

BMJ Open Case management in primary healthcare for people with complex needs to improve integrated care: a large-scale implementation study protocol

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ABSTRACT

Introduction Case management (CM) is among the most studied effective models of integrated care for people with complex needs. The goal of this study is to scale up and assess CM in primary healthcare for people with complex needs.

Methods and analysis The research questions are: (1) which mechanisms contribute to the successful scale-up of CM for people with complex needs in primary healthcare?; (2) how do contextual factors within primary healthcare organisations contribute to these mechanisms? and (3) what are the relationships between the actors, contextual factors, mechanisms and outcomes when scaling-up CM for people with complex needs in primary healthcare? We will conduct a mixed methods Canadian interprovincial project in Quebec, New-Brunswick and Nova Scotia. It will include a scale-up phase and an evaluation phase. At inception, a scale-up committee will be formed in each province to oversee the scale-up phase. We will assess scale-up using a realist evaluation guided by the RAMESES checklist to develop an initial programme theory on CM scale-up. Then we will test and refine the programme theory using a mixed-methods multiple case study with 10 cases, each case being the scalable unit of the intervention in a region. Each primary care clinic within the case will recruit 30 adult patients with complex needs who frequently use healthcare services. Qualitative data will be used to identify contexts, mechanisms and certain outcomes for developing context–mechanism–outcome configurations. Quantitative data will be used to describe patient characteristics and measure scale-up outcomes.

Ethics and dissemination Ethics approval was obtained. Engaging researchers, decision-makers, clinicians and patient partners on the study Steering Committee will foster knowledge mobilisation and impact. The dissemination plan will be developed with the Steering Committee with messages and dissemination methods targeted for each audience.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This mixed-methods multiple case study using a realist evaluation design includes different conceptual frameworks to guide the intervention implementation and data analysis, drawing conclusions transferable to other jurisdictions.
- ⇒ Recruiting case managers and changing practices may be challenging in the current context where human resources are scarce and overloaded, but it is feasible using targeted strategies.
- ⇒ When developing scaling-up, scale-up committees will plan enablers to overcome these challenges.
- ⇒ An expert will advise the team and scale-up committees to support providers and managers addressing change management during scale-up.
- ⇒ The timeline includes the team's time and capacity for rapid response to meet urgent integrated care-related evidence needs of our partners.

INTRODUCTION

The WHO defines health as *a state of complete physical, mental and social well-being*.¹ However, 18% of people in primary healthcare face interacting challenges among the physical, mental and/or social dimensions of health,² experiencing complex healthcare needs (hereafter 'complex needs'). Yet, as per the inverse care law,³ with increased complexity of people's needs, comes decreased care accessibility, putting people with complex needs at increased risk of poorer outcomes, mainly decreased quality of life and increased disability and mortality risk.⁴ The COVID-19 pandemic highlighted the unmet needs and health inequities experienced by people with complex needs.⁵



Complex needs call for integrated care across providers and sectors.^{6,7} The WHO proposes the following person-centred definition of integrated care: *My care is planned with people who work together to understand me and my carer(s), put me in control, coordinate and deliver services to achieve my best outcomes.*^{7,8} A systematic review on the effects of integrated care reported beneficial impacts on quality of care, care satisfaction and access to care.⁹ A meta-analysis showed a 19% reduction in the probability of hospitalisation when integrated care was compared with usual care.^{10,11}

Case management (CM) is one of the most studied effective models of integrated care,^{7,11,12} recommended to facilitate the appropriate delivery of healthcare services for people with complex needs.¹³ CM is a collaborative approach used to assess, plan, facilitate and coordinate care with the person, their family and the informal caregivers to better support their healthcare needs, through communication and coordination of available resources across all levels of healthcare systems (such as primary, secondary and tertiary care) as well as sectors outside of the health system (eg, community organisations) with the intent to improve individual and health system outcomes.¹⁴ Five systematic reviews concluded that CM was effective for people with complex needs who frequently used healthcare services to improve clinical and social outcomes (eg, alcohol or drug use, homelessness and psychosocial outcomes) and to reduce emergency department (ED) costs.^{11,15–18} Case management is a complex intervention as it includes multiple components such as care coordination, goal setting and planning, education and self management support. Further, it takes many factors into consideration including the personal characteristics and life circumstances of those involved, as well as the context in which the intervention is implementing.^{19,20} Rather than focusing on effectiveness alone, the revised Medical Research Council Framework for developing and evaluating complex interventions encourages consideration and use of diverse research perspectives and the pragmatic choice of research questions and methods.¹⁹

In line with these recommendations, we conducted a programme of research over the last decade, integrating a plurality of designs to evaluate CM from different perspectives and answer stakeholders' questions.^{21–23} A mixed-method randomised controlled trial of CM in primary healthcare showed that people with complex needs who frequently use healthcare services had improved experience with integrated care (eg, improved access to the healthcare system, better communication and coordination among healthcare and community partners, increased involvement in decision-making, improved transitions between services)²¹ and reduced psychological distress.²² A study of CM in hospital settings underscores the necessity of an experienced, knowledgeable and well-trained case manager with interpersonal skills to optimise CM implementation such that patients are more proactive in their care and their outcomes improve.²³ We developed a programme theory of CM in primary healthcare,

highlighting that a trusting relationship between the patient and the case manager fosters the engagement of both individuals and yields positive outcomes.²⁰ At the beginning of the COVID-19 pandemic, a scoping review of CM using telehealth was conducted and revealed that while this approach increases accessibility and sustainability, face-to-face contact is essential to CM success.²⁴ Other teams' projects^{15,16} and authors' work allowed us to develop, pilot and evaluate an effective CM intervention improving the five dimensions of the healthcare system performance (quintuple aim): (1) patients' experience of integrated care²¹; (2) patients' health^{11,15,16,25}; (3) healthcare providers' satisfaction^{23,26}; (4) healthcare systems' efficiency^{11,15} and (5) health equity.²⁷ Following promising small-scale implementation studies,^{23,28,29} research is now needed to inform the implementation of this integrated care CM intervention on a larger scale (scale-up) across similar (expansion) and different health system contexts (extension).³⁰

The goal of this study is to scale-up CM in primary healthcare for people with complex needs who frequently use healthcare services and generate new evidence to inform policies and healthcare system transformation towards more integrated care. In line with the premises of implementation science,³¹ the research questions are (1) which mechanisms contribute to the successful scale-up of CM for people with complex needs in primary healthcare?; (2) how do contextual factors within primary healthcare organisations contribute to these mechanisms? and (3) what are the relationships between the actors, contextual factors, mechanisms and outcomes (Reach, Effectiveness, Adoption, Implementation and Maintenance) when scaling-up CM for people with complex needs in primary healthcare?

METHODS AND ANALYSIS

Study design

The study includes two concomitant phases: the scale-up phase and the evaluation phase. The scale-up phase will follow the four steps of Milat *et al*,³² based on a systematic review of scale-up models, and a Delphi with stakeholders: (1) assess scalability; (2) develop a scale-up plan; (3) prepare for scale-up and (4) scale-up. Step 1 'assess scalability' has already been performed in the projects aforementioned. Steps 2–4 are presented in [table 1](#). A scale-up committee will be formed in each of the three participating Canadian provinces, composed of decision-makers from the Health Ministry/Authority, members of the research team, managers, providers and patient partners, to develop this project, oversee the scale-up phase, and the delivery of its outputs. A scale-up will be done within all primary healthcare clinics in Quebec, six clinics in New-Brunswick (year 2) and eight clinics in Nova-Scotia (year 2). In Quebec, the intervention will be introduced in primary healthcare clinics of 25% of participating regions bi-annually over 2 years (years 2 and 3).

Table 1 Steps 2–4 of the scale-up phase³²

Step 2	Action	Outputs (year 1)
Develop a scaling-up plan	Complete a situational and stakeholder analysis	Social and organisational environment(s) in which the intervention will be scaled up mapped and potential barriers and enablers to scale-up identified (eg, free up time to introduce this new intervention).
	Determine who should be involved in scale-up and what their role will be	Key functions mapped and matched to those who should be involved.
	Confirm resources	Human, technical and financial resources needed to scale up confirmed.
	Write the scaling up plan	Plan presenting a clear and concise case for scaling up the intervention, as well as an overview of how this will be brought about, including a vision of what scaling up will look like when successfully completed.
Step 3	Action	Outputs (year 1)
Prepare for scale-up	Consult with stakeholders	Scaling up plan assessed with stakeholders, and advocacy and communication strategies designed.
	Build a constituency	Broader ‘community of practice’ mobilised to successfully scale-up the intervention.
Step 4	Action	Outputs (years 2–5)
Scale-up (will be iteratively informed by evaluation)	Modify and strengthen organisations	Change management addressed with involved teams through mentoring, leadership development and coaching.
	Coordinate action and governance	Appropriate governance structures put in place with written agreements to identify issues and resolve any conflict that may arise.
	Ensure sustainability	Strategies identified to ensure the intervention will become part of routine practice.

For the evaluation phase (phase 2), a realist evaluation will be conducted according to Pawson and Tilley,³³ a theory-driven approach to evaluate complex systems and processes to explain how and why they are effective, under what conditions and for which populations,³⁴ based on four concepts: context (C), mechanism (M), outcome (O) and context–mechanism–outcome configuration (CMO-C).^{35 36} This will provide an explanation of the relationships between the actors, contextual factors, mechanisms, and outcomes of scale-up.³⁶

An initial programme theory of CM scale-up (year 1—September 2023 to August 2024) will be developed through a realist synthesis, using the RAMESES standard and the following steps³⁷: (1) focusing the scope of the realist synthesis; (2) searching for the evidence; (3) appraising the quality of evidence; (4) extracting the data and (5) synthesising the data. Results will be shared with the scale-up committees from each province at the end of year 1 to inform the scale-up onset. The programme theory will then be tested and iteratively refined (years 2–5—September 2024 to August 2028). A mixed-method multiple case study will be used,³⁸ which is a recognised design for realist evaluations.^{39–44} Ten cases in three provinces will be included (8 cases in Quebec, 1 case in New Brunswick and 1 case in Nova Scotia). A case will be the scale-up of the intervention in a participating region in Quebec or the whole province of New Brunswick and Nova Scotia. Each case will include up to 20 primary healthcare clinics. The inclusion of multiple cases allows for examination of how contextual factors influence

scale-up, for observation of recurring or singular facilitators and barriers, drawing conclusions transferable to other jurisdictions.⁴⁵ It is recommended that 4 to 10 cases be considered⁴⁶ in a multiple case study logic of theoretical replication, in which contrasting results are to be anticipated.⁴⁷

The CM intervention

The proposed CM intervention improved integrated care^{21 23} for people with complex needs who frequently use healthcare services, focusing on four main components in line with Canadian Institutes of Health Research’s Strategy for Patient-Oriented Research (SPOR)⁴⁸: (1) evaluation of the person’s needs and preferences; (2) codevelopment and maintenance of a person-centred individualised services plan, with the person, family and other providers; (3) coordination of services focusing on the person’s needs across all interdisciplinary and multisectoral partners (eg, community organisations and other relevant sectors within and beyond the healthcare sector) and (4) education and self-management support for the person and their family.^{49–52} The CM intervention is consistent with the practice standards of the National Case Management Network of Canada⁵³ and the Case Management Society of America¹⁴ and focused on people’s experience of integrated care.⁵³ A bilingual French-English toolkit was developed aimed at training case managers and promoting best practices (standards of care, case finding and clinical tools, change management strategies, etc). The intervention is informed by

technology, evidence and best practices, patient partner input as well as by clinical and organisational data to continuously improve health system performance at a reduced cost.^{54–56}

Clinics and participants

The scale-up committees will recruit the 10 scalable cases (including a total of approximately 80 primary healthcare clinics) by wave of implementation (four waves over 2 years in Quebec and one wave in both New Brunswick and Nova Scotia in year 2), using a purposeful sampling strategy,⁵⁷ to represent real-world differences in terms of urban/rural context, size and population diversity.⁴⁵

Each primary healthcare clinic will recruit at least 30 adult people with complex needs who frequently use healthcare services to participate for 1 year, ensuring diversity in relation to age and socioeconomic/cultural factors (eg, gender, ethnicity, language, ability) and the inclusion of indigenous peoples. Since ED visits are a good proxy of frequent use,⁵⁸ the criteria to include the patients will be four visits or more to the ED in the previous year (recognised definition of frequent use⁵⁹) and a score ≥ 19 (cut-off for complex needs)⁶⁰ at the INTERMED Self-Assessment (IMSA),⁶¹ a 15 min questionnaire, available in many languages, measuring the complexity of adult needs with good psychometric properties.^{62–66} IMSA includes 20 questions subdivided into four domains: biological, psychological, social and health system.

Conceptual framework

Informed by the Reach, Effectiveness, Adoption, Implementation and Maintenance Framework,^{67 68} scale-up outcomes will include (1) Reach, the percent and representativeness of primary healthcare clinics willing to implement the intervention in each case, and of patients accepting to receive the intervention; (2) Effectiveness, the impact of the intervention on targeted outcomes (experience of integrated care and quality of life); (3) Adoption, the per cent and representativeness of clinics, which delivered the intervention in each case, and of patients receiving the intervention; (4) Implementation, the consistency with which the four components of the intervention are delivered and (5) Maintenance, the degree to which the intervention is sustained over time.

Mixed methods data collection

A first round of qualitative data will be collected in the first 3 months of scale-up in each case (years 2 and 3) about early Reach, Adoption and Implementation facilitators and challenges to inform scale-up committees. Semistructured individual interviews will be conducted^{69 70} with case managers (n=2/case) and managers (n=5/case) and focus groups with healthcare providers (one focus group of 6–8 providers/case). We will ensure variation for age and diverse socioeconomic/cultural identity factors (eg, gender, ethnicity including self-identification as indigenous, language, disability) in recruiting participants for both rounds. Interview guides will be reviewed by the

scale-up committees. These first-round data will be analysed using an inductive thematic analysis⁷¹ to outline facilitators, challenges, pitfalls and solutions. A second round of qualitative data collection will be conducted 18 months after the introduction of the intervention in the case to identify and better understand contexts, mechanisms, and certain outcomes—Reach and Adoption (representativeness), Implementation and Maintenance (for sustainability over longer time)—for developing CMO-C. Semistructured individual interviews will be conducted to capture the richness of the perspectives^{69 70} of various stakeholders involved in the scale-up: patients (n=5/case); case managers (n=5/case) and managers (n=5/case). Focus groups will be conducted with the scale-up committee from each province and with healthcare providers from various professions in each case (two focus groups of 6–8 providers/case). Interview guides will be informed by the initial theory developed in the realist synthesis and tailored to the participant groups. Interviews and focus groups will be performed using realist interview techniques.^{72 73} Participants will be asked to share how they think their experience relates to this theory and to reflect on what may explain the outcomes in their setting.⁷⁴ Data collection will be iterative until saturation is reached.^{33 72} All interviews and focus groups of both rounds will be digitally recorded and transcribed verbatim.

Quantitative data will be used to describe characteristics of the patients and measure certain outcomes – Percentage of Reach and Adoption, and Effectiveness (patients' experience of integrated care and quality of life) – for developing CMO-C. Self-administered questionnaires will be administered to all participants at baseline to describe their characteristics: age, sex, gender, sexual orientation, ethnicity, self-identification as Indigenous, first language, education, occupation, family income and perception of their economic situation, food security status, social support, health literacy, multimorbidity, situation of disability and self-management. All sociodemographic variables will be measured with the questions of the Canadian Community Health Survey.⁷⁵ Health literacy will be measured using the questionnaire of Chew (three items),^{76 77} multimorbidity with the Disease Burden Morbidity Assessment (21 items),^{78 79} and self-management with the Partners in Health Scale (12 items).^{80 81} The total required time to complete the questionnaires is about 30 min. Complex needs will have already been measured using IMSA⁶¹ prior to recruitment. To evaluate the effectiveness, patients' experience of integrated care and quality of life will be measured before the intervention and after 1 year with the Patient Experience of Integrated Care Scale (14 items)⁸² and the SF-12v2 (12 items).⁸³ French and English validated versions of all questionnaires are available and they present good psychometric properties. A research assistant will offer support to patients who wish to complete the questionnaire, especially with those who have difficulty reading, seeing and/or have other needs to be considered. The

budget includes funds for translation of questionnaires into other languages.

Analysis plan and data integration

Reach and Adoption (representativeness), Implementation, and Maintenance will be evaluated during interviews and focus groups. Qualitative data will be uploaded to NVivo V.12 and analysed by research assistants from the three provinces, guided by the initial programme theory from the realist synthesis. During the analysis, researchers and research assistants will remain open to emergent themes that support further theory refinement. For the quantitative analysis, descriptive statistics will be performed for quantitative variables. Percentage of Reach and Adoption will be calculated. Considering that both effectiveness variables are continuous (experience of integrated care and quality of life) and that these variables will be used to develop CMO-C in each case (and not to calculate non-biased quantitative effects⁸⁴), pre and postresults for each case will be compared using Student's t-test (or Mann-Whitney if not normally distributed) employing SPSS V.29. During the data integration, CMO-C will be identified for each of the five outcomes (Reach, Effectiveness, Adoption, Implementation and Maintenance), first within each case and then across cases. The monitoring committee (principal investigators, patient partners and research assistants in each province) and the steering committee (all members of the team who will contribute the content expertise, technical and scientific expertise) will use a dynamic process to compare and clarify understanding of contexts, mechanisms and outcomes for different subpopulations (gender and other sociocultural identity factors will be considered) to examine in what ways the intervention works or does not work among sub-populations.⁸⁵ A matrix⁸⁶ will be constructed using columns to separate components of the initial theory and rows representing different cases. This approach will facilitate within-case analysis, highlighting similarities or discrepancies across data sources, and cross-case analysis by identifying patterns. Analysis of CMO-C will help complete, confirm or modify the initial theory and ultimately produce a refined theory. Figure 1 illustrates data integration. Results will be reported using the RAMESES II reporting standards for realist evaluation.⁸⁷ The output of this analysis plan will be a programme theory explaining

how and why different mechanisms operate in different contexts to generate different outcomes among different subpopulations and will provide context-sensitive explanations about scale-up of CM. Results will be shared with scale-up committees to inform sustainability.

Patient and public involvement

As members of the research team, patient partners were involved in the development of the research objectives and the planning of the research design. They will also contribute to the development and validation of data collection tools (ie, interview guides), development of patient friendly material for recruitment that will appeal to their interests and help them understand what the programme is about. They will finally be involved in the validation of data analysis tools, analysis of qualitative data and translation and dissemination plan, contributing to knowledge translation activities, such as conference presentations and manuscripts drafting and reviewing.

ETHICS AND DISSEMINATION

Ethics approval and consent to participate

Ethics approval was obtained from the Comité d'éthique du Centre intégré universitaire de santé et services sociaux de l'Estrie—Centre Hospitalier Universitaire de Sherbrooke (project number : MP-31-2024-5175). All participants will provide informed consent prior to participation and all measures will be taken to ensure respect and confidentiality of the participants.

Impact on research, patients and healthcare system

This study will advance the field of implementation science by delivering the first programme theory on CM scale-up. This new scientific knowledge on integrated care and implementation science will generate actionable evidence to inform healthcare transformation. Many people with complex needs in three provinces will benefit from receiving an innovative intervention, including interdisciplinary and multisectoral collaborations and partnerships within and beyond the healthcare sector. The research team will also build a large network providing a nurturing environment sparking new collaborations among interdisciplinary and intersectoral stakeholders, trainees and researchers, and building human

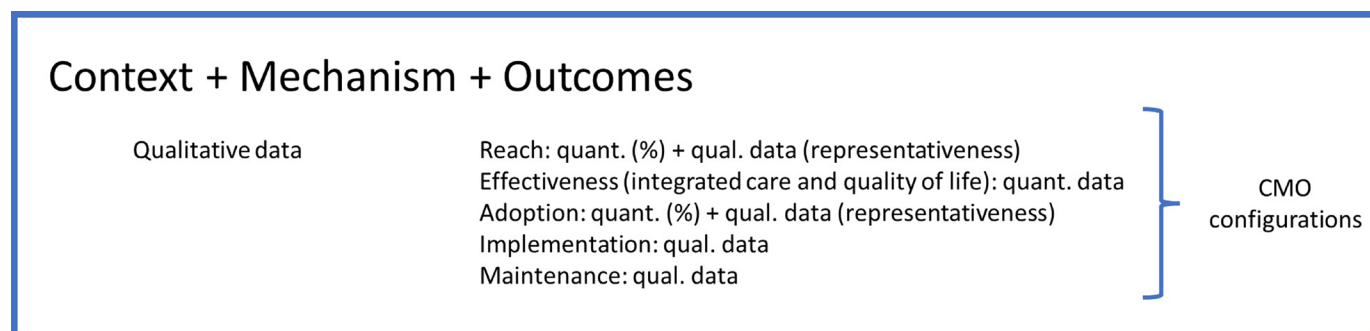


Figure 1 Data integration. CMO, context–mechanism–outcome.

and organisational capacity. Engaging knowledge users from each audience on the steering committee will foster knowledge mobilisation and impact. The research team has already developed partnerships with many of these knowledge users over the past several years,^{88–90} and their perspective will remain central to the research and implementation approach. The dissemination plan will be developed with the steering committee with messages and dissemination methods targeted for each audience (eg, presentations and articles for researchers, infographics for decision-makers and providers and news on social media for the public).

Feasibility assessment and sustainability considerations

As recommended by Milat *et al.*,³² a deeper reflection is planned within scale-up committees to adapt the intervention to the context and put all conditions in place to ensure the intervention remain incorporated into practice after the grant's completion. Our study relies on our recognition of the importance of successfully implementing and sustaining CM for improving the quintuple aim of the healthcare system: (1) patients' experience of integrated care; (2) patients' health; (3) healthcare providers' satisfaction; (4) healthcare systems' efficiency and (5) health equity.

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