. A chart review was conducted for patients 75 years old and older with a diagnosis of dementia. We chose 75 years old as the age cut-off since dementia is highly prevalent in this population(15), thus increasing the number of eligible charts. One retrospective chart review was conducted in each site. The study period is 9 months, either from October 1st, 2014 to July 1st, 2015 or October 1st, 2015 to July 1st, 2016. The target population is all patients 75 years old and older with a diagnosis of dementia who had at least one visit to the site during the study period.

Questionnaires were sent to the medical directors and clinicians from each site between 2014-2018 to be completed within one year of the site's chart review.

Chart review

Outcomes

The primary outcome for the observational study is the quality of dementia care. Because no such measure exists, we developed our own **Quality of Dementia Follow-Up Score,** based on the recommendations and guidelines from a number of expert groups, such as ACOVE-3(16, 17), CCCDTD(4), and others sources(9, 18). This score is comprised of 10 indicators of quality of follow-up for dementia and has been further validated in a pilot study (Table 1)(19). These indicators were selected by our researchers and experts in dementia based on their concordance with Canadian clinical recommendations(4) and their feasibility to be measured through a chart review. Patient's eligibility for each indicator were assessed over the patient's entire medical chart. Based on the validated ACOVE approach, a score will be calculated for each patient by summing the number of indicators performed during the study period by the FMG/FHT divided by the number of eligible indicators for that patient.

Table 1 Summary of variables included in the analyses for the observational study with data source

Type	Variable	Description	Chart review 2014-2016	Organizational questionnaire 2016-2018	Clinicians' questionnaire 2014-2017
Primary outcome	Quality of dementia follow-up	10 ACOVE indicators: Cognitive testing Functional status, Behavioral and psychological symptoms of dementia Weight Caregiver needs Driving status Home care needs Community service needs (e.g., Alzheimer Society) Absence of anticholinergic medication and management of dementia medications (19)	X		
Secondary outcomes	Continuity of primary care	Number of visits to the FMG/FHT; the number of notes, whether or not they were related to dementia, recorded in the charts by the FMG/FHT health professionals; the proportion of patients who have at least two visits to any clinician in the same FMG/FHT during the time period	X		
	Medications management	Proportion of patients with dementia who are treated with dementia medication such as cholinesterase inhibitors or Memantine; the proportion of new dementia medications prescribed or initiated; the proportion of new dementia medications initiated by family physician; the proportion of new dementia medications initiated by	X		

		specialists; and the proportion of patients who are treated with anti-psychotics during the period			
Explanatory variables	Organizational Best Practices for Dementia Score	See Henein et al. (20) Domains include: Leadership within the interdisciplinary primary care clinic, Financial Support, Support from cognition specialists, Training, Clinical information systems, Coordination and Continuity within the interdisciplinary primary care clinic, Caregiver support and involvement, Access to and coordination with home and community services, Coordination with Hospital		X	
	Index of Conformity to an Ideal Type of primary care setting	See Levesque et al. (21) Domains include: Vision, structure, resources, practice		X	
	Clinician KAP Scores	See Arsenault-Lapierre et al. (22, 23) Physicians' and nurses' perceived competency and knowledge related to dementia; the physicians' and nurses' attitudes toward dementia; the physicians' practices in terms of cognitive evaluation; the physicians' attitude toward their collaboration with other FMGs/FHT healthcare professionals; and the nurses' satisfaction with the support from secondary and tertiary care services and the physicians' and nurses' attitudes toward the collCM			X

Confounders	Patients' characteristics	Age, sex, co-morbidities (number of medications)	X		
	FMG/FHT demographic information	number of registered patients, public/private, proximity to memory clinic, university affiliation, Rural/urban and socio-economic area based on the FMG/FHT postal code, percentage of older patients		X	

We will also examine two secondary outcomes: a) **continuity of primary care** for patients with dementia (including the number of visits to the FMG/FHT; the number of notes, whether or not they were related to dementia, recorded in the charts by the FMG/FHT health professionals; the proportion of patients who have at least two visits to any clinician in the same FMG/FHT during the study period); and b) **medications management** (including proportion of patients with dementia treated with dementia medications such as cholinesterase inhibitors or Memantine; proportion of new dementia medications prescribed or initiated; proportion of new dementia medications initiated by family physician; proportion of new dementia medications initiated by specialists; and proportion of patients treated with anti-psychotics during the study period).

Patient characteristics

The age, sex, type of dementia, living status and comorbidities of each patient were collected through the chart review. The number of medications was used as a proxy for comorbidities(24).

Data collection procedure

Patient charts were randomly selected among a list of registered patients 75 years and older with a dementia diagnosis. Data were collected by research assistants from patients' charts in a customized and secure, web-based database. An instruction manual for assessing each indicator

that needed to be collected through the chart review was prepared and tested. To further ensure the quality of the data collection, all the research assistants who reviewed patient charts were trained by a single supervisor, a research nurse, who answered any questions that arose throughout the chart review process.

Organizational questionnaire

Our organizational questionnaire has two parts. The first part assesses the adherence to various components of dementia care recommendations in each site. We adapted a questionnaire developed to assess the implementation of chronic care model in the US patient centered medical home, the PCMH-A questionnaire(25), to the Canadian context using the Canadian recommendations on dementia(26). An overall score, called the **Organizational Best Practices for Dementia Score** ranging from 1 to 100 will be derived from the questions, where a higher score signifies better adherence to best practices according the recommendations(20).

The second part of the questionnaire assesses site demographic information (Table 1) and primary care organizational site characteristics. We adapted a validated questionnaire developed by the Institut national de santé publique du Québec(21) to the Canadian context. From this questionnaires four domain scores (structure, vision, resources, and practice), we will derive a score called the **Index of Conformity to an Ideal Type of primary care setting (ICIT)**, where a higher score indicates a better organized primary care setting (e.g. higher ETP physicians, access to electronic medical records, after-hours care, etc.)(21).

Content validity of our organizational questionnaire has been conducted with eight experts and 11 medical directors across the three provinces and described(20). Our questionnaire was developed in French and later translated into English and back translated into French to ensure equivalency

between the two versions. Our organizational questionnaire was mailed in 2017-2018 to the medical directors at each site, along with two copies of the consent forms and a pre-stamped envelope. Multiple reminders were made to increase the completion rate. Data was entered by a research assistant and 10% of questionnaires were checked for reliability of data entry.

Clinicians' questionnaires

Two clinicians' questionnaires, one for the physicians/nurse practitioners and one for the nurses and other healthcare professionals working in the participating FMG/FHT, will be used to assess their knowledge, attitudes and practices(27) toward dementia care and toward the collCM(22, 23). Both questionnaires have 83 questions, including demographic questions. From these questionnaires, nine **Clinician KAP Scores** are calculated: the physicians/NPs' and nurses' perceived competency and knowledge related to dementia; their attitudes toward dementia care and their attitudes toward the collCM; the physicians' practices in terms of cognitive evaluation; the physicians' attitude toward their collaboration with other FMG/FHT healthcare professionals; and the nurses' satisfaction with the support from secondary and tertiary care services.

Both questionnaires have been developed and validated and are available in French and in English(22, 23). The questionnaires were distributed to every family physician, nurse practitioner and nurse practicing at participating sites in 2014-2017. Multiple reminders were made to increase the completion rate. Data were entered by a research assistant and 10% of questionnaires were checked for reliability of data entry.

Explanatory variables

Explanatory variables in this study will be the scores derived from the organizational and clinician questionnaires; specifically, the Organizational Best Practices for Dementia Score, ICIT score and Clinician KAP scores.

Analysis

Descriptive analyses

A descriptive summary of all study variables (outcomes, explanatory variables, patient and site characteristics) will be conducted overall and by site. For continuous variables, means and standard deviations will be used for normally distributed variables; medians and interquartile ranges will be used for skewed variables. For binary or categorical variables, proportions will be reported.

Statistical modelling

Modelling for primary outcome -Quality of Dementia Follow-Up Score

To determine the association between the organizational and clinician scores with the quality of dementia follow-up, we will construct a linear mixed effects model using the data collected through the chart review, organizational and clinician questionnaires, and site demographic information. The unit of analysis will be the patient. The site ID will be treated as random effect in the model, which will account for the clustering of patients within FMG/FHT. All other independent variables will be treated as fixed effects. Independent variables will include the explanatory variables (Organizational Best Practices for Dementia and Clinician KAP scores). The model will also adjust for potential confounding variables including patient characteristics (age, sex, number of medications) and FMG/FHT demographic characteristics (number of registered patients, public/private, proximity to memory clinic, university affiliation, rural/urban based on

the FMG/FHT postal code, percentage of older patients). See Table 1 for a summary of the variables.

Modelling for secondary outcomes

Similar models will be constructed to explore the association between the explanatory variables (Organizational Best Practices for Dementia, ICIT score and Clinician KAP scores) and the secondary outcomes (continuity of care and medications management) from the chart review while controlling for the same site-level and patient-level characteristics.

Sample Size and Power Determination

We based the sample size and power calculation for this study on the primary outcome of quality of dementia follow-up. As the study was not powered on the secondary outcomes, analyses for secondary outcomes will be considered exploratory in nature. Statistically significant findings for secondary outcomes will be interpreted as hypothesis generating.

To maximize our effective sample size, we strove to maximize the number of FMG/FHT that could be included in the study based on time and budget constraints while also ensuring that an adequate effect size for the statistical models could be detected. With these constraints in mind, we determined that we would be able to include 28 sites in the study. Using an estimated Intraclass Correlation Coefficient (ICC) of 0.16 based on our pilot data, we established that 30 patients from each site would allow us to detect a small effect (Cohen's $f^2 = 0.05$) due to a single factor, with 80% power. This effect size corresponds to an $R^2 = .038$, meaning that we could detect explanatory variables that account for at least 3.8% of the variability in the dementia follow-up scores. Thus, the number of patients required for this study was calculated to be 28 sites x 30 charts = 840 patients.

IMPLEMENTATION STUDY

Main objective

To examine how collCM have been developed, implemented, and evolved over time to improve care of patients with dementia and their caregivers in Canada.

Design

We use a qualitative descriptive design(28). A qualitative descriptive design is appropriate when the aim is to provide an in-depth description of a phenomenon, and when the phenomenon is of particular relevance to clinicians and policy-makers(28).

Sites selection

From the 28 sites selected in the observational study, 22 sites were sampled according to a purposeful maximum variation sampling method based on the type of collCM and rural/urban location.

Data sources and target populations

Two sources of data will be used on different target populations.

Organizational questionnaire

The data collected from the organizational questionnaire will provide descriptive information about each primary care site including the patient population, human resources, and funding model, thus providing important contextual information (see observational study above). Primary care sites will be asked to complete the organizational questionnaire again in 2020 to determine any changes in these categories.

Interviews

In-depth semi-structured interviews(29) will provide the primary source of data for the implementation study.

Interviews were conducted in 2017 and 2019 with three clinicians (one family physician, one nurse, and one other health professional) involved in delivering care and with one leader who implemented the collCM within each site. In addition, interviews will be conducted in both 2017 and 2020 with at least one representative from each provincial Ministry of Health including project managers. In 2019, interviews with two patients from each FHT/FMG were conducted. Physicians identified patients who were capable to participate in an interview, and for whom participation in an interview would not be detrimental to the patient (e.g., it would not cause undue stress or anxiety). This determination was based on the physician's clinical expertise and knowledge of the patient. If the patient preferred, interviews were conducted together with their family/friend caregiver. Patients and caregivers were asked about their experiences with the collCM in their FHT/FMG (i.e., what they enjoyed/found helpful about their experience, what they have not enjoyed/not found helpful, and how their experience could be improved). We interviewed a convenient sample of physicians, nurses and other professionals involved in the day-to-day work. Interviewing this broad range of individuals will enable all aspects of the models to be examined and ensure that all components of the specific objectives will be addressed. The data collection timeline is described in Table 2.

Overall, there will be a total of 201 interviews conducted. Interview guides have been developed based on previous work conducted by our team (not yet published). The interviews will be conducted mainly by phone for the clinicians, managers and government representatives, and in

person (e.g., at home) for patients. All the interview guides will be pilot tested for refinement and validation.

Table 2: Data collection timeline for implementation study

Data Source and Target Population	Date
Organizational questionnaire	2017-2018; repeated 2020
Interviews with Patients	2019
Interviews with Ministry of Health	2017 and 2020
Interviews with Clinicians	2017 and 2019

Analysis

Interviews will be transcribed and entered into NVivo12. Responses to open-ended questions from the organizational questionnaire will also be entered into NVivo12 to allow for analysis of all of the qualitative data. Data will be analyzed using conventional content analysis(30, 31). Interview transcripts will be independently coded by two team researchers, who will compare codes to agree on a codebook for the remaining transcripts. Codes will be collapsed into meaningful themes.

Using the theoretical framework of co-creation of innovation in healthcare(3) we will assess:

1) The theoretical basis for the model (objectives, vision, mechanisms of action, target population, etc.) and its components presently implemented (actions; material, financial and human resources; organizational structure; clinical interventions; timeline; frequency of the actions);

2) Components of the collCM already in place and those still to be implemented; factors at the provincial, organizational, clinical team and community levels that can explain variations in the extent of implementation;

3) *Barriers/Facilitators to Scale-up*: Factors that will be considered in this part of the analysis will include strategy of change management, resource mobilization, training, leadership and the role of champions. Data from interviews will be used in this part of the analysis.

Results from this analysis will not only reveal the common processes through which collCM are co-created but will also explain how models have been tailored to meet the needs of the local partners and contexts.

Strategies to Enhance Rigor

Several strategies will be used to enhance rigor. First, an audit trail of analytical decisions will be kept using 'memoing' in NVivo10. Second, triangulation of data sources and researchers will be carried out. Triangulation enhances the validity of the findings and also provides a more comprehensive understanding of the phenomenon being studies. Triangulation of data sources included the use of interviews with multiple groups (clinicians, patients and caregivers, policy-makers) as well as the organizational questionnaire. Triangulation of researchers included having multiple researchers involved in the coding an interpretation of the interview transcripts.

Integration of the implementation and the observational studies

To understand the link between implementation strategies, characteristics of models of care and quality of dementia follow-up (objective 3), the data and results from both studies will be integrated, which will provide a rich portrait at the site level(12). We will merge qualitative and

quantitative data to compare them. We will develop a full data profile for each site, allowing the joint review of both data types by creating a new dataset(32). First, for the quantitative data, a table of variables for each FMG/FHT will be developed and compared with the overall results across sites. Second, for the qualitative data, summaries of facilitators and barriers for the successful implementation of collCM will be developed for each FMG/FHT. Third, these data will be integrated using a matrix(12), whereby the columns will represent sites and rows will represent findings. This will allow us to draw conclusions on the link between implementation strategies, characteristics of models of care and quality of dementia follow-up.

ETHICS AND DISSEMINATION

This study is conducted using the principles of integrated knowledge transfer(33). Much of this work is completed through three active councils: a Provincial Council with partners in the three provinces where we collect data, a Canadian Council with stakeholders across all provinces, and an International Council with researchers from many middle and high income countries (the Netherlands, the United-States of America, Mexico, the United Kingdom, France, Israel, China, Japan and Pan American Health Organization/World Health Organization). Our dissemination plan includes the following steps. First, we will present clinical sites with their individual results. Second, we will present results to our councils in order to understand the successful elements that build capacity in primary care to support the care of persons with dementia, to allow the different provinces to share successful elements of their Alzheimer plans and strategies, and finally to ensure dissemination and implementation of best practices across Canada and internationally.

Our results will also be disseminated through peer-reviewed journals, conference presentations, and social, broadcast, and print media. Authorship will be determined based on the International Committee of Medical Journal Editors recommendations.

This multicentre study has received Research Ethics Board (REB) approval from the Centre Intégré Universitaire de Santé et de Service Social (CIUSSS) du Centre-Ouest-de-l'île-de-Montréal and from each Centre Intégré de Santé et de Service Social (CISSS) or CIUSSS involved in Quebec; from the REB at the University of Waterloo; and the REB from Université de Moncton and both regional health boards in New Brunswick. Amendments to the protocol will be communicated to all the REB involved and to all regional sites. In addition, each site will give their approval to participate in the study. The director of each site will grant our team permission to access patients' charts. All individuals completing the questionnaires and individual face-to-face interviews will sign a consent form prior to participating (Supplemental File 2). The patients' capacity to consent was evaluated by the clinicians and research team. Personal information for the patient's charts (file number) was collected but will not be shared to the research team and will be kept 10 years at the sites. Names of clinicians and medical directors from the sites were collected to ensure high completion rate but will be kept separately from the dataset.

DISCUSSION

Ensuring accessibility to diagnosis, treatment and management throughout the course of dementia is a very significant challenge worldwide. In order to provide comprehensive care to patients and their caregivers, enhancing primary care-based dementia care is the way forward.

Our program is the first to examine multiple models for patients living with dementia in the primary care setting across different Canadian jurisdictions. It will allow us to identify key factors for good quality of care, as reflected by the application of guidelines, and successful collCM implementation strategies.

Our study program will provide valuable information for other Canadian jurisdictions interested in implementing a collCM. It will provide important and actionable results to provide transformative change both at the local and national levels. The results will be used to support the dissemination and scale up of best dementia primary care practices. This study will produce timely and rigorous measures of quality of care in primary dementia care and its determinants. The results of this study will be used to refine the development of the National Strategy for Alzheimer's Disease and Other Dementias Act in Canada(34). We work closely with the Canadian Academy of Health Science, who was mandated by the Minister of Health of Canada through the Public Health Agency of Canada, to provide an evidence-informed assessment on the state of knowledge to help develop the national strategy(35).

DECLARATIONS

Consent for publication

Not applicable.

Availability of data and materials

Dataset will be accessible to the investigators of the study and will not be made public. Access to full protocol and statistical code will remain accessible to the investigators of the study only and may be available upon request by contacting the principal investigator (Dr. Isabelle Vedel). Vancouver authorship eligibility guidelines will be used throughout the study.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

IV, CM, YC, SP, GAL, NS, CGS, RS and HB made substantial contributions to the conception or design of the study and drafting the manuscript. All other authors revised the manuscript critically for important intellectual content.

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Figure Legend

Figure 1: Flowchart representing the research program design.

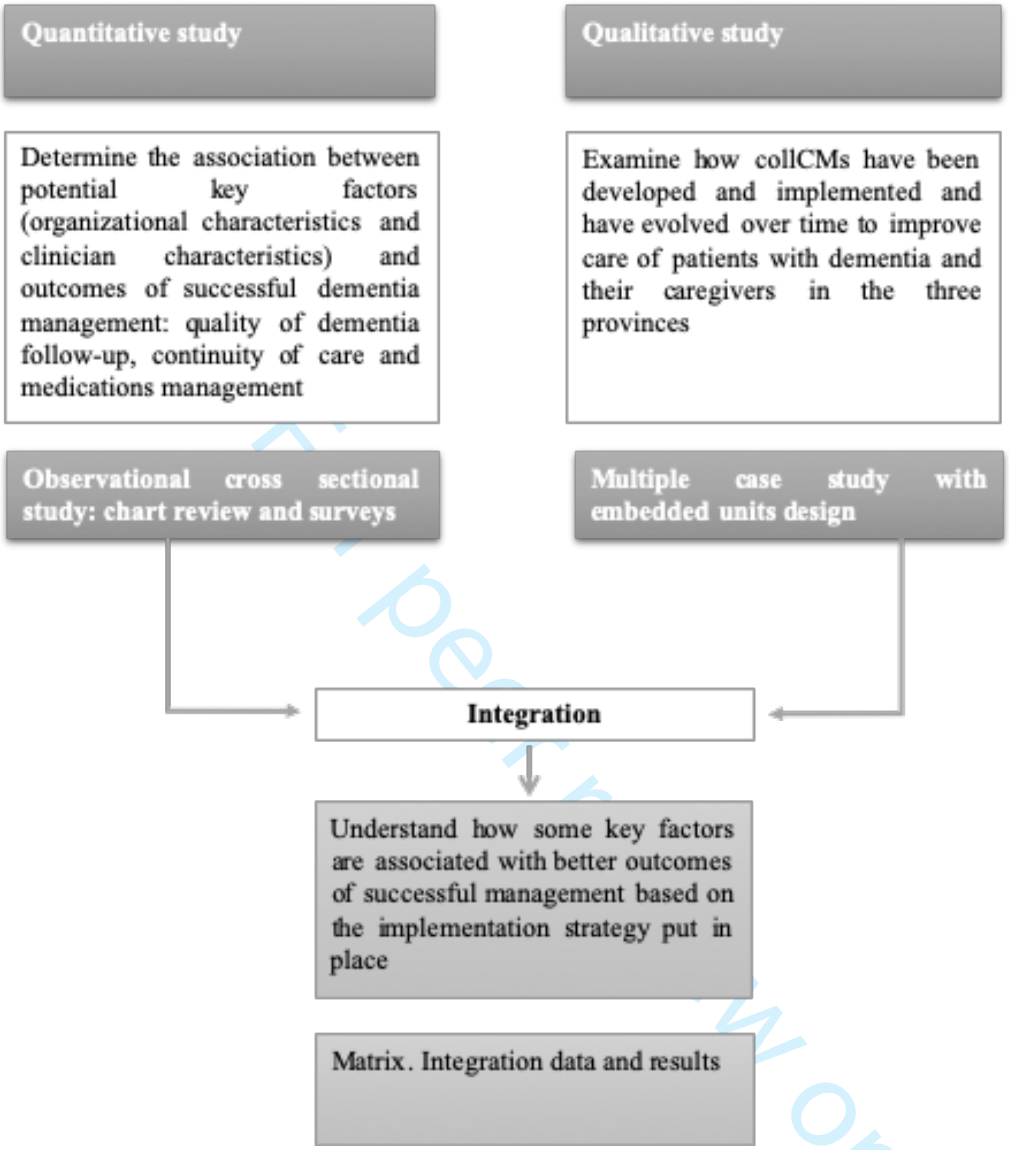

Figure 1: Research program design

Supplemental file 1. Main clinical, organizational and change management components of collaborative care models

Main clinical components of the collCM
- Early detection of cognitive decline and assessment by the FMG/FHT clinicians
- Early diagnosis of Alzheimer's disease and related disorders for typical cases; complicated cases to be referred to a specialist physicians
- Explanation of the diagnosis to the patient and caregiver by the FMG/FHT physician followed by the nurse to assure that the information is well understood
- Initiation of pharmacological treatment by the FMG/FHT physician (for typical case) and follow-up by the FMG/FHT nurse, social worker, or pharmacist
- Identification of patient and caregiver's needs, preferences and expectations by the FMGs' clinicians
- A dedicated FMG/FHT nurse case manager for each patient and caregiver dyad
- Interdisciplinary care among FMG/FHT physicians, nurses, and other disciplines (e.g. social workers, pharmacists, etc.)
- Development of individualized care plans, promotion of self-care, management of multiple chronic diseases
- Early involvement of community-based resources for patients and family caregivers (e.g. Alzheimer Society)
- Deliberate and pro-active systematic follow up
- Care coordination among health and social services, community organizations and patient/family caregiver support groups
Main organizational components of the collCM to support clinical processes
- A strong training program for primary health care professionals
- Collaborative chronic disease management based on a holistic approach to these complex patients and their caregivers, treating them as whole individuals within a socio-cultural context
- A strong partnership between FMG/FHT physicians and nurses with patients and their caregiver
- Agreements to support collaboration between primary health care, secondary/tertiary clinicians and community-based health and social cared professionals, to offer support in a timely sensitive fashion
- Timely access to specialists for Behavioral and Psychological Symptom of Dementia
- The use of standardized clinical tools and evidence-based protocols based on the Canadian Consensus Conference on Alzheimer Disease and Related Disorders (e.g. decisional algorithms, toolkits, guidelines, and clinical assessment tools)
- Shared care between FMG/FHT physicians and specialists for complex cases, such as the involvement of visiting specialists' clinicians
- Coordination of patients transitions between the hospital and FMG/FHT (transitional care) to avoid re-hospitalization and emergency department visits
- Ongoing information exchange between professionals and settings (e.g. information technologies, interoperable electronic medical records)
- Hiring of nurses and social worker in FMG/FHT as case manager

- Use of case discussion at interdisciplinary meetings, with the support of specialists if needed
Main change management components of the collCM
- Identification of a champion
- Creation of users' committee, such as caregivers and patients

FMG/FHT: Family Medicine Group and/or Family Health Teams. collCM: collaborative care models

Supplemental File 2: Patients' consent form for Quebec

Consent form
Patients and family caregivers' interview

Version 4, May 23rd, 2017

Title: Assessing care models implemented in primary health care for persons with Alzheimer's disease and related disorders

Investigator

This study is headed by Dr. Isabelle Vedel, from Montreal Jewish General Hospital's Lady Davis Institute. This interview is supervised by Dr. Yves Couturier (Ph.D.), Professor, Health and Social Services Centre — University Institute of Geriatrics of Sherbrooke.

Before you agree to take part in this study, it is important that you read and understand the information in this consent form. Ask as many questions as you need to understand what is expected of you. You have no obligation to participate if you do not want to participate.

Purpose of the study

The Ministry of Health has recently implemented an intervention in the Quebec Family Medicine Groups (FMG). The purpose of this intervention is to improve the quality of care given to patients with cognitive impairments. In this study, we want to see how this intervention was implemented in the FMG and what its effects are on the quality of the care you receive.

This study was sponsored by the Canadian Institutes for Health Research (CIHR).

What is expected of you

If you agree to participate, we will ask you to do an interview, which will last a maximum of 60 minutes. We will ask you about your experience at the FMG and on the care you receive. Specifically, we will ask you about what you enjoy, what you find helpful about your experience, what you do not enjoy, what you do not find helpful, and how your experience could be improved.

Possible risks associated with participation

During the interview, we will ask you about the care you receive, your diagnosis, how it was given to you and your experience in general. Some questions may remind you of painful memories or stressful moments and trigger negative reactions.

Benefits associated with participation and compensation

Participating in this project gives you a chance to talk to a neutral outsider about your experience. It gives you a chance to think back on the good and not-so-good aspects of the care you are given and to take stock.

You will also receive a 20$ gift-card to compensate for the time you have given this project.

Voluntary participation and right to withdraw

You have no obligation to participate. If you refuse, it will not have any consequences on your care and your refusal to participate will be kept confidential. Even if you agree to participate, you can decide not to do so at any time, without consequences or judgment. You do not even have to tell us your reasons. You can also choose not to answer some of the questions during the interview.

Confidentiality and data management

To make sure that your identity will not be discovered by anyone outside our team, we have taken those steps:

- We will give you a personal identification number (PIN) as soon as you will be enrolled. It will be composed of random numbers. That way, your real name will never appear in our reports;
- We will use your PIN for all of our documents. The researcher is the only one who will have access to the list that links your name and your PIN;
- A member of our team will transcribe your interview;
- We will always present results on groups, never on specific individuals;
- The material we will use for the project (recordings, retranscriptions, researcher's notes…) will be kept on the research network of Sherbrooke University's Research Center on Aging, where Dr Couturier works. To get access to the data, we need a computer linked to the server. Every linked computer is protected by a password;
- Our team might participate in another project on the same subject. If so, your data may be re-used, but only the PIN protected data will be used, protecting your identity;
- All paper documents with your name (consent forms, …) will be kept in a locked file cabinet, inside a locked suite, in McGill University's Department of Family Medicine. Only the principal investigators and their assistants will have access to these documents;
- Other paper data will be kept at all time in a locked drawer in room 2444 (which is also locked) in the Research Center on Aging. Only Yves Couturier (researcher in charge of the interviews) and his assistants will have access to it.
- We will present the results of our project in scientific journals and in different conferences, but it will not be possible to identify you specifically or to recognize you. The results will be presented in a general manner, with no link to your FMG or to your identity. We might, however, use a couple of quotes from your interviews. If so, we will use an alias;
- We will send a short summary of our results to interested participants. If you want to receive one, write down your postal or email address in the Signatures section;
- All data will be safely and permanently destroyed by November 2029, at the latest: the paper data will be shredded and we will ask the IT services to permanently delete the data on our computers and our servers. All your personal data will be destroyed;

For surveillance and monitoring purposes, your research file might be consulted by someone mandated by the West-Central Montreal Health's Research Ethics Committee, the establishment, or by someone mandated by authorized public bodies. Each of those persons and bodies are trained to make sure your identity is kept confidential.

For safety purposes, notably to enable us to communicate with you quickly, your name and surname, your contact information and the dates of the beginning and the end of your participation to the study will be kept for a year after the end of the study in a separate repertory maintained by the investigator in charge of the study.

Additional information

If you have any questions about the study or your participation, please contact the principal investigator, Dr. Isabelle Vedel, at: 514-399-9107, or the email address: isabelle.vedel@mcgill.ca.

You can also contact Yves Couturier, who is in charge of the interviews, at: (819) 780-2220 ext. 45143, or email address: yves.couturier@usherbrooke.ca

If you have any complaints or critics about the study, you can contact the Service Quality and Complaints Commissioner of the Montréal West Island IUHSSC at rsteinberg@jgh.mcgill.ca.

If you feel like you need more information and resources on dementia, you can ask your pivot nurse and/or contact the Alzheimer Society at: 514-369-7891, 1-888-636-6473 (41), or by email: info@alzheimerquebec.ca. You can also visit their website: http://www.alzheimer.ca/en/federationquebecoise.

If you feel isolated or if you want to talk about your situation, you can call the helpline Tel-Aînés at: 514-353-2463.

If you are in a situation of abuse, neglect or mistreatment, you can call your clinic's ombudsman and/or call the helpline Ligne Aide Abus Aînés (1-888-489-2287).

Acknowledgments
Your collaboration is precious and will enable us to successfully conduct this study. Thank you for taking the time to participate despite your heavy schedule.

Signatures

I, _____, freely consent to participate in the study named: « Assessing care models implemented in primary health care for persons with Alzheimer's disease and related disorders».

I have read the above information and I have understood the purpose, nature, benefits, risks and discomforts associated with this study. I am satisfied with the explanations and answers the investigator has given me, if needed, regarding my participation in this project.

_____ _____

Participant's signature Date

A small summary of the results will be sent to the participants who will have written the address where they wish the document to be delivered. **The results won't be available until May 2019. If the address were to change before this date, feel free to give the new address to the investigator.**

_____

Address (postal or electronic) where you want the summary to be sent.

I have explained to the participant the nature, benefits, risks and discomforts associated with the project. I have answered to the best of my knowledge the questions asked by the participant and I have made sure that he/she understood.

_____ _____

Investigator's signature Date

Other consent forms are available upon request by contacting the principal investigator (Dr. Isabelle Vedel) directly