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# BMJ Open

## Case management in primary care for frequent users of healthcare services with chronic diseases and complex care needs: an implementation and realist evaluation protocol

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Complete List of Authors:	<p>Hudon, Catherine; Université de Sherbrooke, Department of family medicine and emergency medicine  Chouinard, Maud-Christine; Université du Québec à Chicoutimi, Département des Sciences de la Santé  Aubrey-Bassler, Kris; Memorial University, Primary Healthcare Research Unit  Burge, Fred ; Dalhousie University, Department of Family Medicine  Doucet, Shelley; University of New Brunswick, Department of Nursing and Health Sciences  Ramsden, Vivian; University of Saskatchewan, Department of Academic Family Medicine  Brodeur, Magaly; Université de Sherbrooke, Département de Médecine de Famille et Médecine d'urgence  Bush, Paula; McGill University, Family Medicine  Couturier, Yves; Université de Sherbrooke, social work  Dubois, Marie-France; Université de Sherbrooke, Department of community health  Guenette, Line; Université Laval, Faculty of Pharmacy and CHU de Québec Research Center;  Legare, France; CHU de Québec and Université Laval, Department of Family Medicine  Morin, Paul; Université de Sherbrooke, School of Social Work  Poder, Thomas; CIUSSS de l'Estrie - CHUS, UETMIS and CRCHUS; Université de Sherbrooke, Département de Médecine de Famille et Médecine d'urgence  Poitras, Marie-Eve; Université du Québec à Chicoutimi, Département des Sciences de la Santé  Roberge, Pasquale; Université de Sherbrooke, Médecine de famille  Valaitis, Ruta; McMaster University, School of Nursing  Bighead, Shirley; Sturgeon Lake First Nation  Campbell, Cameron; Department of Health and Community Services  Couture, Martine; Centre intégré universitaire de santé et de services sociaux du Saguenay-Lac-Saint-Jean  Davis, Breanna; University of Saskatchewan, Department of Academic Family Medicine  Deschenes, Elaine; Centre de pédiatrie sociale Sud-Est (CPSSE)  Edwards, Lynn; Nova Scotia Health Authority  Gander, Sarah; Horizon Health Network  Gauthier, Gilles; Unité SOUTIEN du Québec  Gauthier, Patricia; Centre intégré universitaire de santé et services sociaux</p>

	<p>de l'Estrie – Centre hospitalier universitaire de Sherbrooke  Gibson, Richard; Nova Scotia Health Authority  Godbout, Julie; Centre integre universitaire de sante et de services sociaux  du Saguenay-Lac-Saint-Jean  Landry, Geneviève; Ministère de la Sante et des Services sociaux Quebec  Longjohn, Christine; Sturgeon Lake First Nation  Rabbitskin, Norma; Sturgeon Lake First Nation  Roy, Denis; Institut national d'excellence en santé et en services sociaux  Roy, Judy; Maritime SPOR SUPPORT Unit  Sabourin, Véronique; Unité SOUTIEN du Québec  Sampalli, Tara ; Nova Scotia Health Authority  Saulnier, Amanda; Maritime SPOR SUPPORT Unit  Spence, Claude; Unité SOUTIEN du Québec  Splane, Jennifer; NaviCare/SoinsNavi  Warren, Mike; NL SPOR SUPPORT Unit  Young, Joanne; Government of New Brunswick, Chronic Disease Prevention  and Management Health  Pluye, Pierre; Université McGill, Department of family medicine</p>
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1 **Case management in primary care for frequent users of healthcare services with chronic**  
2 **diseases and complex care needs: an implementation and realist evaluation protocol**

3  
4 Catherine Hudon<sup>1</sup>, Maud-Christine Chouinard<sup>2</sup>, Kris Aubrey-Bassler<sup>3</sup>, Frederick Burge<sup>4</sup>, Shelley  
5 Doucet<sup>5</sup>, Vivian R. Ramsden<sup>6</sup>, Magaly Brodeur<sup>1</sup>, Paula L. Bush<sup>7</sup>, Yves Couturier<sup>8</sup>, Marie-France  
6 Dubois<sup>9</sup>, Line Guénette<sup>10</sup>, France Légaré<sup>11</sup>, Paul Morin<sup>8</sup>, Thomas G Poder<sup>1,12</sup>, Marie-Ève Poitras<sup>2</sup>,  
7 Pasquale Roberge<sup>1</sup>, Ruta Valaitis<sup>13</sup>, Shirley Bighead<sup>14</sup>, Cameron Campbell<sup>15</sup>, Martine Couture<sup>16</sup>,  
8 Breanna Davis<sup>6</sup>, Éline Deschenes<sup>17</sup>, Lynn Edwards<sup>18</sup>, Sarah Gander<sup>19</sup>, Gilles Gauthier<sup>20</sup>, Patricia  
9 Gauthier<sup>21</sup>, Rick Gibson<sup>18</sup>, Julie Godbout<sup>16</sup>, Geneviève Landry<sup>22</sup>, Christine Longjohn<sup>14</sup>, Norma  
10 Rabbitskin<sup>14</sup>, Denis A. Roy<sup>23</sup>, Judy Roy<sup>24</sup>, Veronique Sabourin<sup>20</sup>, Tara Sampalli<sup>18</sup>, Amanda  
11 Saulnier<sup>24</sup>, Claude Spence<sup>20</sup>, Jennifer Splane<sup>25</sup>, Mike Warren<sup>26</sup>, Joanne Young<sup>27</sup>, Pierre Pluye<sup>7</sup>

12  
13 Affiliations

14 <sup>1</sup>Département de Médecine de Famille et Médecine d'urgence, Université de Sherbrooke,  
15 Québec, Canada; <sup>2</sup>Département des Sciences de la Santé, Université du Québec à Chicoutimi,  
16 Québec, Canada; <sup>3</sup>Primary Healthcare Research Unit, Memorial University, Newfoundland and  
17 Labrador, Canada; <sup>4</sup>Department of Family Medicine, Dalhousie University, Nova Scotia, Canada;  
18 <sup>5</sup>Department of Nursing and Health Sciences, University of New Brunswick, New Brunswick,  
19 Canada; <sup>6</sup>Department of Academic Family Medicine, University of Saskatchewan, Saskatchewan,  
20 Canada; <sup>7</sup>Department of Family Medicine, Université McGill, Montréal, Québec, Canada;  
21 <sup>8</sup>School of Social Work, Université de Sherbrooke, Québec, Canada; <sup>9</sup>Département des sciences  
22 de la santé communautaire, Université de Sherbrooke, Québec, Canada; <sup>10</sup>Faculté de Pharmacie,  
23 Université Laval, Québec, Canada; <sup>11</sup>Department of Family Medicine and Emergency Medicine,  
24 Université Laval, Québec, Canada; <sup>12</sup>UETMIS and CRCHUS, CIUSSSE de l'Estrie – CHUS,  
25 Sherbrooke, Canada; <sup>13</sup>School of Nursing, McMaster University, Ontario, Canada; <sup>14</sup>Sturgeon  
26 Lake First Nation, Saskatchewan, Canada; <sup>15</sup>Department of Health and Community Services –

1  
2  
3 27 Newfoundland and Labrador, Canada; <sup>16</sup>Centre intégré universitaire de santé et de services  
4  
5 28 sociaux du Saguenay-Lac-Saint-Jean, Quebec, Canada; <sup>17</sup>Centre de pédiatrie sociale Sud-Est  
6  
7 29 (CPSSE), New Brunswick, Canada; <sup>18</sup>Nova Scotia Health Authority, Nova Scotia, Canada;  
8  
9 30 <sup>19</sup>Horizon Health Network, New Brunswick, Canada; <sup>20</sup>Unité SOUTIEN du Québec, Québec,  
10  
11 31 Canada; <sup>21</sup>Centre intégré universitaire de santé et services sociaux de l'Estrie – Centre hospitalier  
12  
13 32 universitaire de Sherbrooke, Québec, Canada; <sup>22</sup>Ministère de la santé et des services sociaux,  
14  
15 33 Québec, Canada; <sup>23</sup>Institut national d'excellence en santé et en services sociaux, Québec, Canada;  
16  
17 34 <sup>24</sup>Maritime SPOR SUPPORT Unit, New Brunswick, Canada; <sup>25</sup>NaviCare/SoinsNavi, St-John,  
18  
19 35 New Brunswick, Canada; <sup>26</sup>NL SPOR SUPPORT Unit, Newfoundland and Labrador, Canada;  
20  
21 36 <sup>27</sup>Chronic Disease Prevention and Management Health, Government New Brunswick, New  
22  
23 37 Brunswick, Canada  
24  
25 38

26  
27  
28 39 **Corresponding author:**

30 40 Dr Catherine Hudon, Ph.D. Département de Médecine de Famille et Médecine d'urgence, Université  
31  
32 41 de Sherbrooke, 3001, 12<sup>e</sup> Avenue Nord, Sherbrooke, QC, Canada J1H 5N4. Telephone: 819-346-  
33  
34 42 1110 ext: 70540; Email: [Catherine.Hudon@Usherbrooke.ca](mailto:Catherine.Hudon@Usherbrooke.ca)  
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## 45 ABSTRACT

46

47 **Introduction:** Significant evidence in the literature supports case management (CM) as an  
48 effective intervention to improve care for patients with complex healthcare needs. However, there  
49 is still little evidence about the facilitators and barriers to CM implementation in primary care  
50 setting. The three specific objectives of this study are to: (O1) Identify the facilitators and barriers  
51 of CM implementation in primary care clinics across Canada; (O2) Explain and understand the  
52 relationships between the actors, contextual factors, mechanisms, and outcomes of the CM  
53 intervention; (O3) Identify the next steps towards CM spread in primary care across Canada.

54

55 **Methods and analysis:** We will conduct a multiple-case embedded mixed methods study. CM  
56 will be implemented in 10 primary care clinics in five Canadian provinces. Three different units  
57 of analysis will be embedded to obtain an in-depth understanding of each case: the healthcare  
58 system (macro level); the CM intervention in the clinics (meso level); and the individual/patient  
59 (micro level). For each objective, the following strategy will be performed: (O1) an  
60 implementation analysis, (O2) a realist evaluation, and (O3) consensus building among  
61 stakeholders using the TRIAGE method.

62

63 **Ethics and dissemination:** This study, which received ethic approval, will provide innovative  
64 knowledge about facilitators and barriers to implementation of CM in different primary care  
65 jurisdictions, and will explain how and why different mechanisms operate in different contexts to  
66 generate different outcomes among frequent users. Consensual and prioritized statements about  
67 next steps for spread of CM in primary care from the perspectives of all stakeholders will be  
68 provided. Our results will offer context-sensitive explanations that can better inform local  
69 practices and policies, and contribute to improve the health of patients with complex healthcare

70 needs who frequently use healthcare services. Ultimately, this will increase the performance of  
71 healthcare systems, and specifically mitigate ineffective use and costs.

72

73 **Registration details:** A realist evaluation does not need registration.

74

#### 75 **Strengths and limitations of this study**

76 - This multiple-case embedded mixed methods study will provide new knowledge on the  
77 implementation of case management interventions to improve care integration for  
78 individuals/patients who frequently use healthcare services.

79

80 - The design of this study allows adapting the knowledge acquired on case management to local  
81 contexts, the first step to implementation.

82

83 - The multiprovincial nature of this study will allow to spread the new knowledge generated on  
84 CM in primary care settings in different Canadian jurisdictions and will increase  
85 generalizability.

86

87 - While some challenges are expected with this study, mitigated strategies are nevertheless  
88 proposed.

## 89 INTRODUCTION

90 In Canada, as in many industrialized countries <sup>1,2</sup>, close to 80% of healthcare costs are attributable  
91 to 10% of the population <sup>3,4</sup>. Data reveal that this 10% segment of the population comprises  
92 individuals/patients who frequently use hospital services for increasingly complex healthcare  
93 needs. Thus, albeit relatively small, this segment of the population uses a disproportionate amount  
94 of available healthcare and social services. Frequent use of emergency departments (ED) is a  
95 good proxy of high use of other healthcare services <sup>5-7</sup> as it is most commonly accepted in the  
96 literature <sup>8-12</sup>, and provides a convenient and easy measure within a pragmatic context, as  
97 compared to cost for example. As such, five percent of ED's patients account for 30 to 50% of all  
98 visits <sup>8,13</sup>. As frequent use is not optimal for individuals/patients <sup>14</sup> or healthcare systems <sup>15,16</sup>,  
99 better upstream care is a modifiable parameter that can effectively prevent it. Indeed, the majority  
100 of these individuals/patients who frequently use hospital services have a substantial burden of  
101 disease and would be best managed in primary care. <sup>17</sup>.

102  
103 In line with the Agency for Healthcare Research and Quality Multiple Chronic Conditions  
104 Research Network, complex healthcare needs can be defined as the gap between an individual's  
105 needs and the ability of health services to meet those needs <sup>18</sup>. Individuals/patients with complex  
106 healthcare needs often attempt to fulfill their unmet needs by using excessive health and social  
107 services in an uncoordinated way. Requiring a variety of services from various systems (e.g.  
108 health, social, education) and community networks, this often leads to difficulties with the  
109 integration of care<sup>19</sup>. This results in negative experiences for individuals/patients <sup>14</sup>, poorer health  
110 outcomes, high mortality rates and considerable costs <sup>19</sup>.

111  
112 Case management (CM) was reported to be effective for individuals/patients who frequently used  
113 healthcare services <sup>10,20,21</sup>. By definition, CM is a collaborative approach used to assess, plan,  
114 facilitate, and coordinate care to meet individual/patient and family healthcare needs, through



1  
2  
3 115 communication and available resources including all sectors of health care (such as community,  
4  
5 116 primary, secondary and tertiary care), as well as sectors outside of the health system (such as  
6  
7 117 social services, housing, etc.) with the intent of improving individual and health system outcomes  
8  
9 118 <sup>22</sup>. Three systematic reviews (including randomized controlled trials, non-randomized controlled  
10  
11 119 trials, interrupted time series, and controlled and non-controlled before-and-after studies)  
12  
13 120 concluded that CM was effective for individuals/patients who frequently used healthcare services,  
14  
15 121 particularly on ED use and cost as well as on social and clinical outcomes <sup>8 10 11</sup>. A scoping review  
16  
17 122 conducted by our team corroborated these findings by revealing that CM could reduce ED visits  
18  
19 123 and hospitalisations as well as costs <sup>9</sup>.

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22 124  
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24 125 However, despite the evidence supporting CM as an effective intervention for individuals/patients  
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26 126 that frequently use services, there is still a paucity of evidence about the facilitators and barriers  
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28 127 to CM implementation <sup>10 23</sup>. Our literature review with thematic analysis of key factors of CM  
29  
30 128 interventions among frequent users of healthcare services outlined that the case finding processes,  
31  
32 129 the selection and training of the case manager, the intensity of the intervention, as well as care  
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34 130 integration among all partners were important aspects to consider during CM implementation <sup>23</sup>.

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37 131  
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39 132 CM has rarely been implemented in primary care in Canada. Therefore, before spreading this  
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41 133 intervention in primary care settings in different jurisdictions, stakeholders including  
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43 134 individuals/patients/communities need to be engaged in adapting the intervention to their local  
44  
45 135 context. Accordingly, further research is needed to better understand the facilitators and barriers  
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47 136 (mechanisms) to CM implementation, as well as the influence of different primary care contexts  
48  
49 137 on outcomes, e.g., self-management, quality of life, services integration, services use, and costs <sup>9</sup>  
50  
51 138 <sup>24 25</sup>.

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53  
54 139 Therefore, the specific objectives of this study are threefold: (O1) identify the facilitators and  
55  
56 140 barriers of CM implementation in primary care clinics across Canada; (O2) explain and

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3 141 understand the relationships between the actors, contextual factors, mechanisms, and outcomes of  
4  
5 142 the CM intervention; and (O3) identify the next steps towards CM spread in primary care across  
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7 143 Canada.  
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## 11 145 **METHODS AND ANALYSIS**

### 12 13 146 14 15 147 **Study design**

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18 148 To address these objectives, we will conduct, between September 2018 and August 2022, a  
19  
20 149 multiple-case embedded mixed methods study, which constitutes a valuable design for  
21  
22 150 performing research evaluation inquiries on complex systems in varied and dynamic contexts <sup>26</sup>  
23  
24 151 <sup>27</sup>. In addition to allowing an in-depth analysis of each case, this design offers opportunities for  
25  
26 152 comparison between cases. The inclusion of multiple cases capitalizes on organizational variation  
27  
28 153 and allows for examination of how contextual factors influence implementation to develop a  
29  
30 154 more informed understanding of change processes. It also allows for observation recursive or  
31  
32 155 singular facilitators and barriers, and draws conclusions that could be transferable to other  
33  
34 156 primary care contexts<sup>28</sup>. Furthermore, mixed methods involve combining qualitative and  
35  
36 157 quantitative methods in complex program evaluation, primary research, and literature review;  
37  
38 158 they are being increasingly used in health sciences; specifically, case studies can use qualitative,  
39  
40 159 quantitative and mixed methods (multiple sources of evidence) to explain one or more cases <sup>29</sup>.

### 41 42 160 43 44 161 **Study location and sampling**

45  
46 162 Five Canadian provinces are involved in the study: Saskatchewan (SK), Quebec (QC), Nova  
47  
48 163 Scotia (NS), New Brunswick (NB) and Newfoundland and Labrador (NL). Considering that  
49  
50 164 different primary care team models have been implemented throughout Canada <sup>30 31</sup>, the primary  
51  
52 165 care context of each jurisdiction will be taken into account when evaluating implementation and  
53  
54 166 outcomes <sup>31</sup>.

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3 167 Two primary care clinics per province, where CM has not been previously implemented, will be  
4  
5 168 recruited using a purposeful sampling strategy <sup>32</sup>. The recruitment of the clinics will be  
6  
7 169 conditional to: the manager and team interest in implementing CM and engaging in the research  
8  
9 170 project; availability and interest of a registered nurse or nurse practitioner to develop the role of  
10  
11 171 the case manager. We will thus work with 10 cases (two per province), each case being the  
12  
13 172 intervention implemented in each clinic. It is recommended that four to 10 cases be considered <sup>33</sup>  
14  
15 173 in the multiple case study logic of theoretical replication, in which contrasting results are  
16  
17 174 anticipated <sup>26</sup>. Two clinics per province will facilitate variability within each province. Cases will  
18  
19 175 be selected in order to represent real-world differences <sup>34</sup> in terms of geographic location, model  
20  
21 176 of practice, diversity of care teams, and size, based on the opinion of team members in each  
22  
23 177 jurisdiction. Three different units of analysis will be explored to obtain an in-depth understanding  
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25 178 of each case: (a) the healthcare system (macro level); (b) the CM intervention in the clinics (meso  
26  
27 179 level); and, (c) the patient including their family and community (micro level).  
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33 181 **Objective 1: To identify facilitators and barriers of CM implementation in primary care**  
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35 182 **clinics in Canada**  
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39 184 An implementation analysis will be conducted for identifying facilitators and barriers to, and  
40  
41 185 informing implementation of, CM in primary care in different provinces <sup>35</sup>. Implementation  
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43 186 analysis is very useful with complex interventions that can be influenced by the context within  
44  
45 187 dynamic environments. The case study design is appropriate for implementation analysis of  
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47 188 interventions <sup>35</sup>.  
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49 189  
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51 190 *Conceptual framework*  
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54 191 Data collection and analysis will rely on the Consolidated Framework for Implementation  
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56 192 Research (CFIR) of Damschroder *et al.* <sup>36</sup>, which is aimed to foster implementation of findings  
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3 193 into practice. The CFIR is composed of five major domains: outer setting, inner setting,  
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5 194 characteristics of the individuals involved, intervention characteristics, and, the process of  
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7 195 implementation. Four constructs are related to the outer setting (e.g., external policies); 12 are  
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9 196 related to the inner setting (e.g., culture and leadership engagement); five are related to individual  
10  
11 197 characteristics (e.g., knowledge and beliefs); eight are related to the intervention (e.g.,  
12  
13 198 adaptability); and eight are related to process (e.g., planning). *'The CFIR provides a practical*  
14  
15 199 *structure for approaching complex and transient states of constructs in the real world by*  
16  
17 200 *embracing, consolidating, and unifying key constructs from published implementation theories.'*<sup>36</sup>  
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22 202 To properly address care integration, the CFIR will be linked to the Valentijn et al. framework<sup>37</sup>  
23  
24 203 combining the concepts of primary care and integrated care. In this framework, person-focused  
25  
26 204 care is the guiding principle for achieving integration across the care continuum, i.e. system  
27  
28 205 integration (macro level), professional and organisational integration (meso level) as well as  
29  
30 206 clinical integration (micro level).  
31  
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### 33 207

### 34 208 *Pre-implementation*

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37 209 A CM nurse mentor will facilitate 3-day training sessions for all CM nurses and will also lead  
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39 210 monthly 1-hr community-of-practice meetings by teleconference, to assist with mentoring,  
40  
41 211 collective learning and support<sup>38</sup>. As recommended by Damschroder et al. CFIR<sup>36</sup>, team  
42  
43 212 stakeholders will interact with the clinics in their province to co-design the adaptation of the CM  
44  
45 213 intervention to their reality. According to the CFIR<sup>36</sup>, the core components of the intervention,  
46  
47 214 such as patient assessment, individualized care plan, care coordination and self-management  
48  
49 215 support<sup>39-42</sup>, will be maintained across all clinics, whereas more peripheral elements will be  
50  
51 216 adaptable, e.g., as integration in the context. This adaptability will increase knowledge uptake<sup>24</sup>  
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53  
54 217 and promote integration with complementary programs outside of the clinics, while ensuring that  
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3 218 CM is being rigorously evaluated.  
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7 220 *Recruitment*

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9 221 Each clinic will identify 30 patients with the most complex healthcare needs and who, according  
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11 222 to their clinical experience of the existing gap between the individual's needs and the ability of  
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13 223 health services to meet those needs<sup>18</sup> could benefit from CM. Inclusion criteria will be: living  
14  
15 224 with at least one chronic condition; frequent ED users as defined by  $\geq 4$  ED visits in the previous  
16  
17 225 year<sup>43 44</sup> (which have been recognized as a good proxy of frequent use of other healthcare  
18  
19 226 services<sup>5-7</sup>); and, a score  $\geq 17$  on the INTERMED-Self-Assessment Questionnaire<sup>45</sup> evaluating  
20  
21 227 complex healthcare needs. Exclusion criteria will be: frail elderly with loss of autonomy;  
22  
23 228 individuals/patients without a chronic condition or with a prognosis of less than a year; or,  
24  
25 229 patients already followed by a case manager in another program, e.g., mental health, senior care,  
26  
27 230 addiction program. Case managers will offer the CM intervention to these individuals/patients  
28  
29 231 over a 12-month period.  
30

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35 233 *Intervention*

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37 234 The intervention will focus on four main recognized components of CM<sup>39-42</sup>: (C1) evaluation of  
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39 235 patient needs and preferences; (C2) co-development and maintenance of a patient-centred  
40  
41 236 individualized care plan, with the patient, family and other partners; (C3) coordination of health  
42  
43 237 and social services among all partners; and (C4) education and self-management support for  
44  
45 238 patients and families. This intervention is congruent with criteria from the *Case Management*  
46  
47 239 *Society of America*<sup>22</sup> and the six standards of practice of the *National Case Management Network*  
48  
49 240 *of Canada*<sup>46</sup>: (S1) determining and verifying patient eligibility; (S2) assessing patient needs; (S3)  
50  
51 241 documenting patient goals and priorities; (S4) planning and adjusting services included in  
52  
53 242 individualized service plans, including patient education and self-management support; (S5)  
54  
55 243 monitoring patient needs and progress; and (S6) supporting transition processes. The intervention  
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244 also aligns with the six care integration characteristics proposed to consider a patient's  
245 experience<sup>47</sup>: (I1) consideration of patient and family needs; (I2) communication with the patient  
246 and between healthcare providers; (I3) access to information; (I4) involvement in decision-  
247 making; (I5) care planning; and, (I6) transitions between various professionals.

248

#### 249 *Data collection*

250 The mixed method data collection will rely on the five following complementary strategies.

251

252 (1) Individual semi-structured interviews (qualitative data) will be conducted between six and  
253 nine months following initiation of CM intervention with all case managers, patients/families and  
254 clinic managers. Two focus groups per clinic will be also scheduled, enrolling eight primary care  
255 providers per group (including physicians, nurses, social workers, pharmacists and others)  
256 through purposive sampling<sup>48</sup>. All interviews and focus groups, conducted using a semi-  
257 structured interview guide composed of open-ended questions on facilitators and barriers of CM  
258 implementation and adapted to each category of stakeholders, will be digitally recorded and  
259 transcribed verbatim. Interview guides will address the domains and constructs of Damschroder's  
260 CFIR<sup>36</sup> and Valentijn Framework<sup>37</sup>. Data saturation will not necessarily be reached for each  
261 category of stakeholders, but their diversity will allow for a comprehensive representation of each  
262 case<sup>49</sup>.

263

264 (2) Non-participant observation (qualitative data) of CM activities and meetings, e.g., patient-case  
265 manager, individualized service plan development, team discussions, at each clinic for thirty  
266 hours at 6 months will be conducted. Research assistants will collect data by means of an  
267 observation grid and field notes<sup>48</sup>.

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3 269 (3) Self-administered and validated questionnaires (quantitative data) with accepted psychometric  
4  
5 270 properties will be administered to all individuals/patients in the presence of the research assistant.  
6  
7 271 At baseline, the following characteristics will be assessed: age; gender; marital status; education;  
8  
9 272 occupation; economic status with family income and patient perception of his or her economic  
10  
11 273 situation; health literacy<sup>50 51</sup>; multimorbidity<sup>52 53</sup>; care integration<sup>54</sup>; self-management<sup>55 56</sup> and  
12  
13 274 health related quality of life<sup>57</sup>. Care integration, self-management and health related quality of  
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15 275 life, will be re-evaluated at 12 months.  
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20 277 (4) Clinical data on service use during the year of the intervention (quantitative data) will be  
21  
22 278 collected through the patient's electronic medical record: ED visits; overnight stays; primary care  
23  
24 279 and specialist visits. Costs will be measured from a healthcare system perspective, including costs  
25  
26 280 of the CM intervention and of healthcare expenditures. Costs of the intervention will consider  
27  
28 281 nurse training, mentoring, and CM implementation. Participant healthcare expenditures, such as  
29  
30 282 ED visits, overnight stays, professional visits, will be calculated using predetermined fees, e.g.,  
31  
32 283 from the CIHI Patient Cost Database<sup>58</sup>.  
33  
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35 284  
36  
37 285 (5) Intervention fidelity evaluation (quantitative data) will be assessed to determine whether the  
38  
39 286 intervention was delivered as intended<sup>59</sup>. For this purpose, research assistants will collect data  
40  
41 287 relevant to the delivery of the main components of the CM intervention from the medical records  
42  
43 288 of participants after six and 12 months using a fidelity grid. Similar data on CM intervention  
44  
45 289 fidelity were collected successfully in our previous study<sup>60</sup>.  
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#### 48 290 49 291 *Data analysis*

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51 292 Qualitative data analysis: Interview- and observation-based data will be analysed together using a  
52  
53 293 deductive (themes based on the Damschroder et al. CFIR and Valentijn frameworks) and  
54  
55 294 inductive (themes suggested by the data while not in frameworks) thematic analyses<sup>61</sup>.  
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3 295 Qualitative data will be managed using multi-site NVivo 10 server software (QSR International  
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5 296 Pty Ltd).

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9 298 Quantitative data analysis: Descriptive statistics will be performed. Intervention fidelity will be  
10  
11 299 represented by the proportion of delivery for each component of the CM intervention. Regression  
12  
13 300 models will be developed to evaluate relationships between contextual elements, i.e. intervention  
14  
15 301 fidelity, patients' characteristics and outcomes, using SPSS version 24. An incremental cost-  
16  
17 302 effectiveness/utility ratio<sup>62</sup> will be calculated, using data collected on costs and QALY (i.e., SF-  
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19 303 6D), at baseline, and 12 months after the CM implementation. Multivariate parametric analyses  
20  
21 304 with bootstrap replications will be conducted along with cost-effectiveness acceptability curves<sup>63</sup>.

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26 306 Integration of qualitative and quantitative methods - Two types of integration will be performed:  
27  
28 307 qualitative and quantitative results will be compared, and qualitative and quantitative data will be  
29  
30 308 merged for each case<sup>29</sup>. Considering the inherent variety and changing contexts of the study,  
31  
32 309 results of qualitative and quantitative data analyses will be compared, and the comparison  
33  
34 310 interpreted using a side-by-side joint comparison table (rather than trying to calculate non-biased  
35  
36 311 quantitative effects<sup>64</sup>). Then for each case, qualitative and quantitative data will be merged<sup>26</sup>. A  
37  
38 312 case history will be reported (synthesizing merged data), and the 10 case histories will be used to  
39  
40 313 compare cases by means of a descriptive and interpretative matrix (mixed methods matrix),  
41  
42 314 allowing systematic comparisons among cases and analysis units (macro, meso and micro)<sup>61</sup>.  
43  
44 315 Different analytical techniques for case study will be used among which pattern comparison,  
45  
46 316 research of competing explanations and construction of explanations<sup>26</sup>. Management, data  
47  
48 317 reduction and cross care comparisons will be conducted with NVivo 10 software using matrix  
49  
50 318 queries. All categories of stakeholders will be invited to participate in key steps of the analysis to  
51  
52 319 ensure meaningful interpretation.

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3 321 **Objective 2: To explain and understand the relationships between actors, contextual**  
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5 322 **factors, mechanisms and outcomes of CM intervention**  
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9 324 A realist evaluation will be conducted according to Pawson and Tilley<sup>65</sup>. Realist evaluation is a  
10 325 theory-driven approach for studying complex interventions to explain how and why they are  
11 326 effective, under what conditions and for which groups of patients. It is based on four concepts for  
12 327 explaining and understanding the complex relationships in a given intervention: context (C);  
13 328 mechanism (M); outcome (O); and, context–mechanism–outcome (CMO) configuration<sup>65-67</sup>. The  
14 329 multiple-case study is a recognised design for investigating CMO configurations in healthcare  
15 330 research<sup>68-73</sup>. The realist evaluation will use a multi-method (quantitative and qualitative), theory-  
16 331 driven approach to provide an explanation of why outcomes occur<sup>67</sup>, and will follow three  
17 332 phases: stating an initial program theory; testing this program theory; and, refining this program  
18 333 theory.  
19

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21 335 *Stating an initial program theory*

22 336 A proposed initial middle-range program theory developed in our realist synthesis<sup>74</sup> of the  
23 337 literature on CM for individuals/patients that frequently use healthcare services in primary care  
24 338 will provide a rigorous basis for the next two phases of data collection (testing and refining the  
25 339 program theory).  
26

27 340

28 341 *Data collection (testing and refining the program theory)*

29 342 In the next year, same participant sampling and data collection will be repeated in the same  
30 343 clinics identified in Objective 1, with a new cohort of patients. However, qualitative data will be  
31 344 used to identify and better understand CMOs. The same quantitative data will be used to measure  
32 345 outcomes, i.e. self-management, health related quality of life, care integration, services use and  
33 346 costs at baseline, 6- and 12-months for developing CMOs. For qualitative data collection,  
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3 347 interview guides and the observation grid will be informed by the initial theory and tailored to the  
4  
5 348 participant groups. Interviews and focus groups will be performed using realist interview  
6  
7 349 techniques<sup>75</sup>. The theory will be discussed with individuals/patients who will then provide their  
8  
9 350 own experience and vision for collaborative conceptual refinement. The interviewer will play an  
10  
11 351 active role in explaining the contexts and outcomes of interest, and in ensuring that participants  
12  
13 352 understand the terminology of the realist evaluation. Participants will be asked to share how they  
14  
15 353 think their experience relates to this theory and to reflect on what may explain the outcomes in  
16  
17 354 their setting<sup>76</sup>. Data collection will be iterative until reaching saturation<sup>65 75</sup>.  
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### 22 356 *Data analysis*

23  
24 357 Quantitative data will be analyzed, as described above, to inform outcomes. Qualitative data,  
25  
26 358 including interviews, focus groups and observation, will be analysed with NVivo using thematic  
27  
28 359 analysis, guided by the initial program theory from the realist synthesis. Analysis will remain  
29  
30 360 open to emergent themes that support further theory refinement. Similar to the above integration,  
31  
32 361 quantitative and qualitative results will be compared (producing joint display table), and  
33  
34 362 quantitative and qualitative data will be merged for each case (producing case histories and a  
35  
36 363 mixed method matrix).  
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41 365 Research assistants from the various provinces will co-analyze quantitative, qualitative and mixed  
42  
43 366 methods evidence. They will identify CMO configurations, first within each primary care clinic  
44  
45 367 (case) and then across sites. All team members will be involved in certain steps of the analysis. A  
46  
47 368 recap table<sup>77</sup> will be constructed using columns to separate components of the initial theory and  
48  
49 369 rows representing different cases. This approach will facilitate within-case analysis, highlighting  
50  
51 370 similarities or discrepancies between data sources. It will also facilitate cross-case analysis to  
52  
53 371 identify patterns (demi-regularities or semi predictable patterns) across cases. Analysis of CMO  
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55 372 configurations will help complete, confirm, or modify the components of our initial theory, and  
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3 373 ultimately produce a refined theory explaining how and why CM works, in specific contexts, and  
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5 374 for specific categories of patients. Results will be reported in line with the RAMESES II reporting  
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7 375 standards for realist evaluation <sup>78</sup>.  
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11 377 **Objective 3: To identify the next steps towards CM spread in primary care across Canada**

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16 379 The Technique for Research of Information by Animation of a Group of Experts (TRIAGE)  
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18 380 method will be used to reach consensus among all stakeholders about the next steps forward with  
19  
20 381 spread (expansion and extension), in light of our case study results. The process of developing a  
21  
22 382 shared understanding from the different stakeholders' perspectives through discussion improves  
23  
24 383 progress of an innovation towards spread <sup>25</sup>. TRIAGE is a research method based on the  
25  
26 384 attainment of a group consensus to supply first-hand information for decision-making <sup>79</sup>. It is a  
27  
28 385 structured and inductive method of data collection comprising three successive phases:  
29  
30 386 preparation; individual production; and interactive production.  
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35 388 *Preparation*

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37 389 A full-day meeting will be organized, gathering the tripartite structure (clinical, scientific and  
38  
39 390 policymaker leads) of all pan-Canadian SPOR Networks in Primary and Integrated Health Care  
40  
41 391 Innovations (PIHCI) and at least one individual/patient from each province in order to embody  
42  
43 392 categories of stakeholders across Canada. PIHCI is a network building on regional and national  
44  
45 393 achievements in community-based primary and integrated health care <sup>80</sup>. During this preparation  
46  
47 394 phase, a brief executive summary of project results will be produced and tailored to inform each  
48  
49 395 specific audience and category of stakeholders. The evaluation question that will be discussed and  
50  
51 396 disseminated to the participants is as follows: Based on your own experience, what should be the  
52  
53 397 next steps towards the spread of CM in primary care, in your area of expertise (patient  
54  
55 398 engagement, clinical care, policy and research)?  
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3 399 *Individual production*  
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5 400 All stakeholders will receive the executive summary of the results, two months prior to the  
6  
7 401 meeting, and will be asked to provide a maximum of five statements in response to the question  
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9 402 stated above. Beyond five statements, information is expected to become redundant <sup>79</sup>. These  
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11 403 statements will be kept confidential and sent back to the organisation team.  
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16 405 *Interactive production*  
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18 406 This phase will take place during the full-day meeting. The project and results will be presented  
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20 407 to all participants. Each group of stakeholders will gather to identify, by consensus, the most  
21  
22 408 important and relevant statements among those brought forth in their stakeholder category. An  
23  
24 409 expert animator will act as a facilitator and lead interactions among group experts. The interactive  
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26 410 step of TRIAGE relies on a prominent visual aid. A wall of the room will be used and divided  
27  
28 411 into three main sections: memory, groupings and selection. The memory section is, in fact, a bank  
29  
30 412 of all statements gathered in the previous step, which have been numbered and transcribed. As  
31  
32 413 group interactions occur, the selection process will evolve, with cards moving from one section to  
33  
34 414 another, from left (memory) to right (selection). It will also be possible to modify the statements.  
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36 415 “Selected” statements will also be ranked and prioritized. At the end of the meeting, each group  
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38 416 of stakeholders will present their selected statements in order of priority.  
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43 418 **ETHICS AND DISSEMINATION**  
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45 419 This project received approval from the CIUSSS de l'Estrie - CHUS Research Ethic Board  
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47 420 (project number MP-31-2019-2830). All participants will provide informed consent prior to  
48  
49 421 engagement and recruitment. In addition, certificates of approval will be obtained in each of the  
50  
51 422 provinces before data collection is commenced. If appropriate, adherence to Chapter 9 of the  
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53 423 TCPS2 (2014) will be observed and upheld.  
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3 425 This four-year multiple-case, mixed-method study will result in the potential for great impact  
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5 426 with stakeholders, but mostly for individuals/patients. New evidence-based knowledge will be  
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7 427 provided on the implementation of CM interventions, which can contribute to improve care  
8  
9 428 integration for individuals/patients who frequently use healthcare services, and ultimately reduce  
10  
11 429 ineffective healthcare use and costs. The proposed design will allow adapting the knowledge  
12  
13 430 acquired on CM to local contexts, the first essential step towards implementation<sup>81</sup>. Moreover,  
14  
15 431 recognition of facilitators and barriers to implementation as well as, the influence that context  
16  
17 432 exerts on outcomes will pave the way for the spread of CM in primary care settings in different  
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19 433 Canadian jurisdictions.

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24 435 This study built on various strengths, but mostly on the engagement of knowledge users who  
25  
26 436 were and will be involved throughout the entire process to ensure that the new knowledge  
27  
28 437 generated by CM in primary care will be refined and tailored to their own specific needs<sup>81</sup>. These  
29  
30 438 stakeholders will then be best suited to further adapt CM knowledge to their own local context  
31  
32 439 and to increase the chance of successfully implementing CM in their setting<sup>81</sup>. All of these steps  
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34 440 will increase spread and positively influence the healthcare system as well as  
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36 441 individuals/patients/communities and clinicians' experiences, and outcomes<sup>24 25 36</sup>.

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41 443 This study builds on many important aspects related to the rigour of the approach and  
42  
43 444 methodology. As such, all stakeholders, including individuals/patients, from the five provinces  
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45 445 (SK, QC, NB, NS, NL) already working together, have participated in the elaboration of research  
46  
47 446 questions that were relevant from their perspectives. This partnership with stakeholders is  
48  
49 447 strengthened by a solid engagement plan as well as a relevant knowledge transfer plan tailored for  
50  
51 448 each stakeholder audience. The conceptual basis of this study is based on a rigorous research plan  
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53 449 that unifies key constructs from published implementation theories (CFIR)<sup>36</sup> as well as a  
54  
55 450 framework combining the concepts of primary care and integration of care (Valentijn)<sup>37</sup>. The

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3 451 intervention is evidence-based and shaped for individuals/patients who frequently use healthcare  
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5 452 services<sup>8-12 82</sup>. As for data collection, appropriate sampling strategies will be pursued, while data  
6  
7 453 quality and reliability will be ensured through three main strategies<sup>26</sup>: the 10 case histories will  
8  
9 454 integrate relevant qualitative and quantitative data in a Master database; the database will contain  
10  
11 455 sufficient information about data collection; and, data collection will follow published methods.  
12  
13 456 Validity of the study will be ensured by mixing qualitative and quantitative methods (comparison  
14  
15 457 of results and data merging), multiple data sources and evaluators triangulation<sup>26</sup>. Transferability  
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17 458 will be ensured by several strategies such as theoretical basis, observation replication across cases  
18  
19 459<sup>26</sup>, and thorough description of the context<sup>61</sup>.

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24 461 While some challenges are expected with this study, mitigated strategies are nevertheless  
25  
26 462 proposed. To ensure meaningful involvement of all provinces and team members in the project,  
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28 463 relationships and team building will be nurtured and stakeholders will be encouraged to speak in  
29  
30 464 their preferred language (English or French). Being engaged with our patient partners over the  
31  
32 465 last four years, solutions have been developed to accommodate their needs, e.g., help with a  
33  
34 466 wheelchair, being flexible regarding schedule if hospitalization or deterioration, training.  
35  
36 467 Partnerships will also be monitored annually. The circumstances of this vulnerable clientele may  
37  
38 468 also influence data collection as well as study validity. This challenge will be overcome by  
39  
40 469 research assistants administering the questionnaire to patients and assisting them as needed and  
41  
42 470 by patient partners that will advise on ways to enhance feasibility and patient's acceptability. In a  
43  
44 471 similar study conducted by our team, a 93% retention rate was achieved, demonstrating the  
45  
46 472 efficacy of our strategies<sup>60</sup>.

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51 474 Based on popular conceptual frameworks and rigorous methodology, design, and methods, this  
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53 475 pan-Canadian study holds promise to guide policy decision-making, and to ultimately and  
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55 476 positively impact health services systems as well and most importantly, the health of Canadians.

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3 477 This study will generate findings on the implementation of CM in primary care for  
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5 478 individuals/patients with chronic conditions and complex healthcare needs who frequently use  
6  
7 479 healthcare services, as well as to implement an evidence-based intervention that will not only  
8  
9 480 improve the care experience and outcomes but will also mitigate ineffective use and costs.  
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11 481

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3 **488 LIST OF ABBREVIATIONS**  
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5 489 CM: Case management; CFIR: Consolidated Framework for Implementation Research; CIHI:  
6 Canadian Institute for Health Information; CMO: Context-Mechanism-Outcome; ED: Emergency  
7 490 department; NB: New Brunswick; NL: Newfoundland and Labrador; NS: Nova Scotia; PIHCI:  
8 491 Primary and Integrated Health Care Innovations; QC: Quebec; SK: Saskatchewan; SPOR:  
9 492 Strategy in Patient Oriented Research; TRIAGE: Technique for Research of Information by  
10 493 Animation of a Group of Experts.  
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3 737 **AUTHORS' CONTRIBUTION**

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5 738 CH, M-CC, KAB, FB, SD and VR are the principal investigators of the study. All authors  
6  
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24  
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# BMJ Open

## Case management in primary care for frequent users of healthcare services with chronic diseases and complex care needs: an implementation and realist evaluation protocol

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Complete List of Authors:	<p>Hudon, Catherine; Université de Sherbrooke, Department of family medicine and emergency medicine  Chouinard, Maud-Christine; Université du Québec à Chicoutimi, Département des Sciences de la Santé  Aubrey-Bassler, Kris; Memorial University, Primary Healthcare Research Unit  Burge, Fred ; Dalhousie University, Department of Family Medicine  Doucet, Shelley; University of New Brunswick, Department of Nursing and Health Sciences  Ramsden, Vivian; University of Saskatchewan, Department of Academic Family Medicine  Brodeur, Magaly; Université de Sherbrooke, Département de Médecine de Famille et Médecine d'urgence  Bush, Paula; McGill University, Family Medicine  Couturier, Yves; Université de Sherbrooke, social work  Dubois, Marie-France; Université de Sherbrooke, Department of community health  Guenette, Line; Université Laval, Faculty of Pharmacy and CHU de Québec Research Center;  Legare, France; CHU de Québec and Université Laval, Department of Family Medicine  Morin, Paul; Université de Sherbrooke, School of Social Work  Poder, Thomas; CIUSSS de l'Estrie - CHUS, UETMIS and CRCHUS; Université de Sherbrooke, Département de Médecine de Famille et Médecine d'urgence  Poitras, Marie-Eve; Université du Québec à Chicoutimi, Département des Sciences de la Santé  Roberge, Pasquale; Université de Sherbrooke, Médecine de famille  Valaitis, Ruta; McMaster University, School of Nursing  Bighead, Shirley; Sturgeon Lake First Nation  Campbell, Cameron; Department of Health and Community Services  Couture, Martine; Centre intégré universitaire de santé et de services sociaux du Saguenay-Lac-Saint-Jean  Davis, Breanna; University of Saskatchewan, Department of Academic Family Medicine  Deschenes, Elaine; Centre de pédiatrie sociale Sud-Est (CPSSE)  Edwards, Lynn; Nova Scotia Health Authority  Gander, Sarah; Horizon Health Network  Gauthier, Gilles; Unité SOUTIEN du Québec  Gauthier, Patricia; Centre intégré universitaire de santé et services sociaux</p>

	de l'Estrie – Centre hospitalier universitaire de Sherbrooke Gibson, Richard; Nova Scotia Health Authority Godbout, Julie; Centre integre universitaire de sante et de services sociaux du Saguenay-Lac-Saint-Jean Landry, Geneviève; Ministère de la Sante et des Services sociaux Quebec Longjohn, Christine; Sturgeon Lake First Nation Rabbitsskin, Norma; Sturgeon Lake Health Centre Roy, Denis; Institut national d'excellence en santé et en services sociaux Roy, Judy; Maritime SPOR SUPPORT Unit Sabourin, Véronique; Unité SOUTIEN du Québec Sampalli, Tara ; Nova Scotia Health Authority Saulnier, Amanda; Maritime SPOR SUPPORT Unit Spence, Claude; Unité SOUTIEN du Québec Splane, Jennifer; NaviCare/SoinsNavi Warren, Mike; NL SPOR SUPPORT Unit Young, Joanne; Government of New Brunswick, Chronic Disease Prevention and Management Health Pluye, Pierre; Université McGill, Department of family medicine
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Manuscripts

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1 **Case management in primary care for frequent users of healthcare services with chronic**  
2 **diseases and complex care needs: an implementation and realist evaluation protocol**

3  
4 Catherine Hudon<sup>1</sup>, Maud-Christine Chouinard<sup>2</sup>, Kris Aubrey-Bassler<sup>3</sup>, Frederick Burge<sup>4</sup>, Shelley  
5 Doucet<sup>5</sup>, Vivian R. Ramsden<sup>6</sup>, Magaly Brodeur<sup>1</sup>, Paula L. Bush<sup>7</sup>, Yves Couturier<sup>8</sup>, Marie-France  
6 Dubois<sup>9</sup>, Line Guénette<sup>10</sup>, France Légaré<sup>11</sup>, Paul Morin<sup>8</sup>, Thomas G Poder<sup>1,12</sup>, Marie-Ève Poitras<sup>2</sup>,  
7 Pasquale Roberge<sup>1</sup>, Ruta Valaitis<sup>13</sup>, Shirley Bighead<sup>14</sup>, Cameron Campbell<sup>15</sup>, Martine Couture<sup>16</sup>,  
8 Breanna Davis<sup>6</sup>, Éleine Deschenes<sup>17</sup>, Lynn Edwards<sup>18</sup>, Sarah Gander<sup>19</sup>, Gilles Gauthier<sup>20</sup>, Patricia  
9 Gauthier<sup>21</sup>, Richard J Gibson<sup>18</sup>, Julie Godbout<sup>16</sup>, Geneviève Landry<sup>22</sup>, Christine Longjohn<sup>14</sup>,  
10 Norma Rabbitskin<sup>14</sup>, Denis A. Roy<sup>23</sup>, Judy Roy<sup>24</sup>, Veronique Sabourin<sup>20</sup>, Tara Sampalli<sup>18</sup>,  
11 Amanda Saulnier<sup>24</sup>, Claude Spence<sup>20</sup>, Jennifer Splane<sup>25</sup>, Mike Warren<sup>26</sup>, Joanne Young<sup>27</sup>, Pierre  
12 Pluye<sup>7</sup>

13  
14 Affiliations

15 <sup>1</sup>Département de Médecine de Famille et Médecine d'urgence, Université de Sherbrooke,  
16 Québec, Canada; <sup>2</sup>Département des Sciences de la Santé, Université du Québec à Chicoutimi,  
17 Québec, Canada; <sup>3</sup>Primary Healthcare Research Unit, Memorial University, Newfoundland and  
18 Labrador, Canada; <sup>4</sup>Department of Family Medicine, Dalhousie University, Nova Scotia, Canada;  
19 <sup>5</sup>Department of Nursing and Health Sciences, University of New Brunswick, New Brunswick,  
20 Canada; <sup>6</sup>Department of Academic Family Medicine, University of Saskatchewan, Saskatchewan,  
21 Canada; <sup>7</sup>Department of Family Medicine, Université McGill, Montréal, Québec, Canada;  
22 <sup>8</sup>School of Social Work, Université de Sherbrooke, Québec, Canada; <sup>9</sup>Département des sciences  
23 de la santé communautaire, Université de Sherbrooke, Québec, Canada; <sup>10</sup>Faculté de Pharmacie,  
24 Université Laval, Québec, Canada; <sup>11</sup>Department of Family Medicine and Emergency Medicine,  
25 Université Laval, Québec, Canada; <sup>12</sup>UETMIS and CRCHUS, CIUSSSE de l'Estrie – CHUS,  
26 Sherbrooke, Canada; <sup>13</sup>School of Nursing, McMaster University, Ontario, Canada; <sup>14</sup>Sturgeon

1  
2  
3 27 Lake First Nation, Saskatchewan, Canada; <sup>15</sup>Department of Health and Community Services –  
4  
5 28 Newfoundland and Labrador, Canada; <sup>16</sup>Centre intégré universitaire de santé et de services  
6  
7 29 sociaux du Saguenay-Lac-Saint-Jean, Quebec, Canada; <sup>17</sup>Centre de pédiatrie sociale Sud-Est  
8  
9 30 (CPSSE), New Brunswick, Canada; <sup>18</sup>Nova Scotia Health Authority, Nova Scotia, Canada;  
10  
11 31 <sup>19</sup>Horizon Health Network, New Brunswick, Canada; <sup>20</sup>Unité SOUTIEN du Québec, Québec,  
12  
13 32 Canada; <sup>21</sup>Centre intégré universitaire de santé et services sociaux de l'Estrie – Centre hospitalier  
14  
15 33 universitaire de Sherbrooke, Québec, Canada; <sup>22</sup>Ministère de la santé et des services sociaux,  
16  
17 34 Québec, Canada; <sup>23</sup>Institut national d'excellence en santé et en services sociaux, Québec, Canada;  
18  
19 35 <sup>24</sup>Maritime SPOR SUPPORT Unit, New Brunswick, Canada; <sup>25</sup>NaviCare/SoinsNavi, St-John,  
20  
21 36 New Brunswick, Canada; <sup>26</sup>NL SPOR SUPPORT Unit, Newfoundland and Labrador, Canada;  
22  
23 37 <sup>27</sup>Chronic Disease Prevention and Management Health, Government New Brunswick, New  
24  
25 38 Brunswick, Canada  
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40 **Corresponding author:**

41 Dr Catherine Hudon, Ph.D. Département de Médecine de Famille et Médecine d'urgence, Université  
42 de Sherbrooke, 3001, 12<sup>e</sup> Avenue Nord, Sherbrooke, QC, Canada J1H 5N4. Telephone: 819-346-  
43 1110 ext: 70540; Email: [Catherine.Hudon@Usherbrooke.ca](mailto:Catherine.Hudon@Usherbrooke.ca)  
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3 46 **ABSTRACT**  
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8 48 **Introduction:** Significant evidence in the literature supports case management (CM) as an  
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10 49 effective intervention to improve care for patients with complex healthcare needs. However, there  
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12 50 is still little evidence about the facilitators and barriers to CM implementation in primary care  
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14 51 setting. The three specific objectives of this study are to: (O1) Identify the facilitators and barriers  
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16 52 of CM implementation in primary care clinics across Canada; (O2) Explain and understand the  
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18 53 relationships between the actors, contextual factors, mechanisms, and outcomes of the CM  
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20 54 intervention; (O3) Identify the next steps towards CM spread in primary care across Canada.  
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24 56 **Methods and analysis:** We will conduct a multiple-case embedded mixed methods study. CM  
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26 57 will be implemented in 10 primary care clinics in five Canadian provinces. Three different units  
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28 58 of analysis will be embedded to obtain an in-depth understanding of each case: the healthcare  
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30 59 system (macro level); the CM intervention in the clinics (meso level); and the individual/patient  
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32 60 (micro level). For each objective, the following strategy will be performed: (O1) an  
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34 61 implementation analysis, (O2) a realist evaluation, and (O3) consensus building among  
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36 62 stakeholders using the TRIAGE method.  
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41 64 **Ethics and dissemination:** This study, which received ethic approval, will provide innovative  
42  
43 65 knowledge about facilitators and barriers to implementation of CM in different primary care  
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45 66 jurisdictions, and will explain how and why different mechanisms operate in different contexts to  
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47 67 generate different outcomes among frequent users. Consensual and prioritized statements about  
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49 68 next steps for spread of CM in primary care from the perspectives of all stakeholders will be  
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51 69 provided. Our results will offer context-sensitive explanations that can better inform local  
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53 70 practices and policies, and contribute to improve the health of patients with complex healthcare  
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3 71 needs who frequently use healthcare services. Ultimately, this will increase the performance of  
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5 72 healthcare systems, and specifically mitigate ineffective use and costs.  
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9 74 **Registration details:** A realist evaluation does not need registration.  
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13 76 **Strengths and limitations of this study**

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16 77 - This multiple-case embedded mixed methods study will provide new knowledge on the  
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18 78 implementation of case management interventions to improve care integration for  
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20 79 individuals/patients who frequently use healthcare services.  
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24 81 - The design of this study allows adapting the knowledge acquired on case management to local  
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26 82 contexts, the first step to implementation.  
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30 84 - The multiprovincial nature of this study will allow to spread the new knowledge generated on  
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32 85 CM in primary care settings in different Canadian jurisdictions and will increase  
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34 86 generalizability.  
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38 88 - While some challenges are expected with this study, mitigated strategies are nevertheless  
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40 89 proposed.  
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## 90 INTRODUCTION

91 In Canada, as in many industrialized countries <sup>1,2</sup>, close to 80% of healthcare costs are attributable  
92 to 10% of the population <sup>3,4</sup>. Data reveal that this 10% segment of the population comprises  
93 individuals/patients who frequently use hospital services for increasingly complex healthcare  
94 needs. Thus, albeit relatively small, this segment of the population uses a disproportionate amount  
95 of available healthcare and social services. Frequent use of emergency departments (ED) is a  
96 good proxy of high use of other healthcare services <sup>5-7</sup> as it is most commonly accepted in the  
97 literature <sup>8-12</sup>, and provides a convenient and easy measure within a pragmatic context, as  
98 compared to cost for example. As such, five percent of ED's patients account for 30 to 50% of all  
99 visits <sup>8,13</sup>. As frequent use is not optimal for individuals/patients <sup>14</sup> or healthcare systems <sup>15,16</sup>,  
100 better upstream care is a modifiable parameter that can effectively prevent it. Indeed, the majority  
101 of these individuals/patients who frequently use hospital services have a substantial burden of  
102 disease and would be best managed in primary care. <sup>17</sup>.

103  
104 In line with the Agency for Healthcare Research and Quality Multiple Chronic Conditions  
105 Research Network, complex healthcare needs can be defined as the gap between an individual's  
106 needs and the ability of health services to meet those needs <sup>18</sup>. Individuals/patients with complex  
107 healthcare needs often attempt to fulfill their unmet needs by using excessive health and social  
108 services in an uncoordinated way. Requiring a variety of services from various systems (e.g.  
109 health, social, education) and community networks, this often leads to difficulties with the  
110 integration of care<sup>19</sup>. This results in negative experiences for individuals/patients <sup>14</sup>, poorer health  
111 outcomes, high mortality rates and considerable costs <sup>19</sup>.

112  
113 Case management (CM) was reported to be effective for individuals/patients who frequently used  
114 healthcare services <sup>10,20,21</sup>. By definition, CM is a collaborative approach used to assess, plan,  
115 facilitate, and coordinate care to meet individual/patient and family healthcare needs, through

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3 116 communication and available resources including all sectors of health care (such as community,  
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5 117 primary, secondary and tertiary care), as well as sectors outside of the health system (such as  
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7 118 social services, housing, etc.) with the intent of improving individual and health system outcomes  
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9 119 <sup>22</sup>. Three systematic reviews (including randomized controlled trials, non-randomized controlled  
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11 120 trials, interrupted time series, and controlled and non-controlled before-and-after studies)  
12  
13 121 concluded that CM was effective for individuals/patients who frequently used healthcare services,  
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15 122 particularly on ED use and cost as well as on social and clinical outcomes <sup>8 10 11</sup>. A scoping review  
16  
17 123 conducted by our team corroborated these findings by revealing that CM could reduce ED visits  
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19 124 and hospitalisations as well as costs <sup>9</sup>.

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24 126 However, despite the evidence supporting CM as an effective intervention for individuals/patients  
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26 127 that frequently use services, there is still a paucity of evidence about the facilitators and barriers  
27  
28 128 to CM implementation <sup>10 23</sup>. Our literature review with thematic analysis of key factors of CM  
29  
30 129 interventions among frequent users of healthcare services outlined that the case finding processes,  
31  
32 130 the selection and training of the case manager, the intensity of the intervention, as well as care  
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34 131 integration among all partners were important aspects to consider during CM implementation <sup>23</sup>.

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39 133 CM has rarely been implemented in primary care in Canada. Therefore, before spreading this  
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41 134 intervention in primary care settings in different jurisdictions, stakeholders including  
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43 135 individuals/patients/communities need to be engaged in adapting the intervention to their local  
44  
45 136 context. Accordingly, further research is needed to better understand the facilitators and barriers  
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47 137 (mechanisms) to CM implementation, as well as the influence of different primary care contexts  
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49 138 on outcomes, e.g., self-management, quality of life, services integration, services use, and costs <sup>9</sup>  
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51 139 <sup>24 25</sup>.

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54 140 Therefore, the specific objectives of this study are threefold: (O1) identify the facilitators and  
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56 141 barriers of CM implementation in primary care clinics across Canada; (O2) explain and

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3 142 understand the relationships between the actors, contextual factors, mechanisms, and outcomes of  
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5 143 the CM intervention; and (O3) identify the next steps towards CM spread in primary care across  
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7 144 Canada.  
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## 11 146 **METHODS AND ANALYSIS**

### 13 147

### 14 148 **Study design**

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18 149 To address these objectives, we will conduct, between September 2018 and August 2022, a  
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20 150 multiple-case embedded mixed methods study, which constitutes a valuable design for  
21  
22 151 performing research evaluation inquiries on complex systems in varied and dynamic contexts <sup>26</sup>  
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24 152 <sup>27</sup>. In addition to allowing an in-depth analysis of each case, this design offers opportunities for  
25  
26 153 comparison between cases. The inclusion of multiple cases capitalizes on organizational variation  
27  
28 154 and allows for examination of how contextual factors influence implementation to develop a  
29  
30 155 more informed understanding of change processes. It also allows for observation recursive or  
31  
32 156 singular facilitators and barriers, and draws conclusions that could be transferable to other  
33  
34 157 primary care contexts<sup>28</sup>. Furthermore, mixed methods involve combining qualitative and  
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36 158 quantitative methods in complex program evaluation, primary research, and literature review;  
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38 159 they are being increasingly used in health sciences; specifically, case studies can use qualitative,  
39  
40 160 quantitative and mixed methods (multiple sources of evidence) to explain one or more cases <sup>29</sup>.  
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### 45 162 **Study location and sampling**

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47 163 Five Canadian provinces are involved in the study: Saskatchewan (SK), Quebec (QC), Nova  
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49 164 Scotia (NS), New Brunswick (NB) and Newfoundland and Labrador (NL). Considering that  
50  
51 165 different primary care team models have been implemented throughout Canada <sup>30 31</sup>, the primary  
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53 166 care context of each jurisdiction will be taken into account when evaluating implementation and  
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55 167 outcomes <sup>31</sup>.  
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168 Two primary care clinics per province, where CM has not been previously implemented, will be  
169 recruited using a purposeful sampling strategy <sup>32</sup>. The recruitment of the clinics will be  
170 conditional to: the manager and team interest in implementing CM and engaging in the research  
171 project; availability and interest of a registered nurse or nurse practitioner to develop the role of  
172 the case manager. We will thus work with 10 cases (two per province), each case being the  
173 intervention implemented in each clinic. It is recommended that four to 10 cases be considered <sup>33</sup>  
174 in the multiple case study logic of theoretical replication, in which contrasting results are  
175 anticipated <sup>26</sup>. Two clinics per province will facilitate variability within each province. Cases will  
176 be selected in order to represent real-world differences <sup>34</sup> in terms of geographic location, model  
177 of practice, diversity of care teams, and size, based on the opinion of team members in each  
178 jurisdiction. Three different units of analysis will be explored to obtain an in-depth understanding  
179 of each case: (a) the healthcare system (macro level); (b) the CM intervention in the clinics (meso  
180 level); and, (c) the patient including their family and community (micro level).

181

182 **Objective 1: To identify facilitators and barriers of CM implementation in primary care**  
183 **clinics in Canada**

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185 An implementation analysis will be conducted for identifying facilitators and barriers to, and  
186 informing implementation of, CM in primary care in different provinces <sup>35</sup>. Implementation  
187 analysis is very useful with complex interventions that can be influenced by the context within  
188 dynamic environments. The case study design is appropriate for implementation analysis of  
189 interventions <sup>35</sup>.

190

191 *Conceptual framework*

192 Data collection and analysis will rely on the Consolidated Framework for Implementation  
193 Research (CFIR) of Damschroder *et al.* <sup>36</sup>, which is aimed to foster implementation of findings

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3 194 into practice. The CFIR is composed of five major domains: outer setting, inner setting,  
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5 195 characteristics of the individuals involved, intervention characteristics, and, the process of  
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7 196 implementation. Four constructs are related to the outer setting (e.g., external policies); 12 are  
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9 197 related to the inner setting (e.g., culture and leadership engagement); five are related to individual  
10  
11 198 characteristics (e.g., knowledge and beliefs); eight are related to the intervention (e.g.,  
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13 199 adaptability); and eight are related to process (e.g., planning). *'The CFIR provides a practical*  
14  
15 200 *structure for approaching complex and transient states of constructs in the real world by*  
16  
17 201 *embracing, consolidating, and unifying key constructs from published implementation theories.'*<sup>36</sup>  
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22 203 To properly address care integration, the CFIR will be linked to the Valentijn et al. framework<sup>37</sup>  
23  
24 204 combining the concepts of primary care and integrated care. In this framework, person-focused  
25  
26 205 care is the guiding principle for achieving integration across the care continuum, i.e. system  
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28 206 integration (macro level), professional and organisational integration (meso level) as well as  
29  
30 207 clinical integration (micro level).  
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### 34 209 *Pre-implementation*

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37 210 A CM nurse mentor will facilitate 3-day training sessions for all CM nurses and will also lead  
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39 211 monthly 1-hr community-of-practice meetings by teleconference, to assist with mentoring,  
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41 212 collective learning and support<sup>38</sup>. As recommended by Damschroder et al. CFIR<sup>36</sup>, team  
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43 213 stakeholders will interact with the clinics in their province to co-design the adaptation of the CM  
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45 214 intervention to their reality. According to the CFIR<sup>36</sup>, the core components of the intervention,  
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47 215 such as patient assessment, individualized care plan, care coordination and self-management  
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49 216 support<sup>39-42</sup>, will be maintained across all clinics, whereas more peripheral elements will be  
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51 217 adaptable, e.g., as integration in the context. This adaptability will increase knowledge uptake<sup>24</sup>  
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53 218 and promote integration with complementary programs outside of the clinics, while ensuring that  
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3 219 CM is being rigorously evaluated.  
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7 221 *Recruitment*  
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9 222 Each clinic will identify 30 patients with the most complex healthcare needs and who, according  
10 223 to their clinical experience of the existing gap between the individual's needs and the ability of  
11 224 health services to meet those needs<sup>18</sup> could benefit from CM. Inclusion criteria will be: living  
12 225 with at least one chronic condition; frequent ED users as defined by  $\geq 4$  ED visits in the previous  
13 226 year<sup>43 44</sup> (which have been recognized as a good proxy of frequent use of other healthcare  
14 227 services<sup>5-7</sup>); and, a score  $\geq 17$  on the INTERMED-Self-Assessment Questionnaire<sup>45</sup> evaluating  
15 228 complex healthcare needs. Exclusion criteria will be: frail elderly with loss of autonomy;  
16 229 individuals/patients without a chronic condition or with a prognosis of less than a year; or,  
17 230 patients already followed by a case manager in another program, e.g., mental health, senior care,  
18 231 addiction program. Case managers will offer the CM intervention to these individuals/patients  
19 232 over a 12-month period.  
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22 235 *Intervention*  
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24 236 The intervention will focus on four main recognized components of CM<sup>39-42</sup>: (C1) evaluation of  
25 237 patient needs and preferences; (C2) co-development and maintenance of a patient-centred  
26 238 individualized care plan, with the patient, family and other partners; (C3) coordination of health  
27 239 and social services among all partners; and (C4) education and self-management support for  
28 240 patients and families. This intervention is congruent with criteria from the *Case Management*  
29 241 *Society of America*<sup>22</sup> and the six standards of practice of the *National Case Management Network*  
30 242 *of Canada*<sup>46</sup>: (S1) determining and verifying patient eligibility; (S2) assessing patient needs; (S3)  
31 243 documenting patient goals and priorities; (S4) planning and adjusting services included in  
32 244 individualized service plans, including patient education and self-management support; (S5)  
33 245 monitoring patient needs and progress; and (S6) supporting transition processes. The intervention  
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245 also aligns with the six care integration characteristics proposed to consider a patient's  
246 experience<sup>47</sup>: (I1) consideration of patient and family needs; (I2) communication with the patient  
247 and between healthcare providers; (I3) access to information; (I4) involvement in decision-  
248 making; (I5) care planning; and, (I6) transitions between various professionals.

249

### 250 *Data collection*

251 The mixed method data collection will rely on the five following complementary strategies.

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253 (1) Individual semi-structured interviews (qualitative data) will be conducted between six and  
254 nine months following initiation of CM intervention with all case managers, patients/families and  
255 clinic managers. Two focus groups per clinic will be also scheduled, enrolling eight primary care  
256 providers per group (including physicians, nurses, social workers, pharmacists and others)  
257 through purposive sampling<sup>48</sup>. All interviews and focus groups, conducted using a semi-  
258 structured interview guide composed of open-ended questions on facilitators and barriers of CM  
259 implementation and adapted to each category of stakeholders, will be digitally recorded and  
260 transcribed verbatim. Interview guides will address the domains and constructs of Damschroder's  
261 CFIR<sup>36</sup> and Valentijn Framework<sup>37</sup>. Data saturation will not necessarily be reached for each  
262 category of stakeholders, but their diversity will allow for a comprehensive representation of each  
263 case<sup>49</sup>.

264

265 (2) Non-participant observation (qualitative data) of CM activities and meetings, e.g., patient-case  
266 manager, individualized service plan development, team discussions, at each clinic for thirty  
267 hours at 6 months will be conducted. Research assistants will collect data by means of an  
268 observation grid and field notes<sup>48</sup>.

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3 270 (3) Self-administered and validated questionnaires (quantitative data) with accepted psychometric  
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5 271 properties will be administered to all individuals/patients in the presence of the research assistant.  
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7 272 At baseline, the following characteristics will be assessed: age; gender; marital status; education;  
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9 273 occupation; economic status with family income and patient perception of his or her economic  
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11 274 situation; health literacy<sup>50 51</sup>; multimorbidity<sup>52 53</sup>; care integration<sup>54</sup>; self-management<sup>55 56</sup> and  
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13 275 health related quality of life<sup>57</sup>. Care integration, self-management and health related quality of  
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15 276 life, will be re-evaluated at 12 months.  
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20 278 (4) Clinical data on service use during the year of the intervention (quantitative data) will be  
21  
22 279 collected through the patient's electronic medical record: ED visits; overnight stays; primary care  
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24 280 and specialist visits. Costs will be measured from a healthcare system perspective, including costs  
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26 281 of the CM intervention and of healthcare expenditures. Costs of the intervention will consider  
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28 282 nurse training, mentoring, and CM implementation. Participant healthcare expenditures, such as  
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30 283 ED visits, overnight stays, professional visits, will be calculated using predetermined fees, e.g.,  
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32 284 from the CIHI Patient Cost Database<sup>58</sup>.  
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37 286 (5) Intervention fidelity evaluation (quantitative data) will be assessed to determine whether the  
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39 287 intervention was delivered as intended<sup>59</sup>. For this purpose, research assistants will collect data  
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41 288 relevant to the delivery of the main components of the CM intervention from the medical records  
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43 289 of participants after six and 12 months using a fidelity grid. Similar data on CM intervention  
44  
45 290 fidelity were collected successfully in our previous study<sup>60</sup>.  
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#### 49 292 *Data analysis*

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51 293 Qualitative data analysis: Interview- and observation-based data will be analysed together using a  
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53 294 deductive (themes based on the Damschroder et al. CFIR and Valentijn frameworks) and  
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55 295 inductive (themes suggested by the data while not in frameworks) thematic analyses<sup>61</sup>.  
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3 296 Qualitative data will be managed using multi-site NVivo 10 server software (QSR International  
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5 297 Pty Ltd).  
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9 299 Quantitative data analysis: Descriptive statistics will be performed. Intervention fidelity will be  
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11 300 represented by the proportion of delivery for each component of the CM intervention. Regression  
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13 301 models will be developed to evaluate relationships between contextual elements, i.e. intervention  
14  
15 302 fidelity, patients' characteristics and outcomes, using SPSS version 24. An incremental cost-  
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17 303 effectiveness/utility ratio<sup>62</sup> will be calculated, using data collected on costs and QALY (i.e., SF-  
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19 304 6D), at baseline, and 12 months after the CM implementation. Multivariate parametric analyses  
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21 305 with bootstrap replications will be conducted along with cost-effectiveness acceptability curves<sup>63</sup>.  
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26 307 Integration of qualitative and quantitative methods - Two types of integration will be performed:  
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28 308 qualitative and quantitative results will be compared, and qualitative and quantitative data will be  
29  
30 309 merged for each case<sup>29</sup>. Considering the inherent variety and changing contexts of the study,  
31  
32 310 results of qualitative and quantitative data analyses will be compared, and the comparison  
33  
34 311 interpreted using a side-by-side joint comparison table (rather than trying to calculate non-biased  
35  
36 312 quantitative effects<sup>64</sup>). Then for each case, qualitative and quantitative data will be merged<sup>26</sup>. A  
37  
38 313 case history will be reported (synthesizing merged data), and the 10 case histories will be used to  
39  
40 314 compare cases by means of a descriptive and interpretative matrix (mixed methods matrix),  
41  
42 315 allowing systematic comparisons among cases and analysis units (macro, meso and micro)<sup>61</sup>.  
43  
44 316 Different analytical techniques for case study will be used among which pattern comparison,  
45  
46 317 research of competing explanations and construction of explanations<sup>26</sup>. Management, data  
47  
48 318 reduction and cross care comparisons will be conducted with NVivo 10 software using matrix  
49  
50 319 queries. All categories of stakeholders will be invited to participate in key steps of the analysis to  
51  
52 320 ensure meaningful interpretation.  
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3 322 **Objective 2: To explain and understand the relationships between actors, contextual**  
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5 323 **factors, mechanisms and outcomes of CM intervention**  
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9 325 A realist evaluation will be conducted according to Pawson and Tilley<sup>65</sup>. Realist evaluation is a  
10  
11 326 theory-driven approach for studying complex interventions to explain how and why they are  
12  
13 327 effective, under what conditions and for which groups of patients. It is based on four concepts for  
14  
15 328 explaining and understanding the complex relationships in a given intervention: context (C);  
16  
17 329 mechanism (M); outcome (O); and, context–mechanism–outcome (CMO) configuration<sup>65-67</sup>. The  
18  
19 330 multiple-case study is a recognised design for investigating CMO configurations in healthcare  
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21 331 research<sup>68-73</sup>. The realist evaluation will use a multi-method (quantitative and qualitative), theory-  
22  
23 332 driven approach to provide an explanation of why outcomes occur<sup>67</sup>, and will follow three  
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25 333 phases: stating an initial program theory; testing this program theory; and, refining this program  
26  
27 334 theory.  
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33 336 *Stating an initial program theory*

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35 337 A proposed initial middle-range program theory developed in our realist synthesis<sup>74</sup> of the  
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37 338 literature on CM for individuals/patients that frequently use healthcare services in primary care  
38  
39 339 will provide a rigorous basis for the next two phases of data collection (testing and refining the  
40  
41 340 program theory).  
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45 342 *Data collection (testing and refining the program theory)*

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47 343 In the next year, same participant sampling and data collection will be repeated in the same  
48  
49 344 clinics identified in Objective 1, with a new cohort of patients. However, qualitative data will be  
50  
51 345 used to identify and better understand CMOs. The same quantitative data will be used to measure  
52  
53 346 outcomes, i.e. self-management, health related quality of life, care integration, services use and  
54  
55 347 costs at baseline, 6- and 12-months for developing CMOs. For qualitative data collection,  
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3 348 interview guides and the observation grid will be informed by the initial theory and tailored to the  
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5 349 participant groups. Interviews and focus groups will be performed using realist interview  
6  
7 350 techniques<sup>75</sup>. The theory will be discussed with individuals/patients who will then provide their  
8  
9 351 own experience and vision for collaborative conceptual refinement. The interviewer will play an  
10  
11 352 active role in explaining the contexts and outcomes of interest, and in ensuring that participants  
12  
13 353 understand the terminology of the realist evaluation. Participants will be asked to share how they  
14  
15 354 think their experience relates to this theory and to reflect on what may explain the outcomes in  
16  
17 355 their setting<sup>76</sup>. Data collection will be iterative until reaching saturation<sup>65 75</sup>.  
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### 22 357 *Data analysis*

23  
24 358 Quantitative data will be analyzed, as described above, to inform outcomes. Qualitative data,  
25  
26 359 including interviews, focus groups and observation, will be analysed with NVivo using thematic  
27  
28 360 analysis, guided by the initial program theory from the realist synthesis. Analysis will remain  
29  
30 361 open to emergent themes that support further theory refinement. Similar to the above integration,  
31  
32 362 quantitative and qualitative results will be compared (producing joint display table), and  
33  
34 363 quantitative and qualitative data will be merged for each case (producing case histories and a  
35  
36 364 mixed method matrix).  
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41 366 Research assistants from the various provinces will co-analyze quantitative, qualitative and mixed  
42  
43 367 methods evidence. They will identify CMO configurations, first within each primary care clinic  
44  
45 368 (case) and then across sites. All team members will be involved in certain steps of the analysis. A  
46  
47 369 recap table<sup>77</sup> will be constructed using columns to separate components of the initial theory and  
48  
49 370 rows representing different cases. This approach will facilitate within-case analysis, highlighting  
50  
51 371 similarities or discrepancies between data sources. It will also facilitate cross-case analysis to  
52  
53 372 identify patterns (demi-regularities or semi predictable patterns) across cases. Analysis of CMO  
54  
55 373 configurations will help complete, confirm, or modify the components of our initial theory, and  
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3 374 ultimately produce a refined theory explaining how and why CM works, in specific contexts, and  
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5 375 for specific categories of patients. Results will be reported in line with the RAMESES II reporting  
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7 376 standards for realist evaluation <sup>78</sup>.  
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11 378 **Objective 3: To identify the next steps towards CM spread in primary care across Canada**

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16 380 The Technique for Research of Information by Animation of a Group of Experts (TRIAGE)  
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18 381 method will be used to reach consensus among all stakeholders about the next steps forward with  
19  
20 382 spread (expansion and extension), in light of our case study results. The process of developing a  
21  
22 383 shared understanding from the different stakeholders' perspectives through discussion improves  
23  
24 384 progress of an innovation towards spread <sup>25</sup>. TRIAGE is a research method based on the  
25  
26 385 attainment of a group consensus to supply first-hand information for decision-making <sup>79</sup>. It is a  
27  
28 386 structured and inductive method of data collection comprising three successive phases:  
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30 387 preparation; individual production; and interactive production.  
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35 389 *Preparation*

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37 390 A full-day meeting will be organized, gathering the tripartite structure (clinical, scientific and  
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39 391 policymaker leads) of all pan-Canadian SPOR Networks in Primary and Integrated Health Care  
40  
41 392 Innovations (PIHCI) and at least one individual/patient from each province in order to embody  
42  
43 393 categories of stakeholders across Canada. PIHCI is a network building on regional and national  
44  
45 394 achievements in community-based primary and integrated health care <sup>80</sup>. During this preparation  
46  
47 395 phase, a brief executive summary of project results will be produced and tailored to inform each  
48  
49 396 specific audience and category of stakeholders. The evaluation question that will be discussed and  
50  
51 397 disseminated to the participants is as follows: Based on your own experience, what should be the  
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53 398 next steps towards the spread of CM in primary care, in your area of expertise (patient  
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55 399 engagement, clinical care, policy and research)?  
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3 400 *Individual production*  
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5 401 All stakeholders will receive the executive summary of the results, two months prior to the  
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7 402 meeting, and will be asked to provide a maximum of five statements in response to the question  
8  
9 403 stated above. Beyond five statements, information is expected to become redundant <sup>79</sup>. These  
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11 404 statements will be kept confidential and sent back to the organisation team.  
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16 406 *Interactive production*  
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18 407 This phase will take place during the full-day meeting. The project and results will be presented  
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20 408 to all participants. Each group of stakeholders will gather to identify, by consensus, the most  
21  
22 409 important and relevant statements among those brought forth in their stakeholder category. An  
23  
24 410 expert animator will act as a facilitator and lead interactions among group experts. The interactive  
25  
26 411 step of TRIAGE relies on a prominent visual aid. A wall of the room will be used and divided  
27  
28 412 into three main sections: memory, groupings and selection. The memory section is, in fact, a bank  
29  
30 413 of all statements gathered in the previous step, which have been numbered and transcribed. As  
31  
32 414 group interactions occur, the selection process will evolve, with cards moving from one section to  
33  
34 415 another, from left (memory) to right (selection). It will also be possible to modify the statements.  
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36 416 “Selected” statements will also be ranked and prioritized. At the end of the meeting, each group  
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38 417 of stakeholders will present their selected statements in order of priority.  
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43 419 **Patient and Public Involvement**  
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45 420 This project was developed in close collaboration with patient-partners, with which we developed  
46  
47 421 a trusty relationship and a collaborative approach. These partners are listed as co-authors (GG,  
48  
49 422 CL, JR, AS, CS, VS, MW). These patient-partners were involved in the elaboration of the  
50  
51 423 research questions that were relevant from their perspectives. Patient-partners will advise on ways  
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53 424 to enhance study feasibility and patient’s acceptability. They will be engaged in interpretation of  
54  
55 425 data. Results will be disseminated to patients through lay language newsletters and local media.  
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3 426 **ETHICS AND DISSEMINATION**

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5 427 This project received approval from the CIUSSS de l'Estrie - CHUS Research Ethic Board  
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7 428 (project number MP-31-2019-2830). All participants will provide informed consent prior to  
8  
9 429 engagement and recruitment. In addition, certificates of approval will be obtained in each of the  
10  
11 430 provinces before data collection is commenced. If appropriate, adherence to Chapter 9 of the  
12  
13 431 TCPS2 (2014) will be observed and upheld.  
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18 433 This four-year multiple-case, mixed-method study will result in the potential for great impact  
19  
20 434 with stakeholders, but mostly for individuals/patients. New evidence-based knowledge will be  
21  
22 435 provided on the implementation of CM interventions, which can contribute to improve care  
23  
24 436 integration for individuals/patients who frequently use healthcare services, and ultimately reduce  
25  
26 437 ineffective healthcare use and costs. The proposed design will allow adapting the knowledge  
27  
28 438 acquired on CM to local contexts, the first essential step towards implementation<sup>81</sup>. Moreover,  
29  
30 439 recognition of facilitators and barriers to implementation as well as, the influence that context  
31  
32 440 exerts on outcomes will pave the way for the spread of CM in primary care settings in different  
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34 441 Canadian jurisdictions.  
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39 443 This study built on various strengths, but mostly on the engagement of knowledge users who  
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41 444 were and will be involved throughout the entire process to ensure that the new knowledge  
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43 445 generated by CM in primary care will be refined and tailored to their own specific needs<sup>81</sup>. These  
44  
45 446 stakeholders will then be best suited to further adapt CM knowledge to their own local context  
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47 447 and to increase the chance of successfully implementing CM in their setting<sup>81</sup>. All of these steps  
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49 448 will increase spread and positively influence the healthcare system as well as  
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51 449 individuals/patients/communities and clinicians' experiences, and outcomes<sup>24 25 36</sup>.

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3 451 This study builds on many important aspects related to the rigour of the approach and  
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5 452 methodology. As such, all stakeholders, including individuals/patients, from the five provinces  
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7 453 (SK, QC, NB, NS, NL) already working together, have participated in the elaboration of research  
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9 454 questions that were relevant from their perspectives. This partnership with stakeholders is  
10  
11 455 strengthened by a solid engagement plan as well as a relevant knowledge transfer plan tailored for  
12  
13 456 each stakeholder audience. The conceptual basis of this study is based on a rigorous research plan  
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15 457 that unifies key constructs from published implementation theories (CFIR) <sup>36</sup> as well as a  
16  
17 458 framework combining the concepts of primary care and integration of care (Valentijn) <sup>37</sup>. The  
18  
19 459 intervention is evidence-based and shaped for individuals/patients who frequently use healthcare  
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21 460 services <sup>8-12 82</sup>. As for data collection, appropriate sampling strategies will be pursued, while data  
22  
23 461 quality and reliability will be ensured through three main strategies <sup>26</sup>: the 10 case histories will  
24  
25 462 integrate relevant qualitative and quantitative data in a Master database; the database will contain  
26  
27 463 sufficient information about data collection; and, data collection will follow published methods.  
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29 464 Validity of the study will be ensured by mixing qualitative and quantitative methods (comparison  
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31 465 of results and data merging), multiple data sources and evaluators triangulation <sup>26</sup>. Transferability  
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33 466 will be ensured by several strategies such as theoretical basis, observation replication across cases  
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35 467 <sup>26</sup>, and thorough description of the context <sup>61</sup>.

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41 469 While some challenges are expected with this study, mitigated strategies are nevertheless  
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43 470 proposed. To ensure meaningful involvement of all provinces and team members in the project,  
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45 471 relationships and team building will be nurtured and stakeholders will be encouraged to speak in  
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47 472 their preferred language (English or French). Being engaged with our patient partners over the  
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49 473 last four years, solutions have been developed to accommodate their needs, e.g., help with a  
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51 474 wheelchair, being flexible regarding schedule if hospitalization or deterioration, training.  
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53 475 Partnerships will also be monitored annually. The circumstances of this vulnerable clientele may  
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55 476 also influence data collection as well as study validity. This challenge will be overcome by



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3 477 research assistants administrating the questionnaire to patients and assisting them as needed. In a  
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5 478 similar study conducted by our team, a 93% retention rate was achieved, demonstrating the  
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7 479 efficacy of our strategies<sup>60</sup>.  
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11 481 Based on popular conceptual frameworks and rigorous methodology, design, and methods, this  
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13 482 pan-Canadian study holds promise to guide policy decision-making, and to ultimately and  
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15 483 positively impact health services systems as well and most importantly, the health of Canadians.  
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17 484 This study will generate findings on the implementation of CM in primary care for  
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19 485 individuals/patients with chronic conditions and complex healthcare needs who frequently use  
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21 486 healthcare services, as well as to implement an evidence-based intervention that will not only  
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23 487 improve the care experience and outcomes but will also mitigate ineffective use and costs.  
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3 495 **LIST OF ABBREVIATIONS**  
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5 496 CM: Case management; CFIR: Consolidated Framework for Implementation Research; CIHI:  
6  
7 497 Canadian Institute for Health Information; CMO: Context-Mechanism-Outcome; ED: Emergency  
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9 498 department; NB: New Brunswick; NL: Newfoundland and Labrador; NS: Nova Scotia; PIHCI:  
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11 499 Primary and Integrated Health Care Innovations; QC: Quebec; SK: Saskatchewan; SPOR:  
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13 500 Strategy in Patient Oriented Research; TRIAGE: Technique for Research of Information by  
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15 501 Animation of a Group of Experts.  
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3 744 **AUTHORS' CONTRIBUTION**  
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49 766 All authors declare that they have no competing interests.  
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