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Protocol for a mixed-method analysis of implementation of case management in primary care for frequent users of health care services with chronic diseases and complex care needs

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3 1 **Protocol for a mixed-method analysis of implementation of case management in primary care for**
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5 2 **frequent users of health care services with chronic diseases and complex care needs**
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52 23 **Word Count:** 6508 words
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3 24 **Abstract**
4

5 25 *Introduction:* Case management (CM) in a primary care setting is a promising approach to integrating
6
7 26 and improving health care services and outcomes for patients with chronic conditions and complex care
8
9
10 27 needs who frequently use healthcare services. Despite evidence supporting CM and interest in
11
12 28 implementing it in Canada, little is known about how to do this. This research aims to identify the
13
14 29 barriers and facilitators to the implementation of a CM intervention in different primary care contexts
15
16 30 (objective 1) and to explain the influence of the clinical context on the degree of implementation
17
18 31 (objective 2) and on the outcomes of the intervention (objective 3).
19
20
21 32

22
23 33 *Methods and analysis:* A multiple-case embedded mixed methods study will be conducted on CM
24
25 34 implemented in ten primary care clinics across five Canadian provinces. Each clinic will represent a sub-
26
27 35 unit of analysis, detailed through a case history. Cases will be compared and contrasted using multiple
28
29 36 analytical approaches. Qualitative data (objectives 1 and 2) from individual semi-structured interviews
30
31 37 (N=130), focus group discussions (N=20) and participant observation of each clinic (36 hours) will be
32
33 38 compared and integrated with quantitative (objective 3) clinical data on services use (N=300) and
34
35 39 patient questionnaires (N=300). An evaluation of intervention fidelity will be integrated into the data
36
37 40 analysis.
38
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41
42

43 42 *Ethics and dissemination:* This project received approval from the CIUSSS de l'Estrie – CHUS Research
44
45 43 Ethic Board (project number MP-31-2019-2830). To our knowledge, this is the first study to analyze the
46
47 44 implementation of CM in Canadian primary care settings. Results will provide the opportunity to refine
48
49 45 the CM intervention and to facilitate effective evaluation, replication and scale-up. This research
50
51 46 provides knowledge on how to respond to the needs of individuals with chronic conditions and complex
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3 47 care needs in a cost-effective way that improves patient reported outcomes and health care use, while
4
5 48 ensuring care team well-being.
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9

10 50 **Keywords**

11
12 51 Primary health care; case management; chronic illness; complex care needs; frequent users;
13
14 52 implementation; evaluation; context, intervention fidelity.
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17 53

18 54 **Article Summary**

19 55 *Strength and limitations of this study*

- 20
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23 56
- 24 • This protocol details the steps for the implementation of a case management (CM) intervention
25 for frequent users of health services with chronic conditions and complex care needs.
26 57
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28 58
 - 29
30 59 • A novel conceptual model for CM implementation is proposed based on the integrative
31 functions of primary care and the effective implementation of health care interventions.
32 60
33
34 61
 - 35
36 62 • The barriers and facilitators to implementing CM will be detailed and the influence of the clinical
37 context on the degree of implementation and on the outcomes of the intervention will be
38 evaluated.
39 63
40
41 64
 - 42
43 65
 - 44 66 • While the proposed conceptual model does not cover every possible construct for effective
45 implementation, an inductive approach to data analysis will be used to allow for emergent
46 themes and all stakeholders will participate in data analysis in order to ensure validity.
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51 69

52 53 54 70 **Introduction**

1
2
3 71 A priority for primary care research and the Canadian health care system is to address the complex
4
5 72 needs of patients who frequently use health care services (1, 2). These patients may suffer from a
6
7 73 combination of chronic illnesses, mental illness and/or socioeconomic vulnerabilities (3-5). Patients with
8
9
10 74 chronic illnesses typically have a wide range of needs that require them to adopt new behaviours, such
11
12 75 as meeting with care providers on a regular basis, adhering to treatment plans, monitoring their
13
14 76 symptoms and making important decisions while also changing aspects of their lifestyle to preserve their
15
16 77 physical, psychological and social well-being (6-8). Far from “misusing” the health care system, studies
17
18 78 show that frequent users do so in an attempt to address unmet needs for health care and social services
19
20 79 (3, 9). Studies suggest that these attempts are often unsuccessful and result in repetitive use of services
21
22 80 in an uncoordinated way through frequent hospitalizations or visits to the emergency department (10,
23
24 81 11). This leads to negative experiences for both the care providers and for the patients, poor health
25
26 82 indicators and high mortality rates for the patients and considerable costs to the health care system (11-
27
28 83 13). Several countries have therefore experimented with new models of health care delivery that can
29
30 84 achieve better coordination and integration of services, some of which have been found to reduce
31
32 85 fragmentation and improve care continuity (14). Early examples of such models include the Chronic Care
33
34 86 Model (CCM) (15) and the Innovative Care for Chronic Conditions framework (16). These models
35
36 87 emphasize the importance of providing support to patients for self-management and decision-making,
37
38 88 seeking innovative approaches within available clinical information systems and proposing ways to
39
40 89 redesign the delivery of health care (14).
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48 91 Individuals with chronic illnesses require organized care and close follow-up delivered over an extended
49
50 92 period of time (17). The primary care setting is the most suitable for supporting individuals with chronic
51
52 93 illnesses due to its defining features of patient-centered first contact, continuous, comprehensive, and
53
54 94 coordinated care (17, 18). Health systems built on the principles of primary care achieve better health
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3 95 outcomes and greater equity, at a lower cost (19) than systems with a specialty care orientation (18).
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5 96 Integrated care may be achieved in a primary care setting through the creation of inter-sectorial linkages
6
7 97 between health and social policies, i.e. the linking of health care to other human service systems (eg.
8
9 98 long-term care, education, vocational and housing services) in order to improve clinical outcomes,
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11 99 patient and provider satisfaction and efficiency (14, 18, 20).
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100

101 **Case management**

102 Case management (CM) in a primary care setting is one approach that has been shown to increase the
103 integration of health services (21, 22) and to improve care and outcomes for patients with chronic
104 conditions and complex needs who frequently use health care services (23, 24). Defined as “a
105 collaborative, client-driven process for the provision of quality health and support services through the
106 effective and efficient use of resources” (25), CM is among the best models available to mitigate the
107 high utilization of the health care system and associated costs (23, 26). An adaptive randomized trial of
108 CM interventions targeting frequent users of health services demonstrated that appropriate patient
109 identification, staff training and centralized intervention delivery are components of CM that can be
110 successfully implemented on a large scale and lead to a decrease in health consumption (27). A recent
111 systematic review (10) identified the most common components of CM interventions for chronically ill
112 patients including the integration of services between hospitals and home or other facilities, regular
113 home visits, regular telephone calls, individual assessment and care planning, education and self-
114 management support, psychosocial support, and ongoing supervision and assessment. The same study
115 found that a reduction in hospital admission rates was reported after implementation of CM
116 interventions (10). A systematic review of literature on the characteristics of CM interventions in
117 primary care reporting positive outcomes for frequent users of health care revealed three essential
118 requisites for success. First, the intervention must identify and target patients with the greatest needs,

1
2
3 119 and who are therefore most likely to benefit from the intervention. Second, the intervention must be
4
5 120 delivered with sufficient intensity (i.e. frequently enough or with a high enough dose) to produce the
6
7 121 desired effect. Third, an interdisciplinary approach to care planning is preferred, where a variety of
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9
10 122 professionals from both care and cure sectors actively participate in the intervention (28).

11
12 123
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14 124 Despite the evidence base supporting CM as an intervention for frequent users, little evidence exists
15
16 125 about the facilitators and barriers to CM implementation (29). Although there is a strong interest in
17
18 126 implementing CM in the Canadian primary care setting, little information is available on how to do this.
19
20
21 127 CM has rarely been implemented and documented systematically in order to identify and replicate best
22
23 128 practices. This protocol is part of a larger research program on CM in primary care for frequent users of
24
25 129 healthcare services with chronic diseases and complex care needs (2) and details the steps for the
26
27 130 implementation analysis that was not described in the original protocol of the whole program.

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31 32 132 **Objectives**

- 33
34 133 1) To identify the barriers and the facilitators to implementation of the CM intervention in different
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36 134 primary care contexts.
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38 135 2) To explain the influence of the clinical context on the degree of implementation.
39
40 136 3) To evaluate the influence of the context of implementation on the outcomes of the intervention.
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44 45 138 **Methods/Design**

46 47 139 *Conceptual model*

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50 140 The conceptual model developed to guide this research protocol was informed by two multi-level
51
52 141 conceptual frameworks in order to analyze the effective implementation of an integrative primary care
53
54 142 intervention. Multi-level frameworks represent the interacting layers of phenomena inherent to
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1
2
3 143 organizations and are commonly used to develop theories, measure and analyze phenomena while
4
5 144 accounting for the complexity inherent to these systems (30, 31). Multi-level interventions mobilize
6
7 145 resources and facilitate linkages across organizations “to solve coordination problems and adapt to
8
9 146 change” (31).
10
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12 147

13
14 148 The first framework used to guide this research protocol is the Valentijn et al. framework for integrated
15
16 149 care based on the integrative functions of primary care (18). The concept of integration originates from
17
18 150 organizational theory and refers to “the quality of the state of collaboration” that may exist among the
19
20 151 multiple levels of service delivery with the purpose of achieving a required mutual effort and agreement
21
22 152 (14). Integrated health care interventions are a means to improve access, quality and continuity of
23
24 153 services in a more efficient way, especially for people with complex needs (18) . This framework
25
26 154 describes the central role of primary care in integrating the multiple levels of health care: system
27
28 155 integration at the macro level; organizational and professional integration at the meso level; clinical
29
30 156 integration at the micro level; and functional and normative integration to link the macro, meso and
31
32 157 micro levels (18). Valentijn et al.’s framework is intended for analyzing and testing the causal
33
34 158 relationships within and between the integration levels, which interact to varying degrees depending on
35
36 159 the specific context of health care delivery (18). This framework is therefore suitable for studying the
37
38 160 different primary care contexts of the CM intervention from the perspective of integrated care and is
39
40 161 the unifying thread to the implementation and evaluation of the CM intervention.
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47
48 163 The second framework used to guide this research protocol is the Consolidated Framework for
49
50 164 Implementation Research (CFIR), intended to promote effective implementation and formative
51
52 165 evaluation of complex, multi-level interventions in health care (32). The CFIR provides a taxonomy of
53
54 166 constructs that can be used to understand, measure and assess implementation across a variety of
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3 167 contexts. The constructs are categorized into five major domains that similar to the Valentijn et al.
4
5 168 (2013) framework, reflect a multilevel perspective. The *outer setting* refers to the economic, political
6
7 169 and social context in which the implementing organization is situated and corresponds to the macro
8
9
10 170 level. The *inner setting* corresponds to the meso level of the organizational context and includes
11
12 171 constructs such as the structure and culture of the implementing organization. At the micro level, the
13
14 172 *individuals* involved in the intervention are described. The CFIR includes two additional domains: the
15
16 173 *characteristics of the intervention*, a description of its core components, and the *implementation*
17
18 174 *process*, considered a dynamic, non-sequential and non-linear domain that can stem from any level,
19
20
21 175 macro, meso or micro (32). When understood, process provides insight that links the various levels of
22
23 176 analysis and shed light on the causal or generative mechanisms underlying the intervention being
24
25 177 studied (32, 33). Barriers and facilitators may arise at multiple levels of intervention delivery, as external
26
27
28 178 influencers, organizational or professional components or during the process by which an intervention is
29
30 179 adopted within an organization (32).

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32 180
33
34 181 The conceptual model developed to guide this research protocol is presented in Figure 1. On the left
35
36 182 side of the figure are the core components of the CM intervention, described in the proceeding section.
37
38
39 183 During implementation, the intervention takes on unique properties and characteristics related to the
40
41 184 local context in which it is introduced (referred to in Figure 1 as the *context of implementation*) (32). The
42
43 185 context of implementation includes macro, meso and micro level determinants, depicted by the
44
45 186 concentric circles in the middle of the figure. The process of implementation is represented by the arrow
46
47
48 187 at the bottom of the figure, which represents the dynamic and continuous nature of intervention
49
50 188 implementation. Finally, to the right, are the final expected outcomes of the intervention, based on the
51
52 189 quadruple aims to optimize health system performance: improved patient outcomes, health care use,
53
54
55 190 care team well-being and cost effectiveness (34).

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5 192 Constructs were selected from both Valentijn et al. (2013) and Damschroder et al. (2009) to reflect the
6
7 193 objectives of this research. The characteristics of the intervention after implementation in a particular
8
9 194 local context will be analyzed based on the intervention's *adaptability* to meet local needs, its *relative*
10
11 195 *advantage* to the context, and its *complexity* or difficulty of implementation. At the macro level, how
12
13 196 the intervention contributes to *system integration* will be examined, including vertical integration and
14
15 197 collaboration across care sectors and horizontal integration through a holistic view of the patient (18).
16
17 198 This construct reflects the implementing organization's knowledge of the needs of its patient population
18
19 199 and its ability to respond with appropriate structures, techniques and resources (*patient needs and*
20
21 200 *resources*) (32). The organization's degree of networking with external services and structures
22
23 201 (*cosmopolitanism*) will be examined, as well as its formal strategies and policies supporting external
24
25 202 linkages (*external policies and incentives*).
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30 203
31
32 204 At the meso level, *organizational* and *professional integration* will be examined, which refer to the
33
34 205 partnerships between services and professionals within the implementing organization. The *structural*
35
36 206 *characteristics* of the organization and the *implementation climate* will be described. At the micro level,
37
38 207 interest will shift to *clinical integration*, which reflects the level of coordination and coherence of the
39
40 208 primary care delivery process (18). The *knowledge and beliefs* of the various professionals involved in
41
42 209 the intervention will be examined, as well as their perceived *self-efficacy* to implement CM, and their
43
44 210 *individual stage of change*, which refers to their progress towards full adoption and sustained use of the
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46 211 intervention (32).
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52 213 Finally, the process of implementation will be analyzed by examining how the CM intervention was
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54 214 planned and executed at the local level, how professionals were mobilized and engaged for participation
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3 215 in the intervention, and by examining the mechanisms put in place to discuss and provide feedback
4
5 216 about the experience, progress and quality of implementation (*planning/executing; engaging;*
6
7 217 *reflecting/evaluating*). These constructs reflect the level of *functional* and *normative integration*
8
9
10 218 resulting from the implementation of the intervention: how the implementing organization mobilized
11
12 219 management functions in support of the intervention, as well as the degree of development of a shared
13
14 220 goal or mission among participating individuals and partner organizations for the implementation of the
15
16 221 intervention (18).
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21 223 *The intervention*

22
23 224 An intervention was designed to reflect the standards of practice of the National Case Management of
24
25 225 Canada as well as the Case management society of America (25, 35). The activities of the intervention
26
27 226 follow the Canadian Institutes for Health Research (CIHR) Strategy for Patient Oriented research and
28
29 227 incorporate the integration characteristics of the National Collaboration for Integrated Care and Support
30
31 228 (36, 37). Patients with chronic conditions most often seek and receive comprehensive care in a primary
32
33 229 care setting (38) and the leadership of a case manager who is experienced in primary care has been
34
35 230 shown to facilitate the successful implementation of chronic care models (39). The CM intervention is
36
37 231 therefore designed to be delivered by a primary care health professional in a primary care clinical setting
38
39 232 over a period of 12 months.
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44
45 234 In consideration of these guidelines and of the results of previously cited studies (10, 11, 23, 27, 28), an
46
47 235 intervention was designed comprised of four main components: 1) evaluation of patient needs and
48
49 236 preferences; 2) co-development and maintenance of a patient-centered individualized services plan; 3)
50
51 237 coordination of services among all partners; and 4) education and self-management support for patients
52
53 238 and families.
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240 1. Evaluation of patient needs and preferences

241 The identification of patients who are in need of intervention and who stand to benefit the most from
242 CM is an essential first step (27, 28), ideally executed by an interdisciplinary team (5, 40). Patients are
243 identified by searching administrative data or clinical records in addition to their referral for the CM
244 intervention by primary care professionals. This approach combines clinician judgement with objective
245 data from electronic medical record (EMR) or administrative databases (2, 41). The CM intervention
246 targets patients who present with at least one chronic illness, including mental illness, who frequently
247 use health services as determined by 4 or more emergency department visits or hospitalizations in the
248 previous 12 months, and who have complex needs as determined by the care team. Once a patient has
249 been identified for inclusion in the CM intervention, the case manager examines the patient's medical
250 records going back 12 months in order to understand the reasons for the frequent use of services. The
251 case manager identifies the patient's physical and/or mental illnesses as well as social challenges such as
252 insecure housing or employment, poverty, violence, substance use disorders, etc. The case manager also
253 documents the health and social services previously provided to the patient, as well as the names, roles
254 and contact information of professionals currently involved with the patient or who may eventually be
255 called upon to participate in the care of the patient.

256

257 The case manager validates with the patient the information collected from the medical records and
258 determines the patient's personal needs and preferences for future services and resources. This step
259 constitutes the first in-depth interaction between the case manager and the patient, and is essential for
260 building mutual trust and respect (21), for establishing a patient-centered care process, and for
261 encouraging the commitment of the patient as a partner in the care process (42, 43). The patient may
262 prefer to be accompanied by a caregiver or advocate with lived experience of the patient's health

1
2
3 263 situation who can assist in navigating the health and social services system (44). When referring to “the
4
5 264 patient” in this article, we also refer to an individual who may stand in for the patient at any point
6
7 265 during the intervention. Finally, the case manager seeks the patient’s consent to communicate with
8
9
10 266 potential care professionals throughout the intervention and ensures that the patient understands and
11
12 267 agrees to the next step of the intervention: the creation of an Individualized Services Plan (ISP). The ISP
13
14 268 is a tool for planning and coordinating tailored services intended to give meaning and direction to the
15
16 269 patient in consideration of his or her life goals (45), personal environment, resources and culture, in
17
18 270 collaboration with a multidisciplinary team of professionals (46) and health and social services
19
20
21 271 organizations.
22

272

273 2. Co-development and maintenance of a patient-centered ISP

274 The ISP for patients with chronic conditions may lead to improvements in physical and psychological
275 health, as well as in their ability to self-manage their condition (46-48). It is among the most commonly
276 used strategies in CM interventions (10, 11). The case manager identifies resources available in the local
277 health and social services network and within the community that may be appropriate for the patient.
278 This involves a holistic analysis of the patient’s situation and the identification of clinical-administrative
279 issues and a final list of care professionals that will be invited to examine the patient’s situation. These
280 may be health care and social services professionals, managers or representatives of community
281 organizations. The case manager communicates directly with targeted care professionals to request
282 their involvement, to ensure that the reason for the intervention is understood and to agree upon a
283 mutually convenient date, time and place for an ISP meeting with the patient. The case manager
284 prepares the agenda for the ISP meeting and communicates with the patient to reconfirm consent
285 regarding the professionals who will participate in the meeting and to maintain a relationship of trust

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2
3 286 and transparency with the patient. The ISP meeting is ideally held in-person, but may be done by phone
4
5 287 or online.
6

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9
10 289 At the beginning of the ISP meeting, the care team reviews the potential resources and services that
11
12 290 may be proposed to the patient prior to the patient's arrival. This allows the care team to collaboratively
13
14 291 examine the patient's situation, needs and preferences and to mobilize their multidisciplinary
15
16 292 perspectives (46). The ISP is then developed with the patient and their advocate upon their arrival. The
17
18 293 ISP includes a maximum of 3 or 4 objectives in line with the patient's overall expectations and life
19
20 294 project (49). The group proposes preferred methods of communication and strategies for exchanging
21
22 295 information for the duration of the intervention. The case manager writes up the ISP in plain language
23
24 296 and validates that the patient understands and agrees to it.
25
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28 297

29
30 298 3. Coordination of services among all partners
31

32 299 Patients with chronic illnesses and complex care needs are often cared for by multiple providers in
33
34 300 various locations and experience difficulty navigating the health system and other resources resulting
35
36 301 in unmet needs, a lower quality of life and higher mortality rates (48). A coordinated response by care
37
38 302 providers that promotes patient empowerment over an extended period of time is recommended (14).
39
40 303 In this intervention, the case manager transmits a copy of the written ISP to the patient and the care
41
42 304 team and follows-up regularly with the patient's primary care providers in the clinical setting, ensuring
43
44 305 active engagement and direct communication. As the principal contact-person and advocate for the
45
46 306 patient, the case manager establishes contact with the services or resources identified in the ISP,
47
48 307 providing a personalized reference for the patient, explaining the case and informing care professionals
49
50 308 of past and potential challenges facing the patient.
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3 310 Regular communication and follow-up encourages the patient's active engagement in the intervention,
4
5 311 a strategy that has been shown to reduce future use of emergency services (26, 50, 51). The case
6
7 312 manager talks to the patient about their preferred method for reaching the case manager and other
8
9
10 313 relevant services. Adherence to the ISP throughout the intervention is ensured by maintaining contact
11
12 314 with the care professionals involved with each patient, and by verifying if the patient's goals have been
13
14 315 attained. The ISP should be reviewed at least once every 3 months. If the patient desires a change in
15
16 316 their ISP, or if a care professional identifies any issues throughout the intervention, the case manager
17
18 317 reassesses the situation with the patient and adjusts the ISP as necessary.
19
20

21 318

23 319 4. Education and self-management support for patients and families

25 320 Self-management support was found to be the strategy most frequently associated with health
26
27 321 improvements in patients with chronic diseases in a primary care setting (17). Education and self-
28
29 322 management support activities aim to increase the patient's skills, confidence and motivation to control
30
31 323 and manage their symptoms and to follow their ISP with structured support for problem solving and
32
33 324 continuous assessment of the patient's objectives and progress (52). This component of the intervention
34
35 325 is considered an ongoing and transversal process to be performed as needed throughout the
36
37 326 intervention.
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40 327

43 328 Case managers aim to develop the patient's ability to monitor their condition, take appropriate action
44
45 329 and identify when and how to ask for professional help by assessing the patient's knowledge and
46
47 330 learning needs and suggesting beneficial activities, such as journaling symptoms and vitals, and
48
49 331 informational resources based on the patient's unique situation. Case managers are trained in
50
51 332 motivational interviewing, a "client-centered, directive communication method aimed at changing
52
53 333 behavior" (53). The case manager supports the patient to set realistic goals through a "smart" action
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3 334 plan that includes specific behavioral goals that are measurable and attractive to the patient, that may
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5 335 be accomplished in a realistic time frame and that build on previous positive experiences. The case
6
7 336 manager helps the patient prepare for meetings with the various care professionals to ensure that the
8
9
10 337 patient is empowered to communicate his or her goals and to receive the desired care. Patients are
11
12 338 coached on how to effectively communicate with their relatives, to establish expectations, and to
13
14 339 ensure a successful care partnership.

16 340 *Study setting*

18
19 341 The CM intervention will be implemented in ten primary care clinics, each representing a unique case.
20
21 342 Two clinics were selected from each of the five participating Canadian provinces of Newfoundland, Nova
22
23 343 Scotia, New Brunswick, Québec and Saskatchewan using a purposeful sampling strategy (54). Clinics
24
25 344 were selected that had not previously implemented CM and that were interested in implementing the
26
27 345 CM intervention and participating in the research project. The interest of a health care professional, a
28
29 346 nurse or a social worker, to develop the role of the case manager and to be available to dedicate
30
31 347 approximately 1 day per week to the study was essential. The case manager was required to have
32
33 348 primary care experience and was offered training in the intervention and continuous support and
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35 349 follow-up through the establishment of a community of practice.
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41 351 *Patient and public involvement*

42
43 352 Patient partners were involved in this research since its inception, including the design of the research
44
45 353 questions and the development of this protocol of which they are coauthors (VS and MW). They
46
47 354 continue to provide their expertise regarding study feasibility and acceptability. They will be involved in
48
49 355 the interpretation of data and in the dissemination of results.
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55 357 *Timeline*

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3 358 The implementation of the CM intervention will take place over a period of one year. A cohort of
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5 359 patients will be recruited at each clinic and will be administered the intervention over the course of 12
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7 360 months.
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11 362 *Patient recruitment*

12 363 Each clinic will identify 30 patients for enrolment in the CM intervention, for a total of 300 patients
13
14 364 across the 5 participating provinces. Patients are selected who are most likely to benefit from CM, based
15
16 365 on the clinical judgement of the case manager and the family physician. Criteria for inclusion in the
17
18 366 study are as follows: 1) living with at least one chronic physical or mental illness; 2) frequent user of
19
20 367 health care services ie. having 4 or more hospitalizations or visits to the emergency department in the
21
22 368 previous year; 3) having complex care needs as determined by the care team. Patients who are ineligible
23
24 369 for participation in the study include individuals whose prognosis is less than one year or who are
25
26 370 exhibiting a loss of autonomy.
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31 372 *Study design*

32 373 The implementation analysis is designed as a multiple-case embedded study, where each of the ten
33
34 374 clinics will represent one sub-unit of analysis. This design is best-suited to analyzing complex
35
36 375 interventions implemented in variable and dynamic settings, and where the underlying context is
37
38 376 difficult to isolate from the intervention itself (55). This design allows several levels of analysis, the
39
40 377 observation of various organizational processes or behaviours, the examination of the context and
41
42 378 process of implementation, and the interaction among involved stakeholders (56). It also favors the use
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44 379 of mixed methods of data collection and analysis (57).
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51 381 *Data collection*

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3 382 To accomplish the objectives of this research, a mixed methods data collection is planned. Multiple
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5 383 sources of information will be used to collect both qualitative and quantitative data.
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10 385 **Individual semi-structured interviews** will be administered to all case managers (1-2 per clinic) and
11
12 386 clinic managers (1 per clinic) at each study site at the start of the intervention (T0), and at the end of the
13
14 387 intervention (T12 months). At the end of the intervention (T12 months), 10 patients and/or their
15
16 388 representative will also be interviewed. Patients will be purposefully selected to achieve maximum
17
18 389 variation (54). A total of 130 individual semi-structured interviews will be administered across the 10
19
20 390 participating clinical sites. An interview guide was developed composed of 18 open-ended questions
21
22 391 based on the constructs of the conceptual model (Figure 1). The first part of the interview will address
23
24 392 the clinical context of the CM intervention, the services offered at each clinical site to patients with
25
26 393 chronic conditions and complex care needs, and the way in which the clinic works with other health and
27
28 394 social services organizations. In the second part of the interview, questions will be asked about the
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30 395 implementation of the four components CM intervention, the context of implementation, the barriers
31
32 396 and facilitators to intervention, and about individual perceptions and attitudes towards the intervention.
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39 **Focus groups**

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41 399 A focus group discussion will be held at each participating clinic, once at the beginning of the
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43 400 intervention (T0) and once at T9-12 months, for a total of 20 focus groups throughout the CM
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45 401 intervention. Primary care providers, including physicians, nurses, social workers, pharmacists and any
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47 402 health and social services professionals involved in the intervention will be invited to take part in a
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49 403 discussion facilitated by a member of the PriCare research team. The interview guide described above
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51 404 for the semi-structured interviews will be adapted and used to guide the focus group discussion.
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3 406 **Non-participant observation**
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5 407 The activities of the intervention at each of the ten clinical sites will be observed for thirty-six hours
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7 408 during the implementation year. A member of the PriCare research team will observe the CM activities
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10 409 including the meetings between the patient and the case manager, the development of the ISP,
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12 410 meetings between the primary care professionals, and any other activities adopted by the clinic under
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14 411 observation. Data collection will be guided by means of an observation grid developed to reflect the four
15
16 412 components of the CM intervention and the constructs of the conceptual framework.
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21 414 **Clinical data on services use**
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23 415 Quantitative data from patient medical records will be collected at the beginning (T0) of the
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25 416 intervention for a period of 12 months, before the patient's first visit with the case manager, and at the
26
27 417 end of the intervention 12 months) (N=300). The purpose of this data collection is to compare the
28
29 418 utilization of services in the year before the intervention with utilization during the intervention. Data
30
31 419 will include the number of emergency department visits, overnight stays in the hospital and primary
32
33 420 care professional visits. Patient expenditures from these activities will be calculated using an established
34
35 421 fee schedule from the Canadian Institute of Health Information (CIHI) patient cost estimator (58). The
36
37 422 cost of the intervention will be measured by tracking expenditures related to the CM activities.
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43 424 **Patient self-administered questionnaires**
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45 425 Participating patients (N=300) will be asked to complete a 30-minute questionnaire at baseline (T0), at
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47 426 the halfway point (T6 months) and at the end of the intervention (T12 months) under the guidance of a
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49 427 member of the PriCare research team. Questionnaires are available in both English and French and have
50
51 428 been validated. Data collected will include age, gender, marital status, education, occupation, economic
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53 429 status with family income and patient perception of his or her economic situation, health literacy,
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3 430 multimorbidity, care integration, self-management and quality of life. Health literacy will be measured
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5 431 using Chew's 3 questions for screening patients with inadequate or marginal health literacy (59, 60),
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7 432 multimorbidity with the Disease Burden Morbidity Assessment (21 items) (61, 62), care integration with
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9 433 the Picker Institute Questionnaire (13 items) (63), self-management with the Partners in Health Scale (12
10
11 434 items) (64, 65), quality of life with the SF-12v2 (12 items) (66) , quality-adjusted life years (QALY) derived
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13 435 from the SF-12v2 (67) and psychological distress with Kesslers' 6 questions regarding a person's
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15 436 emotional state (68).
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21 438 **Intervention fidelity evaluation**

23 439 The degree to which an intervention is delivered as intended is critical to the attainment of expected
24
25 440 outcomes (69, 70). Referred to as intervention fidelity, the delivery and the degree of adherence to the
26
27 441 four main components of the intervention will be assessed based on the qualitative and quantitative
28
29 442 data collected by a member of the PriCare research team during the intervention year. A fidelity grid
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31 443 was developed using the Carroll et al. (2007) conceptual framework for implementation fidelity (71). In
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33 444 addition to identifying the essential components of the intervention as described previously, adherence
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35 445 to the content, frequency, duration and coverage of the intervention as described in this protocol, as
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37 446 well as the moderating factors that may influence implementation such as intervention complexity, the
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39 447 facilitation strategies used, the quality of intervention delivery, and the responsiveness of participants
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41 448 will be documented (71). The fidelity grid guides the data collection via a series of general questions
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43 449 referring to each element of (71) conceptual framework, identifies primary and secondary sources of
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45 450 data and specifies the data collection method for each element of the conceptual framework.
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52 452 *Outcome variables*

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3 453 As described in the conceptual model (Figure 1), the main outcomes of the intervention that will be
4
5 454 examined are based on the quadruple aims to optimize health system performance: *improved patient-*
6
7 455 *reported outcomes, health care use, cost effectiveness and care team well-being* (34). Self-management
8
9 456 and quality of life are the main patient-reported outcomes collected from the patient-administered
10
11 457 questionnaire at baseline and at the end of the intervention (T12 months). Health care use will be based
12
13 458 on the clinical data collected on services use including the number of emergency department visits,
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15 459 overnight hospital stays and primary care professional visits. It will also be based on health services
16
17 460 integration, assessed within the patient-administered questionnaire. Care team well-being will be
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19 461 evaluated from the data collected from the individual semi-structured interviews and focus group
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21 462 discussions with health care professionals. Finally, cost effectiveness will be based on the CIHI cost
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23 463 estimator, as previously described.
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30 465 *Analysis*

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32 466 A combination of analytical strategies will be used to reflect the variability and dynamic nature of
33
34 467 context analysis and the mixed methods approach as used in this research (55, 57, 72). First, qualitative
35
36 468 and quantitative data collected will be integrated through a comparison of results for similarities and
37
38 469 differences throughout the analysis phase (72). Second, qualitative and quantitative data will be
39
40 470 compared for variables measured in several ways such as health services utilization, self-management,
41
42 471 quality of life and care integration (73). Third, qualitative and quantitative data will be merged for each
43
44 472 of the 10 cases (the participating clinical sites). A case history will be reported for each clinical site that
45
46 473 will constitute the synthesis of the merged data. Fourth, a comparison of the cases will be completed
47
48 474 using a mixed methods matrix (54). All categories of stakeholders involved in this research including the
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50 475 principal investigators, research assistants, patient partners, clinical experts, technical and scientific
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52 476 experts and policy makers, will be called upon to participate in the data analysis to ensure valid and
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3 477 meaningful interpretations. Additional analytical techniques for case study research (55) will be used as
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5 478 detailed below.
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10 480 Objective 1

11
12 481 To identify the barriers and the facilitators to implementation of the CM intervention in different
13
14 482 primary care contexts, the qualitative data collected using individual semi-structured interviews, focus
15
16 483 groups and non-participant observation will be analyzed. Responses to questions regarding the
17
18 484 perceived barriers and facilitators to responding to the needs of patients with chronic conditions and
19
20 485 complex care needs, to working with internal clinic partners and external health and social services
21
22 486 partners to care for this patient population, and to the process of implementing the four main
23
24 487 components of the CM intervention will be extracted and analyzed. Information regarding the perceived
25
26 488 complexity of the intervention, ease of implementation, care professional engagement and satisfaction
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28 489 with the intervention, and available support strategies to facilitate implementation will be extracted
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30 490 from the data collection grid used for the non-participant observation and for the fidelity evaluation.
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37 492 Objective 2

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39 493 A similar approach will be taken to explain the influence of the context of implementation on the degree
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41 494 of implementation. Interviewees and participants in the focus group discussions will be asked specific
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43 495 questions regarding the local clinical context, the workplace environment, relationships with external
44
45 496 health and social services partners, individual attitudes and perceptions to the intervention and the
46
47 497 overall process of implementation of the CM intervention. This information will be extracted and
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49 498 compared to the results of the fidelity evaluation to assess the degree of implementation of the
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51 499 intervention.
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3 501 A mixed thematic analysis approach will be used (54). Each of the ten clinical sites will be analyzed
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5 502 separately as an individual case study using a deductive approach based on the conceptual model
6
7 503 (Figure 1), as well as an inductive approach based on emergent constructs. A case history will be
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10 504 reported, guided by the constructs of the conceptual model (Figure 1). Subsequent to individual analysis
11
12 505 of the ten cases, a comparison between the cases will be performed using a descriptive and
13
14 506 interpretative matrix (54). This approach allows systematic comparison among cases and among units of
15
16 507 analysis. Analytical techniques specific to case study research will be used as described in (55) including
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18 508 pattern comparison, research of competing explanations and construction of explanations. Qualitative
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20
21 509 data will be managed using multisite NVivo 12 server software (QSR International Pty Ltd).
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25 511 Objective 3

27 512 To evaluate the influence of the context of implementation on the outcomes of the intervention, clinical
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30 513 data on services use and quantitative data extracted from the patient self-administered questionnaires
31
32 514 will be analyzed using descriptive statistics. Quantitative data will be analyzed first and then interpreted
33
34 515 in integration with qualitative data and the intervention fidelity evaluation described above, rather than
35
36 516 trying to calculate non-biased quantitative effects (73). Regression models will be developed to evaluate
37
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39 517 the relationships between intervention fidelity, patient characteristics, the constructs of the conceptual
40
41 518 model reflecting the contextual elements of the intervention, and the outcomes of the intervention. This
42
43 519 will be done using SPSS version 26. An incremental cost-effectiveness/utility ratio (ICER or ICUR) (74) will
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45
46 520 be calculated using data collected on costs and quality-adjusted life years (QALY) before and after
47
48 521 implementation of the CM intervention. Multivariate parametric analyses with bootstrap replications
49
50 522 will be conducted together with cost-effectiveness acceptability curves (CEAC) (75).
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52 523

54 524 **Discussion**

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3 525 CM is a promising approach to delivering care to patients with chronic illnesses and complex care needs,
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5 526 but little is known about its implementation in a primary care setting (21). As an intervention composed
6
7 527 of multiple components and steps that will be implemented in multiple sites, CM is an example of a
8
9 528 complex, context-dependent intervention (76). Identifying and analyzing the contextual determinants
10
11 529 across a variety of sites is necessary to understand how the intervention can produce its intended
12
13 530 outcomes (77). An implementation analysis achieves a deeper understanding of the conditions that are
14
15 531 most likely to lead to the successful implementation of the core components of the intervention (56). It
16
17 532 serves to identify variation in outcomes associated with different contexts and to identify
18
19 533 implementation problems (73). An implementation analysis can reveal how an intervention causes
20
21 534 change in a particular context and highlights an intervention's strengths and weaknesses in relation to
22
23 535 intended outcomes (56).
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30 537 This research will detail the steps involved in implementing the four main components of the CM
31
32 538 intervention at different clinical sites and will identify barriers and facilitators to implementation,
33
34 539 providing the opportunity to address potential problems and to refine the intervention. This context of
35
36 540 implementation which will be further understood through a detailed, theoretically-based approach to
37
38 541 the identification and analysis of the macro, meso and micro level determinants of implementation (18,
39
40 542 32). The implementation process will be studied, highlighting the development and change across time
41
42 543 of the steps required to implement the intervention in various contexts. This research will respond to
43
44 544 some of the most important issues raised in recent publications on CM for frequent users of health care
45
46 545 services with chronic illnesses and complex care needs (21, 23, 24, 26) , by contributing to the
47
48 546 understanding of how to implement this intervention in different primary care contexts in a cost-
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50 547 effective way that improves patient reported outcomes and health care use, while ensuring the well-
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52 548 being of the care team.
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5 550 The multi-level conceptual framework proposed in this study may be helpful for future research because
6
7 551 it combines the approach to analyzing the effective implementation of health care interventions, with
8
9 552 the principles of the integrative functions of primary care. The resulting framework supports the analysis
10
11 553 of effective implementation not only of CM, but also of primary care interventions aiming to achieve
12
13 554 care integration. The framework reflects the importance of intersectorial linkages and ensures the
14
15 555 incorporation of constructs aimed to improve access, quality and continuity of services for patients with
16
17 556 complex needs (18), regardless of the intervention being implemented. It is also particularly suited to
18
19 557 the analysis and formative evaluation of complex, multi-level interventions in health care, verifying what
20
21 558 works where and why across multiple contexts (32). The conceptual framework represents how patient,
22
23 559 organizational and systems-level elements of implementation, the dynamic, time-dependent process of
24
25 560 implementation, and the defining features of primary care, can translate into meaningful intervention
26
27 561 outcomes, based on the quadruple aims to optimize health system performance. The framework can
28
29 562 inform the effective implementation of complex primary care interventions that seek to facilitate the
30
31 563 continuous, comprehensive and coordinated delivery of services to individuals or populations, and that
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33 564 necessitate the engagement of multiple stakeholders across various sectors.
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41 566 The use of “multi-strategy” or “multi-faceted” frameworks to describe and analyze the implementation
42
43 567 of complex interventions increases the precision and specificity of reporting, which facilitates effective
44
45 568 evaluation and replication (78, 79). The proposed research fulfills an essential step towards replication
46
47 569 and scalability of CM by identifying the implementation strategies that support the adoption, scale-up
48
49 570 and replication of best practices in CM (78, 80). Given the complex nature of the CM intervention,
50
51 571 practitioners report challenges to implementation, especially considering the lack of guidelines or a
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53 572 blueprint on how to operationalize its core components across different settings (81). Implementation is
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3 573 often poorly reported in published literature, which presents a challenge to both research and practice
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5 574 and impedes replication and immediate adoption in a clinical setting (79, 82). To achieve wide-scale
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7 575 adoption and replication, the CM intervention must be tailored to the local context in an approach that
8
9 576 considers the individual, the team of professionals, the organizational setting and the greater system
10
11 577 (81). Few studies have described, categorized and analyzed intervention implementation in a
12
13 578 contextually tailored approach (82). This research will thus provide this information for both researchers
14
15 579 and practitioners, which according to our knowledge, has not yet been done.
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581 **Study validity**

582 Construct validity is ensured through a detailed conceptual model and consistency in the application of
583 its constructs in the data collection and analysis. Internal validity is ensured through a systematic coding
584 and rigorous organization of collected data and the triangulation of several sources of qualitative data
585 acquired from different participating stakeholders including patients, case managers, clinic managers,
586 researchers, clinicians and informal caregivers (55). Analysis and comparison of different case studies in
587 various implementation contexts will reinforce external validity and transferability. The observation and
588 analysis of multiple levels, and their replication across several cases enhances both internal and external
589 validity (55).
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591 **Figure Legend**

592 Figure 1: Conceptual model for the implementation analysis of a case management intervention
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594 **List of Abbreviations**

595 CEAC: Cost-effectiveness acceptability curves

596 CFIR: Consolidated framework for implementation research

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3 597 CIHI: Canadian Institute of Health Information
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5 598 CIHR: Canadian Institutes for Health Research
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7 599 CCM: Chronic care model
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9 600 CM: Case management
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11 601 EMR: Electronic medical record
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13 602 ICER: Incremental cost-effectiveness ratio
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15 603 ICUR: Incremental cost-utility ratio
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17 604 ISP: Individualized services plan
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19 605 QALY: Quality-adjusted life years
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25 607 **Declarations**

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27
28 608 The funders played no role in designing the study, neither did they in data collection, analysis and
29
30 609 interpretation or in the writing of the manuscript.
31

32 610 **Ethics approval**

33
34 611 This project received approval from the CIUSSS de l'Estrie – CHUS Research Ethic Board (project number
35
36 612 MP-31-2019-2830).
37

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39 613 **Consent for publication**

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41 614 This manuscript does not contain any individual person's data in any form.
42

43 615 **Availability of data and materials**

44
45 616 Not applicable.
46

47
48 617 **Competing interests**

49
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51

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27
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29
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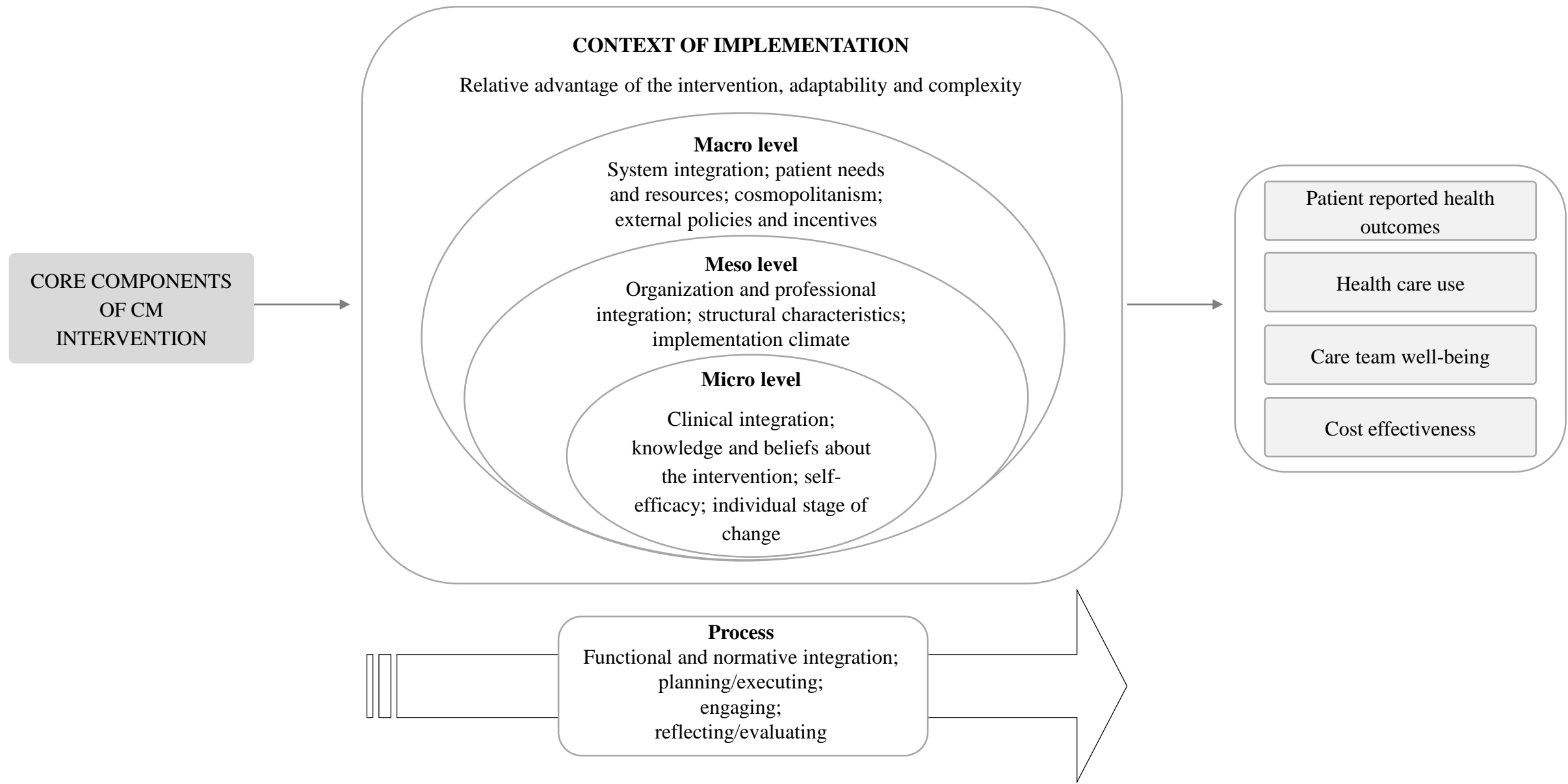
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Figure 1. Conceptual model for the implementation analysis of a case management intervention



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Protocol for a mixed-method analysis of implementation of case management in primary care for frequent users of health care services with chronic diseases and complex care needs

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3 1 **Protocol for a mixed-method analysis of implementation of case management in primary care for**
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10 4 Danish A¹, Chouinard MC², Aubrey-Bassler K³, Burge F⁴, Doucet S⁵, Ramsden V⁶, Bisson M¹, Cassidy M⁵,
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12 5 Condran B⁴, Lambert M², Penney C³, Sabourin V⁷, Warren M⁸, Hudon C^{1,9}.
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52 23 **Word Count:** 6508 words
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3 24 **Abstract**
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5 25 *Introduction:* Case management (CM) in a primary care setting is a promising approach to integrating
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7 26 and improving health care services and outcomes for patients with chronic conditions and complex care
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10 27 needs who frequently use healthcare services. Despite evidence supporting CM and interest in
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12 28 implementing it in Canada, little is known about how to do this. This research aims to identify the
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14 29 barriers and facilitators to the implementation of a CM intervention in different primary care contexts
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16 30 (objective 1) and to explain the influence of the clinical context on the degree of implementation
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18 31 (objective 2) and on the outcomes of the intervention (objective 3).
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23 33 *Methods and analysis:* A multiple-case embedded mixed methods study will be conducted on CM
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25 34 implemented in ten primary care clinics across five Canadian provinces. Each clinic will represent a sub-
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27 35 unit of analysis, detailed through a case history. Cases will be compared and contrasted using multiple
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29 36 analytical approaches. Qualitative data (objectives 1 and 2) from individual semi-structured interviews
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31 37 (N=130), focus group discussions (N=20) and participant observation of each clinic (36 hours) will be
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33 38 compared and integrated with quantitative (objective 3) clinical data on services use (N=300) and
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35 39 patient questionnaires (N=300). An evaluation of intervention fidelity will be integrated into the data
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37 40 analysis.
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43 42 *Ethics and dissemination:* This project received approval from the CIUSSS de l'Estrie – CHUS Research
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45 43 Ethic Board (project number MP-31-2019-2830). Results will provide the opportunity to refine the CM
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47 44 intervention and to facilitate effective evaluation, replication and scale-up. This research provides
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49 45 knowledge on how to respond to the needs of individuals with chronic conditions and complex care
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51 46 needs in a cost-effective way that improves patient reported outcomes and health care use, while
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3 47 ensuring care team well-being. Dissemination of results is planned and executed based on the needs of
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5 48 various stakeholders involved in the research.
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8 **49 Keywords**

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10 50 Primary health care; case management; chronic illness; complex care needs; frequent users;
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12 51 implementation; evaluation; context, intervention fidelity.
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16 **53 Article Summary**

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18 *54 Strength and limitations of this study*

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21 55 • This protocol details the steps for the implementation of a case management (CM) intervention
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23 56 for frequent users of health services with chronic conditions and complex care needs.
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28 58 • A novel conceptual model for CM implementation is proposed based on the integrative
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30 59 functions of primary care and the effective implementation of health care interventions.
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34 61 • The barriers and facilitators to implementing CM will be detailed and the influence of the clinical
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36 62 context on the degree of implementation and on the outcomes of the intervention will be
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38 63 evaluated.
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41 64
42 65 • While the proposed conceptual model does not cover every possible construct for effective
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44 66 implementation, an inductive approach to data analysis will be used to allow for emergent
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46 67 themes and all stakeholders will participate in data analysis in order to ensure validity.
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51 **69 Introduction**

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54 70 A priority for primary care research and the Canadian health care system is to address the complex
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56 71 needs of patients who frequently use health care services (1, 2). These patients may suffer from a
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3 72 combination of chronic illnesses, mental illness and/or socioeconomic vulnerabilities (3-5). Patients with
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5 73 chronic illnesses typically have a wide range of needs that require them to adopt new behaviours, such
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7 74 as meeting with care providers on a regular basis, adhering to treatment plans, monitoring their
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10 75 symptoms and making important decisions while also changing aspects of their lifestyle to preserve their
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12 76 physical, psychological and social well-being (6-8). Far from “misusing” the health care system, studies
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14 77 show that frequent users do so in an attempt to address unmet needs for health care and social services
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16 78 (3, 9). Studies suggest that these attempts are often unsuccessful and result in repetitive use of services
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18 79 in an uncoordinated way through frequent hospitalizations or visits to the emergency department (10,
19
20 80 11). This leads to negative experiences for both the care providers and for the patients, poor health
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22 81 indicators and high mortality rates for the patients and considerable costs to the health care system (11-
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24 82 13). Several countries have therefore experimented with new models of health care delivery that can
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26 83 achieve better coordination and integration of services, some of which have been found to reduce
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28 84 fragmentation and improve care continuity (14). Early examples of such models include the Chronic Care
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30 85 Model (CCM) (15) and the Innovative Care for Chronic Conditions framework (16). These models
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32 86 emphasize the importance of providing support to patients for self-management and decision-making,
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34 87 seeking innovative approaches within available clinical information systems and proposing ways to
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36 88 redesign the delivery of health care (14).
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43 90 Individuals with chronic illnesses require organized care and close follow-up delivered over an extended
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45 91 period of time (17). The primary care setting is the most suitable for supporting individuals with chronic
46
47 92 illnesses due to its defining features of patient-centered first contact, continuous, comprehensive, and
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49 93 coordinated care (17, 18). Health systems built on the principles of primary care achieve better health
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51 94 outcomes and greater equity, at a lower cost (19) than systems with a specialty care orientation (18).
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54 95 Integrated care may be achieved in a primary care setting through the creation of inter-sectorial linkages
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3 96 between health and social policies, i.e. the linking of health care to other human service systems (eg.
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5 97 long-term care, education, vocational and housing services) in order to improve clinical outcomes,
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7 98 patient and provider satisfaction and efficiency (14, 18, 20).
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11 12 100 **Case management**

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14 101 Case management (CM) in a primary care setting is one approach that has been shown to increase the
15
16 102 integration of health services (21, 22) and to improve care and outcomes for patients with chronic
17
18 103 conditions and complex needs who frequently use health care services (23, 24). Defined as “a
20
21 104 collaborative, client-driven process for the provision of quality health and support services through the
22
23 105 effective and efficient use of resources” (25), CM is among the best models available to mitigate the
24
25 106 high utilization of the health care system and associated costs (23, 26). An adaptive randomized trial of
26
27 107 CM interventions targeting frequent users of health services demonstrated that appropriate patient
28
29 108 identification, staff training and centralized intervention delivery are components of CM that can be
30
31 109 successfully implemented on a large scale and lead to a decrease in health consumption (27). A recent
32
33 110 systematic review (10) identified the most common components of CM interventions for chronically ill
34
35 111 patients including the integration of services between hospitals and home or other facilities, regular
36
37 112 home visits, regular telephone calls, individual assessment and care planning, education and self-
38
39 113 management support, psychosocial support, and ongoing supervision and assessment. The same study
40
41 114 found that a reduction in hospital admission rates was reported after implementation of CM
42
43 115 interventions (10). A systematic review of literature on the characteristics of CM interventions in
44
45 116 primary care reporting positive outcomes for frequent users of health care revealed three essential
46
47 117 requisites for success. First, the intervention must identify and target patients with the greatest needs,
48
49 118 and who are therefore most likely to benefit from the intervention. Second, the intervention must be
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51 119 delivered with sufficient intensity (i.e. frequently enough or with a high enough dose) to produce the
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3 120 desired effect. Third, an interdisciplinary approach to care planning is preferred, where a variety of
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5 121 professionals from both care and cure sectors actively participate in the intervention (28).
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10 123 Despite the evidence base supporting CM as an intervention for frequent users, little evidence exists
11
12 124 about the facilitators and barriers to CM implementation (29). Although there is a strong interest in
13
14 125 implementing CM in the Canadian primary care setting, little information is available on how to do this.
15
16 126 CM has rarely been implemented and documented systematically in order to identify and replicate best
17
18 127 practices. This protocol is part of a larger research program on CM in primary care for frequent users of
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20 128 healthcare services with chronic diseases and complex care needs (2) and details the steps for the
21
22 129 implementation analysis that was not described in the original protocol of the whole program.
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131 **Objectives**

- 132 1) To identify the barriers and the facilitators to implementation of the CM intervention in different
133 primary care contexts.
134 2) To explain the influence of the clinical context on the degree of implementation.
135 3) To evaluate the influence of the context of implementation on the outcomes of the intervention.

136

137 **Methods/Design**

138 *Conceptual model*

139 The conceptual model developed to guide this research protocol was informed by two multi-level
140 conceptual frameworks in order to analyze the effective implementation of an integrative primary care
141 intervention. Multi-level frameworks represent the interacting layers of phenomena inherent to
142 organizations and are commonly used to develop theories, measure and analyze phenomena while
143 accounting for the complexity inherent to these systems (30, 31). Multi-level interventions mobilize

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3 144 resources and facilitate linkages across organizations “to solve coordination problems and adapt to
4
5 145 change” (31).
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10 147 The first framework used to guide this research protocol is the Valentijn et al. framework for integrated
11
12 148 care based on the integrative functions of primary care (18). The concept of integration originates from
13
14 149 organizational theory and refers to “the quality of the state of collaboration” that may exist among the
15
16 150 multiple levels of service delivery with the purpose of achieving a required mutual effort and agreement
17
18 151 (14). Integrated health care interventions are a means to improve access, quality and continuity of
19
20 152 services in a more efficient way, especially for people with complex needs (18) . This framework
21
22 153 describes the central role of primary care in integrating the multiple levels of health care: system
23
24 154 integration at the macro level; organizational and professional integration at the meso level; clinical
25
26 155 integration at the micro level; and functional and normative integration to link the macro, meso and
27
28 156 micro levels (18). Valentijn et al.’s framework is intended for analyzing and testing the causal
29
30 157 relationships within and between the integration levels, which interact to varying degrees depending on
31
32 158 the specific context of health care delivery (18). This framework is therefore suitable for studying the
33
34 159 different primary care contexts of the CM intervention from the perspective of integrated care and is
35
36 160 the unifying thread to the implementation and evaluation of the CM intervention.
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43 162 The second framework used to guide this research protocol is the Consolidated Framework for
44
45 163 Implementation Research (CFIR), intended to promote effective implementation and formative
46
47 164 evaluation of complex, multi-level interventions in health care (32). The CFIR provides a taxonomy of
48
49 165 constructs that can be used to understand, measure and assess implementation across a variety of
50
51 166 contexts. The constructs are categorized into five major domains that similar to the Valentijn et al.
52
53 167 (2013) framework, reflect a multilevel perspective. The *outer setting* refers to the economic, political
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3 168 and social context in which the implementing organization is situated and corresponds to the macro
4
5 169 level. The *inner setting* corresponds to the meso level of the organizational context and includes
6
7 170 constructs such as the structure and culture of the implementing organization. At the micro level, the
8
9
10 171 *individuals* involved in the intervention are described. The CFIR includes two additional domains: the
11
12 172 *characteristics of the intervention*, a description of its core components, and the *implementation*
13
14 173 *process*, considered a dynamic, non-sequential and non-linear domain that can stem from any level,
15
16 174 macro, meso or micro (32). When understood, process provides insight that links the various levels of
17
18 175 analysis and shed light on the causal or generative mechanisms underlying the intervention being
19
20 176 studied (32, 33). Barriers and facilitators may arise at multiple levels of intervention delivery, as external
21
22 177 influencers, organizational or professional components or during the process by which an intervention is
23
24 178 adopted within an organization (32).
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30 180 The conceptual model developed to guide this research protocol is presented in Figure 1. On the left
31
32 181 side of the figure are the core components of the CM intervention, described in the proceeding section.
33
34 182 During implementation, the intervention takes on unique properties and characteristics related to the
35
36 183 local context in which it is introduced (referred to in Figure 1 as the *context of implementation*) (32). The
37
38 184 context of implementation includes macro, meso and micro level determinants, depicted by the
39
40 185 concentric circles in the middle of the figure. The process of implementation is represented by the arrow
41
42 186 at the bottom of the figure, which represents the dynamic and continuous nature of intervention
43
44 187 implementation. Finally, to the right, are the final expected outcomes of the intervention, based on the
45
46 188 quadruple aims to optimize health system performance: improved patient outcomes, health care use,
47
48 189 care team well-being and cost effectiveness (34).
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3 191 Constructs were selected from both Valentijn et al. (2013) and Damschroder et al. (2009) to reflect the
4
5 192 objectives of this research. The characteristics of the intervention after implementation in a particular
6
7 193 local context will be analyzed based on the intervention's *adaptability* to meet local needs, its *relative*
8
9 194 *advantage* to the context, and its *complexity* or difficulty of implementation. At the macro level, how
10
11 195 the intervention contributes to *system integration* will be examined, including vertical integration and
12
13 196 collaboration across care sectors and horizontal integration through a holistic view of the patient (18).
14
15 197 This construct reflects the implementing organization's knowledge of the needs of its patient population
16
17 198 and its ability to respond with appropriate structures, techniques and resources (*patient needs and*
18
19 199 *resources*) (32). The organization's degree of networking with external services and structures
20
21 200 (*cosmopolitanism*) will be examined, as well as its formal strategies and policies supporting external
22
23 201 linkages (*external policies and incentives*).
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28 202
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30 203 At the meso level, *organizational* and *professional integration* will be examined, which refer to the
31
32 204 partnerships between services and professionals within the implementing organization. The *structural*
33
34 205 *characteristics* of the organization and the *implementation climate* will be described. At the micro level,
35
36 206 interest will shift to *clinical integration*, which reflects the level of coordination and coherence of the
37
38 207 primary care delivery process (18). The *knowledge and beliefs* of the various professionals involved in
39
40 208 the intervention will be examined, as well as their perceived *self-efficacy* to implement CM, and their
41
42 209 *individual stage of change*, which refers to their progress towards full adoption and sustained use of the
43
44 210 intervention (32).
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48 211
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50 212 Finally, the process of implementation will be analyzed by examining how the CM intervention was
51
52 213 planned and executed at the local level, how professionals were mobilized and engaged for participation
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54 214 in the intervention, and by examining the mechanisms put in place to discuss and provide feedback
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3 215 about the experience, progress and quality of implementation (*planning/executing; engaging;*
4
5 216 *reflecting/evaluating*). These constructs reflect the level of *functional* and *normative integration*
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7 217 resulting from the implementation of the intervention: how the implementing organization mobilized
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9 218 management functions in support of the intervention, as well as the degree of development of a shared
10
11 219 goal or mission among participating individuals and partner organizations for the implementation of the
12
13 220 intervention (18).
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19 222 *The intervention*

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21 223 An intervention was designed to reflect the standards of practice of the National Case Management of
22
23 224 Canada as well as the Case management society of America (25, 35). The activities of the intervention
24
25 225 follow the Canadian Institutes for Health Research (CIHR) Strategy for Patient Oriented research and
26
27 226 incorporate the integration characteristics of the National Collaboration for Integrated Care and Support
28
29 227 (36, 37). Patients with chronic conditions most often seek and receive comprehensive care in a primary
30
31 228 care setting (38) and the leadership of a case manager who is experienced in primary care has been
32
33 229 shown to facilitate the successful implementation of chronic care models (39). The CM intervention is
34
35 230 therefore designed to be delivered by a primary care health professional in a primary care clinical setting
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37 231 over a period of 12 months.
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43 233 In consideration of these guidelines and of the results of previously cited studies (10, 11, 23, 27, 28), an
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45 234 intervention was designed comprised of four main components: 1) evaluation of patient needs and
46
47 235 preferences; 2) co-development and maintenance of a patient-centered individualized services plan; 3)
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49 236 coordination of services among all partners; and 4) education and self-management support for patients
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51 237 and families.
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3 239 1. Evaluation of patient needs and preferences
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5 240 The identification of patients who are in need of intervention and who stand to benefit the most from
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7 241 CM is an essential first step (27, 28), ideally executed by an interdisciplinary team (5, 40). Patients are
8
9 242 identified by searching administrative data or clinical records in addition to their referral for the CM
10
11 243 intervention by primary care professionals. This approach combines clinician judgement with objective
12
13 244 data from electronic medical record (EMR) or administrative databases (2, 41). The CM intervention
14
15 245 targets patients who present with at least one chronic illness, including mental illness, who frequently
16
17 246 use health services as determined by 4 or more emergency department visits or hospitalizations in the
18
19 247 previous 12 months, and who have complex needs as determined by the care team. Once a patient has
20
21 248 been identified for inclusion in the CM intervention, the case manager examines the patient's medical
22
23 249 records going back 12 months in order to understand the reasons for the frequent use of services. The
24
25 250 case manager identifies the patient's physical and/or mental illnesses as well as social challenges such as
26
27 251 insecure housing or employment, poverty, violence, substance use disorders, etc. The case manager also
28
29 252 documents the health and social services previously provided to the patient, as well as the names, roles
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31 253 and contact information of professionals currently involved with the patient or who may eventually be
32
33 254 called upon to participate in the care of the patient.
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41 256 The case manager validates with the patient the information collected from the medical records and
42
43 257 determines the patient's personal needs and preferences for future services and resources. This step
44
45 258 constitutes the first in-depth interaction between the case manager and the patient, and is essential for
46
47 259 building mutual trust and respect (21), for establishing a patient-centered care process, and for
48
49 260 encouraging the commitment of the patient as a partner in the care process (42, 43). The patient may
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51 261 prefer to be accompanied by a caregiver or advocate with lived experience of the patient's health
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53 262 situation who can assist in navigating the health and social services system (44). When referring to "the
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3 263 patient” in this article, we also refer to an individual who may stand in for the patient at any point
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5 264 during the intervention. Finally, the case manager seeks the patient’s consent to communicate with
6
7 265 potential care professionals throughout the intervention and ensures that the patient understands and
8
9 266 agrees to the next step of the intervention: the creation of an Individualized Services Plan (ISP). The ISP
10
11 267 is a tool for planning and coordinating tailored services intended to give meaning and direction to the
12
13 268 patient in consideration of his or her life goals (45), personal environment, resources and culture, in
14
15 269 collaboration with a multidisciplinary team of professionals (46) and health and social services
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17 270 organizations.
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22 23 272 2. Co-development and maintenance of a patient-centered ISP

24
25 273 The ISP for patients with chronic conditions may lead to improvements in physical and psychological
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27 274 health, as well as in their ability to self-manage their condition (46-48). It is among the most commonly
28
29 275 used strategies in CM interventions (10, 11). The case manager identifies resources available in the local
30
31 276 health and social services network and within the community that may be appropriate for the patient.
32
33 277 This involves a holistic analysis of the patient’s situation and the identification of clinical-administrative
34
35 278 issues and a final list of care professionals that will be invited to examine the patient’s situation. These
36
37 279 may be health care and social services professionals, managers or representatives of community
38
39 280 organizations. The case manager communicates directly with targeted care professionals to request
40
41 281 their involvement, to ensure that the reason for the intervention is understood and to agree upon a
42
43 282 mutually convenient date, time and place for an ISP meeting with the patient. The case manager
44
45 283 prepares the agenda for the ISP meeting and communicates with the patient to reconfirm consent
46
47 284 regarding the professionals who will participate in the meeting and to maintain a relationship of trust
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49 285 and transparency with the patient. The ISP meeting is ideally held in-person, but may be done by phone
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51 286 or online.
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5 288 At the beginning of the ISP meeting, the care team reviews the potential resources and services that
6
7 289 may be proposed to the patient prior to the patient's arrival. This allows the care team to collaboratively
8
9 290 examine the patient's situation, needs and preferences and to mobilize their multidisciplinary
10
11 291 perspectives (46). The ISP is then developed with the patient and their advocate upon their arrival. The
12
13 292 ISP includes a maximum of 3 or 4 objectives in line with the patient's overall expectations and life
14
15 293 project (49). The group proposes preferred methods of communication and strategies for exchanging
16
17 294 information for the duration of the intervention. The case manager writes up the ISP in plain language
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19 295 and validates that the patient understands and agrees to it.
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25 297 3. Coordination of services among all partners

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28 298 Patients with chronic illnesses and complex care needs are often cared for by multiple providers in
29
30 299 various locations and experience difficulty navigating the health system and other resources resulting
31
32 300 in unmet needs, a lower quality of life and higher mortality rates (48). A coordinated response by care
33
34 301 providers that promotes patient empowerment over an extended period of time is recommended (14).
35
36 302 In this intervention, the case manager transmits a copy of the written ISP to the patient and the care
37
38 303 team and follows-up regularly with the patient's primary care providers in the clinical setting, ensuring
39
40 304 active engagement and direct communication. As the principal contact-person and advocate for the
41
42 305 patient, the case manager establishes contact with the services or resources identified in the ISP,
43
44 306 providing a personalized reference for the patient, explaining the case and informing care professionals
45
46 307 of past and potential challenges facing the patient.
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52 309 Regular communication and follow-up encourages the patient's active engagement in the intervention,
53
54 310 a strategy that has been shown to reduce future use of emergency services (26, 50, 51). The case
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3 311 manager talks to the patient about their preferred method for reaching the case manager and other
4
5 312 relevant services. Adherence to the ISP throughout the intervention is ensured by maintaining contact
6
7 313 with the care professionals involved with each patient, and by verifying if the patient's goals have been
8
9 314 attained. The ISP should be reviewed at least once every 3 months. If the patient desires a change in
10
11 315 their ISP, or if a care professional identifies any issues throughout the intervention, the case manager
12
13 316 reassesses the situation with the patient and adjusts the ISP as necessary.
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19 318 4. Education and self-management support for patients and families

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21 319 Self-management support was found to be the strategy most frequently associated with health
22
23 320 improvements in patients with chronic diseases in a primary care setting (17). Education and self-
24
25 321 management support activities aim to increase the patient's skills, confidence and motivation to control
26
27 322 and manage their symptoms and to follow their ISP with structured support for problem solving and
28
29 323 continuous assessment of the patient's objectives and progress (52). This component of the intervention
30
31 324 is considered an ongoing and transversal process to be performed as needed throughout the
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33 325 intervention.
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39 327 Case managers aim to develop the patient's ability to monitor their condition, take appropriate action
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41 328 and identify when and how to ask for professional help by assessing the patient's knowledge and
42
43 329 learning needs and suggesting beneficial activities, such as journaling symptoms and vitals, and
44
45 330 informational resources based on the patient's unique situation. Case managers are trained in
46
47 331 motivational interviewing, a "client-centered, directive communication method aimed at changing
48
49 332 behavior" (53). The case manager supports the patient to set realistic goals through a "smart" action
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51 333 plan that includes specific behavioral goals that are measurable and attractive to the patient, that may
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53 334 be accomplished in a realistic time frame and that build on previous positive experiences. The case
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3 335 manager helps the patient prepare for meetings with the various care professionals to ensure that the
4
5 336 patient is empowered to communicate his or her goals and to receive the desired care. Patients are
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7 337 coached on how to effectively communicate with their relatives, to establish expectations, and to
8
9 338 ensure a successful care partnership.

11 339 *Study setting*

12 340 The CM intervention will be implemented in ten primary care clinics, each representing a unique case.
13
14 341 Two clinics were selected from each of the five participating Canadian provinces of Newfoundland, Nova
15
16 342 Scotia, New Brunswick, Québec and Saskatchewan using a purposeful sampling strategy (54). Clinics
17
18 343 were selected that had not previously implemented CM and that were interested in implementing the
19
20 344 CM intervention and participating in the research project. The interest of a health care professional, a
21
22 345 nurse or a social worker, to develop the role of the case manager and to be available to dedicate
23
24 346 approximately 1 day per week to the study was essential. The case manager was required to have
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26 347 primary care experience and was offered training in the intervention and continuous support and
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28 348 follow-up through the establishment of a community of practice.
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35 350 *Patient and public involvement*

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37 351 Patient partners were involved in this research since its inception, including the design of the research
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39 352 questions and the development of this protocol of which they are coauthors (VS and MW). They
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41 353 continue to provide their expertise regarding study feasibility and acceptability. They will be involved in
42
43 354 the interpretation of data and in the dissemination of results.
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49 356 *Timeline*

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3 357 The implementation of the CM intervention will take place over a period of one year. A cohort of
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5 358 patients will be recruited at each clinic and will be administered the intervention over the course of 12
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7 359 months.
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12 361 *Patient recruitment*
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14 362 Each clinic will identify 30 patients for enrolment in the CM intervention, for a total of 300 patients
15
16 363 across the 5 participating provinces. Patients are selected who are most likely to benefit from CM, based
17
18 364 on the clinical judgement of the case manager and the family physician. Criteria for inclusion in the
19
20 365 study are as follows: 1) living with at least one chronic physical or mental illness; 2) frequent user of
21
22 366 health care services ie. having 4 or more hospitalizations or visits to the emergency department in the
23
24 367 previous year; 3) having complex care needs as determined by the care team. Patients who are ineligible
25
26 368 for participation in the study include individuals whose prognosis is less than one year or who are
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28 369 exhibiting a loss of autonomy.
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32 371 *Study design*
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36 372 The implementation analysis is designed as a multiple-case embedded study, where each of the ten
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38 373 clinics will represent one sub-unit of analysis. This design is best-suited to analyzing complex
39
40 374 interventions implemented in variable and dynamic settings, and where the underlying context is
41
42 375 difficult to isolate from the intervention itself (55). This design allows several levels of analysis, the
43
44 376 observation of various organizational processes or behaviours, the examination of the context and
45
46 377 process of implementation, and the interaction among involved stakeholders (56). It also favors the use
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48 378 of mixed methods of data collection and analysis (57).
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52 380 *Data collection*
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3 381 To accomplish the objectives of this research, a mixed methods data collection is planned. Multiple
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5 382 sources of information will be used to collect both qualitative and quantitative data.
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10 384 **Individual semi-structured interviews** will be administered to all case managers (1-2 per clinic) and
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12 385 clinic managers (1 per clinic) at each study site at the start of the intervention (T0), and at the end of the
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14 386 intervention (T12 months). At the end of the intervention (T12 months), 10 patients and/or their
15
16 387 representative will also be interviewed. Patients will be purposefully selected to achieve maximum
17
18 388 variation (54). A total of 130 individual semi-structured interviews will be administered across the 10
19
20 389 participating clinical sites. An interview guide was developed composed of 18 open-ended questions
21
22 390 based on the constructs of the conceptual model (Figure 1). The first part of the interview will address
23
24 391 the clinical context of the CM intervention, the services offered at each clinical site to patients with
25
26 392 chronic conditions and complex care needs, and the way in which the clinic works with other health and
27
28 393 social services organizations. In the second part of the interview, questions will be asked about the
29
30 394 implementation of the four components CM intervention, the context of implementation, the barriers
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32 395 and facilitators to intervention, and about individual perceptions and attitudes towards the intervention.
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39 **Focus groups**

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41 398 A focus group discussion will be held at each participating clinic, once at the beginning of the
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43 399 intervention (T0) and once at T9-12 months, for a total of 20 focus groups throughout the CM
44
45 400 intervention. Primary care providers, including physicians, nurses, social workers, pharmacists and any
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47 401 health and social services professionals involved in the intervention will be invited to take part in a
48
49 402 discussion facilitated by a member of the PriCare research team. The interview guide described above
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51 403 for the semi-structured interviews will be adapted and used to guide the focus group discussion.
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3 405 **Non-participant observation**
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5 406 The activities of the intervention at each of the ten clinical sites will be observed for thirty-six hours
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7 407 during the implementation year. A member of the PriCare research team will observe the CM activities
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10 408 including the meetings between the patient and the case manager, the development of the ISP,
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12 409 meetings between the primary care professionals, and any other activities adopted by the clinic under
13
14 410 observation. Data collection will be guided by means of an observation grid developed to reflect the four
15
16 411 components of the CM intervention and the constructs of the conceptual framework.
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21 413 **Clinical data on services use**
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23 414 Quantitative data from patient medical records will be collected at the beginning (T0) of the
24
25 415 intervention for a period of 12 months, before the patient's first visit with the case manager, and at the
26
27 416 end of the intervention 12 months) (N=300). The purpose of this data collection is to compare the
28
29 417 utilization of services in the year before the intervention with utilization during the intervention. Data
30
31 418 will include the number of emergency department visits, overnight stays in the hospital and primary
32
33 419 care professional visits. Patient expenditures from these activities will be calculated using an established
34
35 420 fee schedule from the Canadian Institute of Health Information (CIHI) patient cost estimator (58). The
36
37 421 cost of the intervention will be measured by tracking expenditures related to the CM activities.
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43 423 **Patient self-administered questionnaires**
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45 424 Participating patients (N=300) will be asked to complete a 30-minute questionnaire at baseline (T0), at
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47 425 the halfway point (T6 months) and at the end of the intervention (T12 months) under the guidance of a
48
49 426 member of the PriCare research team. Questionnaires are available in both English and French and have
50
51 427 been validated. Data collected will include age, gender, marital status, education, occupation, economic
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53 428 status with family income and patient perception of his or her economic situation, health literacy,
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3 429 multimorbidity, care integration, self-management and quality of life. Health literacy will be measured
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5 430 using Chew's 3 questions for screening patients with inadequate or marginal health literacy (59, 60),
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7 431 multimorbidity with the Disease Burden Morbidity Assessment (21 items) (61, 62), care integration with
8
9 432 the Picker Institute Questionnaire (13 items) (63), self-management with the Partners in Health Scale (12
10
11 433 items) (64, 65), quality of life with the SF-12v2 (12 items) (66) , quality-adjusted life years (QALY) derived
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13 434 from the SF-12v2 (67) and psychological distress with Kesslers' 6 questions regarding a person's
14
15 435 emotional state (68).
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21 437 **Intervention fidelity evaluation**

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23 438 The degree to which an intervention is delivered as intended is critical to the attainment of expected
24
25 439 outcomes (69, 70). Referred to as intervention fidelity, the delivery and the degree of adherence to the
26
27 440 four main components of the intervention will be assessed based on the qualitative and quantitative
28
29 441 data collected by a member of the PriCare research team during the intervention year. A fidelity grid
30
31 442 was developed using the Carroll et al. (2007) conceptual framework for implementation fidelity (71). In
32
33 443 addition to identifying the essential components of the intervention as described previously, adherence
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35 444 to the content, frequency, duration and coverage of the intervention as described in this protocol, as
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37 445 well as the moderating factors that may influence implementation such as intervention complexity, the
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39 446 facilitation strategies used, the quality of intervention delivery, and the responsiveness of participants
40
41 447 will be documented (71). The fidelity grid guides the data collection via a series of general questions
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43 448 referring to each element of (71) conceptual framework, identifies primary and secondary sources of
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45 449 data and specifies the data collection method for each element of the conceptual framework.
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52 451 *Outcome variables*
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3 452 As described in the conceptual model (Figure 1), the main outcomes of the intervention that will be
4
5 453 examined are based on the quadruple aims to optimize health system performance: *improved patient-*
6
7 454 *reported outcomes, health care use, cost effectiveness and care team well-being* (34). Self-management
9
10 455 and quality of life are the main patient-reported outcomes collected from the patient-administered
11
12 456 questionnaire at baseline and at the end of the intervention (T12 months). Health care use will be based
13
14 457 on the clinical data collected on services use including the number of emergency department visits,
15
16 458 overnight hospital stays and primary care professional visits. It will also be based on health services
18
19 459 integration, assessed within the patient-administered questionnaire. Care team well-being will be
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21 460 evaluated from the data collected from the individual semi-structured interviews and focus group
22
23 461 discussions with health care professionals. Finally, cost effectiveness will be based on the CIHI cost
24
25 462 estimator, as previously described.

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28 46330 464 *Analysis*

31
32 465 A combination of analytical strategies will be used to reflect the variability and dynamic nature of
33
34 466 context analysis and the mixed methods approach as used in this research (55, 57, 72). First, qualitative
35
36 467 and quantitative data collected will be integrated through a comparison of results for similarities and
37
38 468 differences throughout the analysis phase (72). Second, qualitative and quantitative data will be
39
40 469 compared for variables measured in several ways such as health services utilization, self-management,
41
42 470 quality of life and care integration (73). Third, qualitative and quantitative data will be merged for each
43
44 471 of the 10 cases (the participating clinical sites). A case history will be reported for each clinical site that
45
46 472 will constitute the synthesis of the merged data. Fourth, a comparison of the cases will be completed
47
48 473 using a mixed methods matrix (54). All categories of stakeholders involved in this research including the
49
50 474 principal investigators, research assistants, patient partners, clinical experts, technical and scientific
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52 475 experts and policy makers, will be called upon to participate in the data analysis to ensure valid and
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3 476 meaningful interpretations. Additional analytical techniques for case study research (55) will be used as
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5 477 detailed below.
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10 479 Objective 1

11
12 480 To identify the barriers and the facilitators to implementation of the CM intervention in different
13
14 481 primary care contexts, the qualitative data collected using individual semi-structured interviews, focus
15
16 482 groups and non-participant observation will be analyzed. Responses to questions regarding the
17
18 483 perceived barriers and facilitators to responding to the needs of patients with chronic conditions and
19
20 484 complex care needs, to working with internal clinic partners and external health and social services
21
22 485 partners to care for this patient population, and to the process of implementing the four main
23
24 486 components of the CM intervention will be extracted and analyzed. Information regarding the perceived
25
26 487 complexity of the intervention, ease of implementation, care professional engagement and satisfaction
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28 488 with the intervention, and available support strategies to facilitate implementation will be extracted
29
30 489 from the data collection grid used for the non-participant observation and for the fidelity evaluation.
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37 491 Objective 2

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39 492 A similar approach will be taken to explain the influence of the context of implementation on the degree
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41 493 of implementation. Interviewees and participants in the focus group discussions will be asked specific
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43 494 questions regarding the local clinical context, the workplace environment, relationships with external
44
45 495 health and social services partners, individual attitudes and perceptions to the intervention and the
46
47 496 overall process of implementation of the CM intervention. This information will be extracted and
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49 497 compared to the results of the fidelity evaluation to assess the degree of implementation of the
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51 498 intervention.
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3 500 A mixed thematic analysis approach will be used (54). Each of the ten clinical sites will be analyzed
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5 501 separately as an individual case study using a deductive approach based on the conceptual model
6
7 502 (Figure 1), as well as an inductive approach based on emergent constructs. A case history will be
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9
10 503 reported, guided by the constructs of the conceptual model (Figure 1). Subsequent to individual analysis
11
12 504 of the ten cases, a comparison between the cases will be performed using a descriptive and
13
14 505 interpretative matrix (54). This approach allows systematic comparison among cases and among units of
15
16 506 analysis. Analytical techniques specific to case study research will be used as described in (55) including
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18 507 pattern comparison, research of competing explanations and construction of explanations. Qualitative
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21 508 data will be managed using multisite NVivo 12 server software (QSR International Pty Ltd).
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24 25 510 Objective 3

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28 511 To evaluate the influence of the context of implementation on the outcomes of the intervention, clinical
29
30 512 data on services use and quantitative data extracted from the patient self-administered questionnaires
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32 513 will be analyzed using descriptive statistics. Quantitative data will be analyzed first and then interpreted
33
34 514 in integration with qualitative data and the intervention fidelity evaluation described above, rather than
35
36 515 trying to calculate non-biased quantitative effects (73). Regression models will be developed to evaluate
37
38 516 the relationships between intervention fidelity, patient characteristics, the constructs of the conceptual
39
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41 517 model reflecting the contextual elements of the intervention, and the outcomes of the intervention. This
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43 518 will be done using SPSS version 26. An incremental cost-effectiveness/utility ratio (ICER or ICUR) (74) will
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45 519 be calculated using data collected on costs and quality-adjusted life years (QALY) before and after
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47
48 520 implementation of the CM intervention. Multivariate parametric analyses with bootstrap replications
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50 521 will be conducted together with cost-effectiveness acceptability curves (CEAC) (75).
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53 54 523 **Discussion**

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3 524 CM is a promising approach to delivering care to patients with chronic illnesses and complex care needs,
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5 525 but little is known about its implementation in a primary care setting (21). As an intervention composed
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7 526 of multiple components and steps that will be implemented in multiple sites, CM is an example of a
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10 527 complex, context-dependent intervention (76). Identifying and analyzing the contextual determinants
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12 528 across a variety of sites is necessary to understand how the intervention can produce its intended
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14 529 outcomes (77). An implementation analysis achieves a deeper understanding of the conditions that are
15
16 530 most likely to lead to the successful implementation of the core components of the intervention (56). It
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18 531 serves to identify variation in outcomes associated with different contexts and to identify
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20 532 implementation problems (73). An implementation analysis can reveal how an intervention causes
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22 533 change in a particular context and highlights an intervention's strengths and weaknesses in relation to
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24 534 intended outcomes (56).

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30 536 This research will detail the steps involved in implementing the four main components of the CM
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32 537 intervention at different clinical sites and will identify barriers and facilitators to implementation,
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34 538 providing the opportunity to address potential problems and to refine the intervention. This context of
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36 539 implementation which will be further understood through a detailed, theoretically-based approach to
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38 540 the identification and analysis of the macro, meso and micro level determinants of implementation (18,
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40 541 32). The implementation process will be studied, highlighting the development and change across time
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42 542 of the steps required to implement the intervention in various contexts. This research will respond to
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44 543 some of the most important issues raised in recent publications on CM for frequent users of health care
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46 544 services with chronic illnesses and complex care needs (21, 23, 24, 26) , by contributing to the
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48 545 understanding of how to implement this intervention in different primary care contexts in a cost-
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50 546 effective way that improves patient reported outcomes and health care use, while ensuring the well-
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54 547 being of the care team.

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5 549 The multi-level conceptual framework proposed in this study may be helpful for future research because
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8 550 it combines the approach to analyzing the effective implementation of health care interventions, with
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10 551 the principles of the integrative functions of primary care. The resulting framework supports the analysis
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12 552 of effective implementation not only of CM, but also of primary care interventions aiming to achieve
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14 553 care integration. The framework reflects the importance of intersectorial linkages and ensures the
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16 554 incorporation of constructs aimed to improve access, quality and continuity of services for patients with
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18 555 complex needs (18), regardless of the intervention being implemented. It is also particularly suited to
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21 556 the analysis and formative evaluation of complex, multi-level interventions in health care, verifying what
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23 557 works where and why across multiple contexts (32). The conceptual framework represents how patient,
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25 558 organizational and systems-level elements of implementation, the dynamic, time-dependent process of
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27 559 implementation, and the defining features of primary care, can translate into meaningful intervention
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29 560 outcomes, based on the quadruple aims to optimize health system performance. The framework can
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31 561 inform the effective implementation of complex primary care interventions that seek to facilitate the
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33 562 continuous, comprehensive and coordinated delivery of services to individuals or populations, and that
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35 563 necessitate the engagement of multiple stakeholders across various sectors.
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41 565 The use of “multi-strategy” or “multi-faceted” frameworks to describe and analyze the implementation
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43 566 of complex interventions increases the precision and specificity of reporting, which facilitates effective
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45 567 evaluation and replication (78, 79). The proposed research fulfills an essential step towards replication
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47 568 and scalability of CM by identifying the implementation strategies that support the adoption, scale-up
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49 569 and replication of best practices in CM (78, 80). Given the complex nature of the CM intervention,
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51 570 practitioners report challenges to implementation, especially considering the lack of guidelines or a
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53 571 blueprint on how to operationalize its core components across different settings (81). Implementation is
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3 572 often poorly reported in published literature, which presents a challenge to both research and practice
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5 573 and impedes replication and immediate adoption in a clinical setting (79, 82). To achieve wide-scale
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7 574 adoption and replication, the CM intervention must be tailored to the local context in an approach that
8
9 575 considers the individual, the team of professionals, the organizational setting and the greater system
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11 576 (81). Few studies have described, categorized and analyzed intervention implementation in a
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13 577 contextually tailored approach (82). This research will thus provide this information for both researchers
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15 578 and practitioners, which according to our knowledge, has not yet been done.
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580 **Study validity**

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23 581 Construct validity is ensured through a detailed conceptual model and consistency in the application of
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25 582 its constructs in the data collection and analysis. Internal validity is ensured through a systematic coding
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27 583 and rigorous organization of collected data and the triangulation of several sources of qualitative data
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29 584 acquired from different participating stakeholders including patients, case managers, clinic managers,
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31 585 researchers, clinicians and informal caregivers (55). Analysis and comparison of different case studies in
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33 586 various implementation contexts will reinforce external validity and transferability. The observation and
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35 587 analysis of multiple levels, and their replication across several cases enhances both internal and external
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37 588 validity (55).
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590 **Figure Legend**

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44 591 Figure 1: Conceptual model for the implementation analysis of a case management intervention
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594 **List of Abbreviations**

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51 595 CEAC: Cost-effectiveness acceptability curves
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55 596 CFIR: Consolidated framework for implementation research
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3 596 CIHI: Canadian Institute of Health Information
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5 597 CIHR: Canadian Institutes for Health Research
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7 598 CCM: Chronic care model
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9 599 CM: Case management
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11 600 EMR: Electronic medical record
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13 601 ICER: Incremental cost-effectiveness ratio
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15 602 ICUR: Incremental cost-utility ratio
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17 603 ISP: Individualized services plan
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19 604 QALY: Quality-adjusted life years
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25 606 **Declarations**
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27
28 607 The funders played no role in designing the study, neither did they in data collection, analysis and
29
30 608 interpretation or in the writing of the manuscript.
31

32 609 **Ethics approval**
33

34 610 This project received approval from the CIUSSS de l'Estrie – CHUS Research Ethic Board (project number
35
36 611 MP-31-2019-2830).
37

38
39 612 **Dissemination plan**
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41 613 Patients and family partners, clinicians, policy makers and researchers have formed a steering
42
43 614 committee to collaborate in planning and executing this research process. A knowledge translation plan
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45 615 has been developed with the goals of increasing awareness and bringing change to practice, policy and
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47 616 future research. Dissemination goals are determined by each stakeholder group and executed by a
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49 617 group representative. Dissemination methods include news releases in social media and local/provincial
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51 618 media outlets, executive-summary reports to clinician audiences, presentations at meetings of Canadian
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3 619 professional associations (for family physicians, nurses and social workers), conference presentations at
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5 620 annual international meetings of the NAPCRG and the CAHSPR, and articles in peer-reviewed journals.
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8 **621 Consent for publication**

9
10 622 This manuscript does not contain any individual person's data in any form.
11

12 **623 Availability of data and materials**

13
14 624 Not applicable.
15

16 **625 Competing interests**

17
18 626 None declared.
19
20

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46 **638 Author Contributions**

47
48 639 AD: conception and design of the work; acquisition, analysis and interpretation of data; drafting and
49
50 640 substantial revisions to the manuscript; MCC: conception of work; analysis and interpretation of data;
51
52 641 substantial revision to the manuscript; KAB: conception of work; analysis and interpretation of data;
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54 642 substantial revision to the manuscript; FB: conception of work; analysis and interpretation of data;
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3 643 substantial revision to the manuscript; SD: conception of work; analysis and interpretation of data;
4
5 644 substantial revision to the manuscript; VR: conception of work; analysis and interpretation of data;
6
7 645 substantial revision to the manuscript; MB: analysis and interpretation of data; substantial revision to
8
9
10 646 the manuscript; MC: analysis and interpretation of data; substantial revision to the manuscript;
11
12 647 BC: analysis and interpretation of data; substantial revision to the manuscript; ML: analysis and
13
14 648 interpretation of data; substantial revision to the manuscript; CP: analysis and interpretation of data;
15
16 649 substantial revision to the manuscript; VS: analysis and interpretation of data; substantial revision to the
17
18
19 650 manuscript; MW: analysis and interpretation of data; substantial revision to the manuscript;
20
21 651 CH: conception and design of the work; acquisition, analysis and interpretation of data; substantial
22
23 652 revisions to the manuscript; guarantor of the manuscript. All authors approved the final manuscript and
24
25 653 agree to be responsible for all aspects of the work.
26
27
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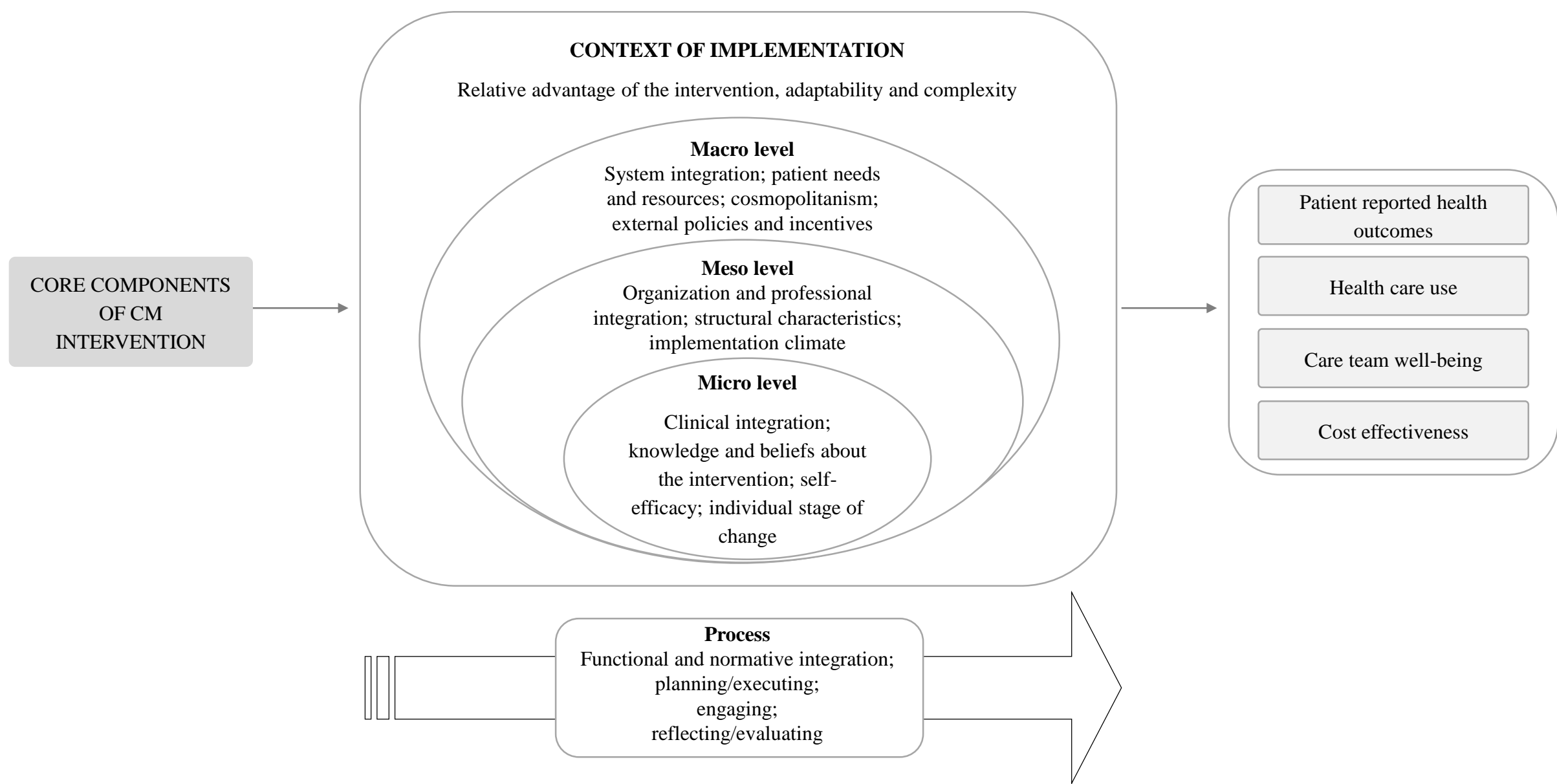
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Figure 1. Conceptual model for the implementation analysis of a case management intervention



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