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An evaluation of an interprofessional primary healthcare team in Quebec: a protocol for an effectiveness-implementation hybrid study

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Title page

An evaluation of an interprofessional primary healthcare team in Quebec: a protocol for an effectiveness-implementation hybrid study

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24 **Keywords**

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28 Primary care, interprofessional team, advanced practice nursing, access, person-
29 centredness, efficiency
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32 **Abstract**

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35 **Introduction:** One Family Medicine Group (FMG) in Quebec (Canada) has
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37
38 commenced a five-year pilot project, which is herein referred to as the *Archimède* model,
39
40 to implement a patient-centred model based on interprofessional care and the optimal use
41
42 of healthcare providers' practice scopes. A research project will be conducted to: (1) assess
43
44 this model's effect on the FMG's operational performance, and its users' resource
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46 utilization at the public health system level; (2) investigate its optimization with respect to
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48 professional roles, interprofessional teamwork, and patient-centredness; and (3) document
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3 users' experience with the model. The aim of this article is to describe the protocol that
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5 will be used for this research.
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8 **Methods and analysis:** A hybrid implementation approach (type 2 model) will be
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10 used. We will collect both quantitative and qualitative data. Regarding the quantitative
11
12 dimension, and because this is a single-unit intervention study, we will use synthetic
13
14 control methods and one-sample generalized linear models for analyses at the FMG level.
15
16 To evaluate the broader impact of *Archimède* on the public health system, we will use
17
18 mixed-effects models and propensity score matching methods. Regarding the qualitative
19
20 research dimension, using an interpretative descriptive approach, we will document users'
21
22 experience and identify the factors that optimize professional scopes of practice,
23
24 collaborative practices, and patient-centredness. We will conduct individual in-depth semi-
25
26 structured interviews with healthcare providers, administrative staff, stakeholders involved
27
28 in the *Archimède* model implementation, and patients.
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33 **Ethics and dissemination:** This study has been approved by the Ethics Committee
34
35 of the Sectoral Research in Population Health and Primary Care of the Centre intégré
36
37 universitaire de santé et de services sociaux de la Capitale-Nationale (#2019-1503). The
38
39 results of the investigation will be presented to the stakeholders involved in the advisory
40
41 committees and at several scientific conferences. Manuscripts will be submitted to peer-
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43 reviewed journals.
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Strengths and limitations of the study

- This study will advance understanding about the effects of a team-based model of care within a FMG that is in a disadvantaged area and whose clientele presents complex biopsychosocial problems.
- This study will advance understanding about the efficiency of primary care models, thus responding to the need to better evaluate primary care reforms.
- Although our study focuses on only one FMG, conducting this project will permit the testing of an ambitious methodology to quantitatively assess the performance of the FMG, and an in-depth exploration of the influences of the implementation context on the deployment of the project.
- The involvement of multiple actors both in the data collection and on the advisory committee should help to mitigate the potential limitations of the Type 2 effectiveness-implementation hybrid study (e.g., poor adoption and fidelity of the implementation strategy).

1 INTRODUCTION

2 Context of the study

3 The aim of the protocol presented in this article is to evaluate the implementation of
4 a new model of primary care. This model differs from the practices in many medical clinics
5 because of its diversified interprofessional team (e.g., primary health nurse practitioners,
6 registered nurses, social workers, physiotherapist), the close collaborations between health
7 and social professionals, and the access to non-physician-centric care.

8 Primary care, which is patients' first point of contact with the health care system (1),
9 provides early care for health problems, chronic disease management, and preventive
10 services. Various models of interprofessional primary care are being created to address
11 human resource shortages in health systems, control health care costs, and reduce overuse
12 of emergency departments visits (2-4). These models are also designed to address the
13 biopsychosocial needs of patients and improve access, continuity of care, and quality of
14 care (5-9).

15 In the early 2000s, in response to inconsistent primary care access, Canadian
16 provinces and territories began developing various initiatives (10, 11), one of these being
17 the creation of interprofessional primary care teams. In Quebec, these teams are called
18 *Groupes de médecine familiale* [Family Medicine Groups (FMGs)], within some of which
19 physicians, nurses, and other health and social services professionals collaborate to deliver
20 health care based on contractual agreements with the provincial government (10). Although
21 the FMGs are private clinics (albeit financed within Quebec's public insurance system),
22 they have direct collaborative links with the *Centres intégré universitaire de santé et de*
23 *services sociaux* (CIUSSS) [Integrated university health and social services centres]; many

24 of the professionals who work in the FMGs are employees of the CIUSSS. The Ministry
25 for Health and Social Services (MSSS) establishes the rules for the distribution of
26 professional and administrative resources.

27 In 2017, the Saint-Vallier FMG in Quebec City, situated within the CIUSSS-Capitale
28 Nationale (CN) territory, commenced a five-year pilot project, titled *Archimède (12)*.
29 Threatened with closure in 2015 due to the retirement of its physicians and the difficulties
30 of medical recruitment in this district, in which it has not always been easy to recruit
31 healthcare personnel, the pilot project enabled the FMG to maintain its activities, and to
32 continue to meet the complex and diversified needs of the population. Due to the COVID-
33 19 pandemic, which necessitated significant changes in both how services could be
34 provided and staff availability, the pilot project period was extended by two years. This
35 project, which was developed in collaboration with relevant stakeholders (e.g., MSSS,
36 CIUSSS-CN), seeks to implement a patient-centred model based on interprofessional care
37 and the optimal use of healthcare providers' scopes of practice. The *Archimède* project is
38 anticipated to improve access to primary care and, given the lower remuneration associated
39 with the services provided by nurses and other health and social services professionals
40 compared to that of physicians, to reduce costs. Also, arising partly from a more efficient
41 allocation of patients across the various professions within the clinic, the improved access
42 is anticipated to reduce hospital utilization (e.g., emergency department visits), thus
43 contributing to health system efficiency (1, 2).

44 Our investigation aims to identify areas of improvement, formulate
45 recommendations to improve the model's functioning, ensure its utility to stakeholders,
46 and foster its sustainability and potential for scaling up. Specifically, this study seeks to

1
2
3 47 determine whether the *Archimède* model is efficient regarding patient and clinic outcomes
4
5 48 and teamwork (e.g., role optimization) in relation to the resources invested. Our objectives
6
7 49 are: (1) to evaluate the impact of the *Archimède* model on operational performance at the
8
9 50 FMG level as well as user resource utilization at the public health system level; (2) to
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11 51 identify the factors that foster or impede the optimization of professional roles,
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13 52 interprofessional teamwork, and patient-centredness, and (3) to document users'
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15 53 experience with the *Archimède* model.
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23 **Setting**

24 56 The St-Vallier FMG is in Quebec City's Saint-Sauveur district. This neighbourhood has
25
26 57 one of the highest rates of demographic fragility within the CIUSSS-CN territory (13).
27
28 58 Although the FMG serves a very broad clientele, a large proportion of its consultations are
29
30 59 conducted with users with chronic health problems or in vulnerable psychosocial
31
32 60 situations. The clinic's clientele is also characterized by a significant number of immigrants
33
34 61 and political refugees. Regarding the FMG's human resources, there are currently 27
35
36 62 employees, including six family physicians (FPs), four primary health care nurse
37
38 63 practitioners (PHCNPs), one mental health nurse practitioner (MHNP), five registered
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40 64 nurses (RNs), six health and social services professionals (social worker, nutritionist,
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42 65 physiotherapist, kinesiologist, psychologist, respiratory therapist), and five administrative
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44 66 staff. All services are free of charge for clients registered in the FMG. When making an
45
46 67 appointment, users are invited to explain their reason for consultation in order to be directed
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48 68 to the right professional resource by administrative staff, according to predefined care
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50 69 trajectories. Complex health problems are managed as a team. The team also contributes
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70 to facilitating access to various outreach services, including in community resources and
71 the various services offered by the CIUSSS-CN.

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73 **METHOD AND ANALYSIS**

74 **Conceptual framework**

75 This study is based on two frameworks : the *Quadruple Aim* framework (14), which
76 is the Canadian framework used for health care transformation research (15); and the
77 optimization of professional scopes of practice (16). The Quadruple Aim framework is
78 designed to foster change in health care systems through the achievement of four goals :
79 improved population health outcomes; improved care and patient experience; improved
80 provider satisfaction; and lower costs/better value (14, 15). Recently, a fifth aim has been
81 added that recognizes health equity as an important outcome to reduce health disparities
82 and address social determinants of health (17, 18). In primary care, the development of
83 interprofessional teams is a key factor in improving quality to achieve these goals (2).

84 Regarding the optimization of professional scopes of practice, the Canadian
85 Academy of Health Sciences (CAHS) identified factors of influence at the micro-, meso-
86 and macro-levels (16). Micro-level factors include professional hierarchies, professional
87 cultures, and communication among healthcare professionals. Meso-level factors include
88 communication across multiple care settings, professional protectionism, accountability,
89 and availability of evidence. Macro-level factors include legislation/regulations, payment
90 models, educational needs/requirements, and healthcare professional accountability.

91

92

93 Design

94 The research on evidence-based interventions frequently favours a stepwise
95 approach; one of the limitations of this approach is the significant time lag between the
96 development of the interventions and its implementation in the field (19). To address this
97 issue, hybrid designs have been developed to promote the examination of effectiveness and
98 implementation outcomes within a single study. Our research will use a hybrid
99 implementation approach, and specifically the type 2 model, that incorporates a dual focus
100 on effectiveness and implementation outcomes (19). This model permits simultaneous
101 testing or piloting of implementation strategies during an effectiveness trial. Specifically,
102 in this investigation, we will collect both quantitative and qualitative data.

103 The overall data collection process is presented in Figure 1 and will commence in
104 mid-February 2023.

105 It is relevant to note that an advisory committee was established at the beginning of
106 the development of the project, the objectives of which are to better understand the broader
107 implementation context, monitor the progress of the research project, discuss
108 methodological and fieldwork aspects and the emerging findings, and develop strategies
109 for knowledge transfer to maximize the impact in the health care system. This committee
110 is composed of members of the research team, and representatives from the management
111 of the St-Vallier FMG, a user partner, and stakeholders from the CIUSSS-CN and the
112 MSSS.

113

114 *Insert Figure 1 here*

115 **Figure 1. Data collection process over a year.**

116 Quantitative approach

117 Our quantitative approach aims to evaluate the impact of the *Archimède* model on
118 operational performance at the FMG level as well as user resource utilization at the public
119 health system level. Because this is a single-unit intervention study, to quantitatively assess
120 the performance of the *Archimède* model at the FMG level (outcomes will include metrics
121 such as *number of patient visits* and *vulnerability-weighted enrollments*), we will use either
122 or both synthetic control methods (20, 21) and one-sample generalized linear models.
123 Synthetic control methods are quasi-experimental and are commonly used in the policy
124 evaluation literature. In the case of our study, this approach will consist of creating a control
125 counterfactual FMG from a weighted average of other FMGs in the Quebec City region.
126 On the other hand, one-sample generalized linear models will be informed by preliminary
127 clustering analyses (such as principal component analysis) for control FMGs' selection,
128 and will allow for hypothesis testing. The choice of methods will heavily depend on data
129 availability, including at what point it is first available, and data structure. The database for
130 the FMG-level analyses will be built from different operational and financial reports of all
131 FMGs in the Quebec City region, including the St-Vallier FMG. These reports are
132 compiled by and will be provided to us by the MSSS and the CIUSSS. We will extract data
133 from reports ranging from 2012 to 2022. A non-exhaustive list of the variables we plan to
134 collect as well as details concerning the reports from which they will be extracted are
135 presented in Table 1.

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Table 1. Non-exhaustive list of FMG-level variables of interest

Variable of interest	Additional information	Source
Year		
Id		
Size		MSSS's financial report of FMGs
Type	Private vs public	MSSS's financial report of FMGs
Number of hours worked for each type of healthcare worker	E.g., nurses, physical therapists, nutritionist, psychologists, etc.	CIUSSS's payroll report
Full time equivalents (FTEs) for each type of healthcare worker	E.g., nurses, physical therapists, nutritionist, psychologists, etc.	CIUSSS's payroll report
Enrolments	Total unweighted number of patient enrollments	MSSS's 8B report
Weighted enrolments	Weights include vulnerability, disadvantage, births, etc.	MSSS's 8B report
Number of physicians		MSSS's 8B report
Patient attendance rate		MSSS's financial report of FMGs
Visits	Subdivided into in person visits vs telemedicine.	MSSS's 8C report
Funding	Total amount of government funding in CAD	MSSS's financial report of FMGs

139 In addition, to evaluate patients' service utilization outside of the FMG, and thus
 140 better understand the broader impact of *Archimède* on the public health system, we will
 141 use both generalized linear mixed-effects models and propensity score matching methods
 142 (22) to compare patients enrolled in the St-Vallier clinic to those enrolled in other FMGs.
 143 The outcomes will include metrics such as *number of urgent care admission events* and
 144 *length of hospitalization*. Confounding factors will include variables such as *age, gender,*
 145 and pre-existing health conditions. The database for this portion of the study will be built
 146 and anonymized by the *Institut de la Statistique du Québec* (ISQ). A short list of some of

147 the variables we will be querying, as well as details about the source database from which
 148 they will be extracted by the ISQ, are presented in Table 2.

149 *Table 2. Public health system-level example variables of interest*

Variable of interest	Additional information	Source database	Source database specifications
ID	Unique patient identifier provided by the ISQ	FIPA	FIPA contains information about patients covered by the public health insurance system
Age		FIPA	
Gender		FIPA	
Partial postal code	First three digits	FIPA	
Urgent care admission event		BDCU	BDCU contains information about urgent care admissions
Length of hospitalization		MED-ECHO	MED-ECHO contains information about hospitalizations
Service request event		I-CLSC	I-CLSC contains information about frontline common health and social services

150 *Note.* FIPA = Fichier d'inscription des personnes assurées, BDCU = Banque de données
 151 commune des urgences. MED-ECHO = Maintenance et exploitation des données pour
 152 l'étude de la clientèle hospitalières, I-CLSC = Système d'information sur la clientèle et
 153 les services des CSSS - mission CLSC. A list of all available variables that the ISQ can
 154 provide can be found at:
 155 <https://statistique.quebec.ca/research/#/donnees/administratives/sante>.

156 The data will subsequently be transferred to us via a secured remote connection service
 157 offered by the ISQ. The final database will comprise upwards of 60 variables for 14,000
 158 randomly selected and uniquely identified patients; 3,500 (25%) will be patients enrolled
 159 in the St-Vallier FMG and 10,500 (75%) will be patients enrolled in other FMGs. The
 160 experimental population sample of 3,500 patients is based on the lowest number of
 161 enrollments in the St-Vallier clinic between 2018 and 2022 (3,924 patients). The 25-75%

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3 162 split was chosen to maximize the likelihood of successfully building synthetic control
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5 163 patients from weighted averages of patients enrolled in other FMGs to match the
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8 164 experimental group. To be included, patients will have to be over 18 years of age and will
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10 165 need to have been enrolled in the same single FMG between 2018 and 2022.
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15 167 **Qualitative approach**

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17 168 We will conduct the qualitative research portion of this study using an interpretive
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19 169 description methodology (23). This approach is appropriate for gaining a rich
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21
22 170 understanding of service providers', stakeholders', and patients' experiences with the
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24 171 *Archimède* model, and their links with meso- and macro-level factors that influence the
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26 172 optimisation of roles, interprofessional collaboration and patient-centredness. To collect
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28 173 this data, we will conduct individual in-depth semi-structured interviews, which will be
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30 174 appropriate given the potentially sensitive data that participants will share, to permit us to
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32 175 capture deeper understanding of the subjective work and patient experience.
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38 177 **Population: eligibility criteria and sampling strategy**

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41 178 We will use a purposive sample (24) of healthcare providers (FPs, PHCNPs, RNs,
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43 179 various health and social services professionals), administrative staff and managers
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45 180 working in the St-Vallier FMG; stakeholders involved in the *Archimède* model
46
47 181 implementation; and patients receiving services at the FMG. All employees from the St-
48
49 182 Vallier FMG will be eligible. We will recruit up to five stakeholders who played a key role
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51 183 in the implementation of the *Archimède* model (e.g., representatives from the MSSS,
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53 184 clinical advisor on interprofessional collaboration), depending on the advisory committee's
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185 suggestions. The sample of patients will be based on the main health problems for which
186 patients seek care, which we will determine during recruitment. We aim to include patients
187 with health problems such as chronic diseases, mental health problems, and loss of
188 autonomy. We believe that 20 patients will be sufficient for providing rich data, although
189 the final number will be determined by the attainment of data saturation (25). Patients will
190 be required to be ≥ 18 years old, enrolled with a FP, and considered able to provide
191 informed consent by healthcare providers. All patients enrolled in the study will be asked
192 to complete a socio-demographic form to provide information on their socio-economic
193 status.

194 195 Recruitment strategy

196 Participation in the individual interviews will be voluntary. For the recruitment of
197 healthcare providers, managers and administrative staff, we will conduct an information
198 session at the Saint-Vallier FMG to present the study and distribute information leaflets.
199 We will also send an email to these personnel categories with detailed information about
200 the study to inform employees who cannot attend the meeting. Employees who are
201 interested in participating in the interviews will be invited to contact us. In addition, we
202 will identify key stakeholders with the help of the advisory committee and contact them
203 directly via email or telephone. For patient recruitment, we will ask healthcare providers
204 to provide them with information leaflets. We will also leave leaflets in the waiting rooms
205 of the FMG. These leaflets, which will inform patients about the entire study so that they
206 have the choice to decline participation, will include a consent form and will inform
207 patients about the \$30 to compensate participants for their time. Patients will have the

208 option to contact the research team directly or leave their contact information in an online
 209 form if they are interested in participating in the interviews.

210

211 Interviews

212 The interviews will be conducted in participants' preferred setting (i.e., home, research
 213 centre, FMG, videoconference), albeit adhering as necessary to current public health
 214 guidelines. The interview guides for individual interviews, developed in collaboration with
 215 the advisory committee, are based on the conceptual framework (see Table 3 for interview
 216 themes). These guides will evolve iteratively such that analyses of the results of the first
 217 interviews will inform questions during subsequent interviews. The interviews will be
 218 audio-taped with participants' consent.

219

220

Table 3. Interview themes

	Themes
Employees	Work organization and motives to work in the FMG Impact of <i>Archimède</i> on professional role and workload Interdisciplinary teamwork dynamics Level of commitment to work in the FMG Experience and satisfaction with the new FMG's work organization Obstacles to the implementation of the model (micro, meso, macro)
Stakeholders	Role in the implementation process Context of emergence and the implementation process Operation of the FMG Assessment of the <i>Archimède</i> model
Patients	Reasons for seeking care and healthcare providers seen Impact of <i>Archimède</i> on care and ability to get involved in one's own care (Saint-Vallier clinic) Satisfaction with care Likes and dislikes about the FMG's work organization Participation in care decision-making

221

222 Data analysis

223 Our analysis of the interview data will be facilitated by using Nvivo software (26).

224 We will follow the stages of thematic analysis: initial coding according to our predefined

225 interview themes and those that emerge during the analysis; categorization; consolidation

226 of categories; linking of categories; and data integration and modeling (27). We will

227 analyze data in light of factors that optimize scope of practice, at the micro, meso, and

228 macro levels, as defined by the CAHS (16). We will give particular attention to the

229 collaboration between healthcare providers, and collaboration between healthcare

230 providers and administrative staff. Furthermore, we will characterize interactions between

231 the micro, meso and macro levels. We will prepare comprehensive summaries of our results

232 and discuss them with the advisory committee group to enhance our interpretation.

233 Subsequently, we will (1) formulate recommendations for optimizing interprofessional

234 collaborative and patient-centred practices and the role of healthcare providers, and (2)

235 highlight the challenges and potential viable solutions related to the sustainability of the

236 *Archimède* project and its potential scaling up in other settings.

237

238 **PATIENT AND PUBLIC INVOLVEMENT**

239 Patients and/or the public were involved in the design, or conduct, or reporting, or

240 dissemination plans of this research. The user-partner played a key role from the very

241 beginning of the pilot project through his participation in several meetings of the advisory

242 committee. The governance of the project has been designed to ensure that user-partners

243 are involved in the decision-making processes, which will allow the advisory committee to

244 remain responsive to user concerns throughout the implementation of the project. Refer to
245 the Methods and analysis section for further details.

246

247 **ETHICS AND DISSEMINATION**

248 This project respects the ethics, integrity and responsible research conduct standards
249 defined by the Fonds de recherche du Québec (FRQS) and the CIUSSS-CN. It has received
250 ethical approval from the regional health organization with which the researchers are
251 affiliated (# 2019-1503). Regarding ethical considerations specific to the participants in the
252 interviews, we specified all their rights in accordance with the rules of the sectoral research
253 ethics committee (CER-S) in population health and primary care (e.g., the right of
254 participants to withdraw from the study at any time and to refuse to answer certain
255 questions; the confidentiality obligations of the researchers; the confidentiality obligations
256 of the focus group participants). The results of the investigation will be presented to the
257 stakeholders involved in the advisory committee and at several scientific conferences.
258 Manuscripts will be submitted to peer-reviewed journals.

259

260 **DISCUSSION**

261 Interprofessional teams are increasingly being established throughout Canada and
262 elsewhere to improve the access, continuity and quality of services provided to individuals
263 living with complex health problems (e.g., chronic diseases, mental health challenges,
264 comorbidities) (6, 28-32). A variety of models exist, characterised both by the organization
265 and degree of interprofessional collaboration, as well as the type of clients served (33-35).

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3 266 This project will advance the understanding of the effects of a team-based model of
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5 267 care within a FMG that is in a disadvantaged area and whose clientele presents complex
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8 268 biopsychosocial problems. Various interprofessional primary care models have been
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10 269 developed that are designed to address complex health problems in specific populations
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12 270 identified as vulnerable, for example, older adults, (36), individuals with HIV (37), and
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14 271 veterans (38). However, these models have frequently been presented as intervention
15
16 272 programs composed of a predefined interprofessional continuum of care, a care manager,
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18 273 and/or case discussions. In comparison, the *Archimède* model is based on a uniform
19
20 274 orientation to the optimization of professional roles (seeing the right professional at the
21
22 275 right time), and the use of predefined pathways enacted by administrative staff when
23
24 276 making appointments. Furthermore, in this model, referrals are made between
25
26 277 professionals, and the continuum of care is facilitated by having an interprofessional team
27
28 278 in the same location. Access to this interprofessional approach also is facilitated because
29
30 279 no fee is charged. In addition, compared to other reported primary care models (34, 39,
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32 280 40), there is no preselection of patients, with all patients being eligible for the appropriate
33
34 281 professional services. Our research project seeks to understand the experience of users
35
36 282 attending a clinic based on this model to assess the relevance of this model for this
37
38 283 population.

39
40 284 One of the strengths of our research includes the measure of efficiency with respect
41
42 285 to operational performance at the FMG level and the use of health network resources (e.g.,
43
44 286 emergency room visits) by *Archimède* users. This study will make an important
45
46 287 contribution to the understanding of the efficiency of primary care models, thus responding
47
48 288 to the need to better evaluate primary care reforms (10, 32).

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3 289 The originality of our research lies in our focus on the interrelations between the
4
5 290 micro, meso and macro levels to better identify the elements that facilitate or hinder the
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7 291 deployment of the model and the optimisation of interprofessional collaboration.
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10 292 Understanding the context of implementation, particularly in relation to the particularity of
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12 293 the dual public and private organisational structures, is an important element in this
13
14 294 research project. That is, although the model is deployed in a private clinic, it is publicly
15
16 295 funded. As well, some staff are paid by the public health organization. Thus, our approach
17
18 296 takes into account: 1) structural issues related to health policies in primary care, types of
19
20 297 funding, and resource management; 2) issues related to the organization of the clinic (e.g.,
21
22 298 dynamics of interprofessional collaboration and management practices); and 3) micro-level
23
24 299 issues related to the subjective work experience of professionals and service users'
25
26 300 experiences (16). Although our research evaluates only one FMG, the findings from this
27
28 301 study could be relevant not only in Quebec but also for other jurisdictions looking to
29
30 302 develop interprofessional primary care models that address the social determinants of
31
32 303 health, and that optimize the use of health and social care providers' respective scopes of
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34 304 practice.
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41
42 306 Regarding the potential limitations of our investigation, there is a possible lack of
43
44 307 generalisation in studying only one FMG. Nevertheless, conducting this project will permit
45
46 308 us to both test our ambitious methodology to quantitatively assess the performance of the
47
48 309 FMG, and to explore in depth the influences of the implementation context on the
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50 310 deployment of the project. A potential limitation of the type 2 effectiveness-
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52 311 implementation hybrid study approach concerns the difficulties that can arise if the
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3 312 implementation strategy leads to poor adoption and fidelity, as it can compromise the
4
5 313 effectiveness trial field (19). In our study, the involvement of multiple actors in the
6
7 314 advisory committee should help to mitigate this limitation. A further possible limitation
8
9 315 concerns the potential for generalisation to other areas with different demographic profiles,
10
11 316 given that the FMG under study is in a disadvantaged area. However, it is unlikely that all
12
13 317 patients attending the FMG are in a vulnerable situation; the use of a socio-demographic
14
15 318 form will allow to establish a socioeconomic profile of the patients interviewed.
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34 325 All authors reviewed and approved this manuscript.
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39 327 **COMPETING INTERESTS**

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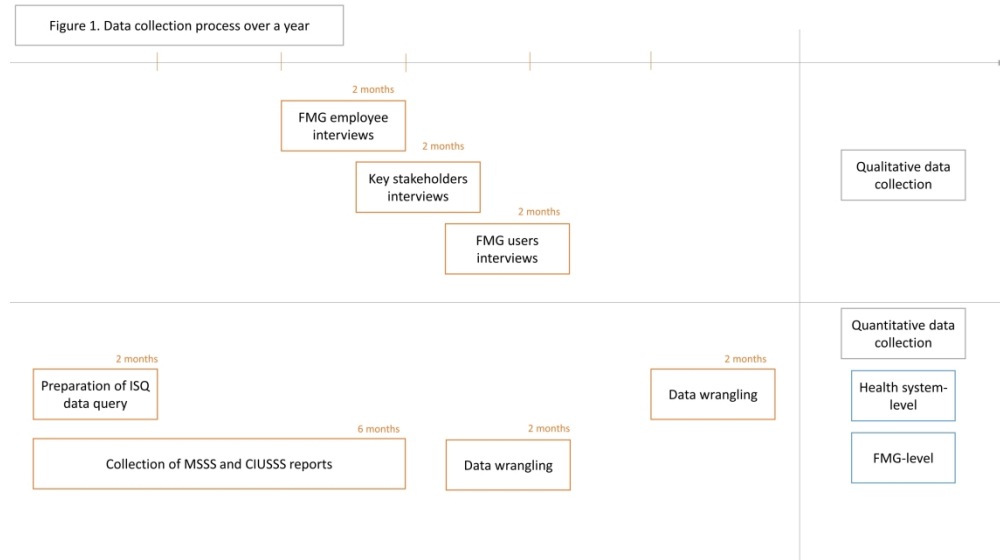
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Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015

Text Section and Item Name	Section or Item Description	
Notes to authors	<ul style="list-style-type: none"> • The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript. 	<p>As you review the manuscript, place a checkmark in this column for each SQUIRE item that is appropriately addressed in the manuscript. Remember that not every item is necessary in every manuscript.</p>
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	p.1
2. Abstract	<ol style="list-style-type: none"> a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions 	pp.2-3

Introduction	<i>Why did you start?</i>	
3. Problem Description	Nature and significance of the local problem	p.5-6
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	p.5-6
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	p.8
6. Specific aims	Purpose of the project and of this report	p.7
Methods	<i>What did you do?</i>	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	p.7
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	a) p.7 b) p.7
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	a) p. 9
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	pp.10-13 (quantitative) pp. 13-15 (qualitative)
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	pp. 10-13 (quantitative) p.16 (qualitative)
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	p.17

Results	<i>What did you find?</i>	
13. Results	<ul style="list-style-type: none"> a. Initial steps of the intervention(s) and their evolution over time (<i>e.g.</i>, time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data 	Not appropriate; protocol article
Discussion	<i>What does it mean?</i>	
14. Summary	<ul style="list-style-type: none"> a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project 	<ul style="list-style-type: none"> a) N/A b) p.4 and pp.18-19
15. Interpretation	<ul style="list-style-type: none"> a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs 	N/A (protocol article)
16. Limitations	<ul style="list-style-type: none"> a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations 	pp.19-20
17. Conclusions	<ul style="list-style-type: none"> a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps 	pp.17-20
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	p.20

BMJ Open

An evaluation of an interprofessional primary healthcare team as a new model of primary care in Quebec: a protocol for a type 2 effectiveness-implementation hybrid study

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Keywords:	PRIMARY CARE, Health Services Accessibility, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, HEALTH ECONOMICS

SCHOLARONE™
Manuscripts

Title page

An evaluation of an interprofessional primary healthcare team as a new model of primary care in Quebec: a protocol for a type 2 effectiveness-implementation hybrid study

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25 **Word count: 4087**
26

27 **Keywords**

28
29 Primary care, interprofessional team, advanced practice nursing, access, person-
30 centredness, efficiency
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35 **Abstract**

36
37 **Introduction:** One Family Medicine Group (FMG) in Quebec has commenced a
38 five-year pilot project, which is herein referred to as the *Archimède* model, to implement a
39 patient-centred model based on interprofessional care and the optimal use of healthcare
40 providers' practice scopes. A research project will be conducted to: (1) assess this model's
41 effect on the FMG's operational performance, and its users' resource utilization at the
42 public health system level; (2) investigate its optimisation with respect to professional
43 roles, interprofessional teamwork, and patient-centredness; and (3) document users'
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3 experience with the model. The aim of this article is to describe the protocol that will be
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5 used for this research.
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7
8 **Methods and analysis:** A hybrid implementation approach (type 2 model) will be
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10 used. We will collect both quantitative and qualitative data. Regarding the quantitative
11
12 dimension, and because this is a single-unit intervention study, we will use either or both
13
14 synthetic control methods and one-sample generalized linear models for analyses at the
15
16 FMG level. To evaluate the broader impact of *Archimède* on the public health system, we
17
18 will use mixed-effects models and propensity score matching methods. Regarding the
19
20 qualitative research dimension, using an interpretative descriptive approach, we will
21
22 document users' experience and identify the factors that optimize professional scopes of
23
24 practice, collaborative practices, and patient-centredness. We will conduct individual in-
25
26 depth semi-structured interviews with healthcare providers, administrative staff,
27
28 stakeholders involved in the *Archimède* model implementation, and patients.
29
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32
33 **Ethics and dissemination:** This study was approved by the Ethics Committee of the
34
35 Sectoral Research in Population Health and Primary Care of the Centre intégré
36
37 universitaire de santé et de services sociaux de la Capitale-Nationale (#2019-1503). The
38
39 results of the investigation will be presented to the stakeholders involved in the advisory
40
41 committees and at several scientific conferences. Manuscripts will be submitted to peer-
42
43 reviewed journals.
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Strengths and limitations of the study

- The measure of efficiency with respect to operational performance at the FMG level and the use of health network resources (e.g., emergency room visits) by Archimède users is a strength.
- The study's inclusion of the analysis of the interrelations between the micro, meso and macro levels to better identify the elements that facilitate or hinder the deployment of the Archimède model and the optimisation of professional roles and interprofessional collaboration is a strength.
- The possible lack of generalisation associated with studying only one FMG will be mitigated by the use of a methodology to quantitatively assess the performance of the FMG, and an in-depth exploration of the influences of the implementation context on the deployment of the project.
- The potential limitations of the Type 2 effectiveness-implementation hybrid study will be mitigated by the involvement of multiple actors on the advisory committee (e.g., able to be rapidly updated about the results; ability to intervene directly to make necessary adjustments).

1 INTRODUCTION

2 Context of the study

3 The aim of the protocol presented in this article is to evaluate the implementation of
4 a new model of primary care. This model differs from the practices in many medical clinics
5 in the sense that access is not automatically through a family physician. Composed of
6 several health and social services professionals, the Archimède model works on the
7 principle of the inverted pyramid. That is, there are more nurses (primary health care nurse
8 practitioners and registered nurses) than physicians, and the clinic relies on the optimisation
9 of professional roles through the close collaborations between health and social
10 professionals.

11 Primary care, which is patients' first point of contact with the health care system (1),
12 provides early care for health problems, chronic disease management, and preventive
13 services. Various models of interprofessional primary care are being created to address
14 human resource shortages in health systems, control health care costs, and reduce overuse
15 of emergency departments visits (2-4). These models are also designed to address the
16 biopsychosocial needs of patients and improve access, continuity and quality of care (5-9).
17 Various effects of these models have been reported for patients, for example : improved
18 access and reduced stigma, especially for individuals with mental health problems (6, 10,
19 11); enhanced chronic disease management (12); better treatment adherence and follow-up
20 (7, 13, 14); and improvement in symptoms or functioning (10, 13). Various positive
21 impacts on providers have also been reported, including: upskilling (7, 11, 15); better job
22 satisfaction (7, 8); and redistribution of workloads (8). However, although some
23 organisational and cost savings benefits by ensuring more efficient practices have been

1
2
3 24 reported (7), limited documentation of the cost-effectiveness of such models has been
4
5 25 carried out.
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7

8 26 In the early 2000s, in response to inconsistent primary care access, Canadian
9
10 27 provinces and territories began developing various initiatives (16, 17), one of these being
11
12 28 the creation of interprofessional primary care teams. The access to these teams remained
13
14 29 for the most part centred on the family physician. In Quebec, these teams are called
15
16 30 *Groupes de médecine familiale* [Family Medicine Groups (FMGs)], within some of which
17
18 31 physicians, nurses, and other health and social services professionals collaborate to deliver
19
20 32 health care based on contractual agreements with the provincial government (16). In
21
22 33 Quebec, some patients have a family doctor and others do not. Those who do have a family
23
24 34 physician must be registered with one physician and ideally attend this clinic. However, if
25
26 35 they are unable to get an appointment with their family physician, these patients can go to
27
28 36 a walk-in clinic. Patients who do not have family physicians have to use walk-in clinics
29
30 37 only. Although the FMGs are private clinics (albeit financed within Quebec's public
31
32 38 insurance system), they have direct collaborative links with the *Centres intégré*
33
34 39 *universitaire de santé et de services sociaux* (CIUSSS); many of the professionals who
35
36 40 work in the FMGs are employees of the CIUSSS. The Ministry for Health and Social
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38 41 Services (MSSS) establishes the rules for the distribution of professional and
39
40 42 administrative resources.
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43 43 In 2017, the Saint-Vallier FMG in Quebec City, situated within the CIUSSS-Capitale
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45 44 Nationale (CN) territory, commenced a five-year pilot project, titled *Archimède* (18).
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47 45 Threatened with closure in 2015 due to the retirement of its physicians and the difficulties
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49 46 of medical recruitment in this district, in which it has not always been easy to recruit
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3 47 healthcare personnel, the pilot project enabled the FMG to maintain its activities, and to
4
5 48 continue to meet the complex and diversified needs of the population. Due to the COVID-
6
7 49 19 pandemic, which necessitated significant changes in both how services could be
8
9 50 provided and staff availability, the pilot project period was extended by two years. This
10
11 51 project, which was developed in collaboration with relevant stakeholders (e.g., MSSS,
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13 52 CIUSSS-CN), seeks to implement a patient-centred model based on interprofessional care
14
15 53 and the optimal use of healthcare providers' scopes of practice. The *Archimède* project is
16
17 54 anticipated to improve access to primary care and, given the lower remuneration associated
18
19 55 with the services provided by nurses and other health and social services professionals
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21 56 compared to that of physicians, to reduce costs. Also, arising partly from a more efficient
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23 57 allocation of patients across the various professions within the clinic, the improved access
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25 58 is anticipated to reduce hospital utilization (e.g., emergency department visits), thus
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27 59 contributing to health system efficiency (1, 2).

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33 60 Our investigation aims to identify areas of improvement, formulate
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35 61 recommendations to improve the model's functioning, ensure its utility to stakeholders,
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37 62 and foster its sustainability and potential for scaling up. Specifically, this study seeks to
38
39 63 determine whether the *Archimède* model is efficient regarding patient and clinic outcomes
40
41 64 and teamwork (e.g., role optimisation) in relation to the resources invested. Our objectives
42
43 65 are: (1) to evaluate the impact of the *Archimède* model on operational performance at the
44
45 66 FMG level as well as user resource utilization at the public health system level; (2) to
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47 67 identify the factors that foster or impede the optimisation of professional roles,
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49 68 interprofessional teamwork, and patient-centredness, and (3) to document users'
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51 69 experience with the *Archimède* model.
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70 **Setting**

71 The St-Vallier FMG is in Quebec City's Saint-Sauveur district. This neighbourhood has
72 one of the highest rates of demographic fragility within the CIUSSS-CN territory (19).
73 Although the FMG serves a very broad clientele, a large proportion of its consultations are
74 conducted with users with chronic health problems or in vulnerable psychosocial
75 situations. The clinic's clientele is also characterized by a significant number of immigrants
76 and political refugees. Regarding the FMG's human resources, there are currently 27
77 employees, including six family physicians (FPs), four primary health care nurse
78 practitioners (PHCNPs), one mental health nurse practitioner (MHNP), five registered
79 nurses (RNs), six health and social services professionals (social worker, nutritionist,
80 physiotherapist, kinesiologist, psychologist, respiratory therapist), and five administrative
81 staff. All services are free of charge for the clinic's clients. Several elements have been put
82 in place to ensure the deployment and operation of the Archimède model. The use of the
83 right professional according to patients' health needs is facilitated by the use of referral
84 pathways by administrative personnel. The electronic medical record is used to facilitate
85 communication between professionals during the management of common patients. The
86 project manager, middle and senior managers of CIUSSS-CN provide ongoing support to
87 professionals to enhance interprofessional collaboration through training, personalised
88 coaching and frequent meetings. Visual aids for clarifying the roles of each are available
89 for professionals. The treatment of service users with complex problems is also facilitated
90 by joint consultations between professionals, or dyads, for example between RNs and
91 PHCNPs. The team also contributes to facilitating access to various outreach services,
92 including in community resources and the various services offered by the CIUSSS-CN.

93 **METHOD AND ANALYSIS**

94 **Conceptual framework**

95 This study is based on two frameworks : the *Quadruple Aim* framework (20), which
96 is the Canadian framework used for health care transformation research (21); and the
97 optimisation of professional scopes of practice (22). The Quadruple Aim framework is
98 designed to foster change in health care systems through the achievement of four goals :
99 improved population health outcomes; improved care and patient experience; improved
100 provider satisfaction; and lower costs/better value (20, 21). Recently, a fifth aim has been
101 added that recognizes health equity as an important outcome to reduce health disparities
102 and address social determinants of health (23, 24). In primary care, the development of
103 interprofessional teams is a key factor in improving quality to achieve these goals (2).

104 Regarding the optimisation of professional scopes of practice, the Canadian
105 Academy of Health Sciences (CAHS) identified factors of influence at the micro-, meso-
106 and macro-levels (22). Micro-level factors include professional hierarchies, professional
107 cultures, and communication among healthcare professionals. Meso-level factors include
108 communication across multiple care settings, professional protectionism, accountability,
109 and availability of evidence. Macro-level factors include legislation/regulations, payment
110 models, educational needs/requirements, and healthcare professional accountability.

111 **Design**

112 The research on evidence-based interventions frequently favours a stepwise
113 approach; one of the limitations of this approach is the significant time lag between the
114 development of the interventions and its implementation in the field (25). To address this

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3 115 issue, we are using a hybrid implementation approach, specifically the type 2 model, which
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5 116 permits simultaneous testing or piloting of implementation strategies during an
6
7 117 effectiveness trial (25). Specifically in this investigation, we will collect both quantitative
8
9 118 and qualitative data to assess the effectiveness and implementation of the Archimède
10
11 119 model, consistent with our specific objectives. The overall data collection process (March
12
13 120 2023-February 2025) is presented in Figure 1.
14

15
16
17 121 It is relevant to note that an advisory committee was established at the beginning of
18
19 122 the development of the project, the objectives of which are to better understand the broader
20
21 123 implementation context, monitor the progress of the research project, discuss
22
23 124 methodological and fieldwork aspects and the emerging findings, and develop strategies
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25 125 for knowledge transfer to maximize the impact in the health care system. This committee
26
27 126 is composed of members of the research team, and representatives from the management
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29 127 of the St-Vallier FMG, a user partner, and stakeholders from the CIUSSS-CN and the
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31 128 MSSS.
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37 130 *Insert Figure 1 here*

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39 131 **Figure 1. Data collection process over a year.**

40 132 **Quantitative approach**

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43 133 Our quantitative approach aims to evaluate the impact of the *Archimède* model on
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45 134 operational performance at the FMG level as well as user resource utilization at the public
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47 135 health system level. In so doing, we will document the lower costs/better value dimension
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49 136 of the Quadruple aim.
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3 137 Because this is a single-unit intervention study, to quantitatively assess the
4
5 138 performance of the *Archimède* model at the FMG level , we will use either or both synthetic
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8 139 control methods (26, 27) and one-sample generalized linear models. See Table 1 for a non-
9
10 140 exhaustive list of outcomes (e.g., *number of patient visits* and *vulnerability-weighted*
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12 141 *enrollments*), their components, and their sources. Synthetic control methods are quasi-
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14
15 142 experimental and are commonly used in the policy evaluation literature. In the case of our
16
17 143 study, this approach will consist of constructing a control counterfactual FMG from a
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19 144 weighted combination of other FMGs in the Quebec City region. On the other hand, one-
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21 145 sample generalized linear models, which will be informed by preliminary clustering
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23 146 analyses (such as principal component analysis) for control FMGs' selection, will allow
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25 147 for testing more streamlined outcome comparison either transversally or longitudinally.

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28 148 The database for the FMG-level analyses will be built from different operational and
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30 149 financial reports of all FMGs in the Quebec City region, including the St-Vallier FMG.
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33 150 These reports are routinely compiled by and will be provided to us by the MSSS and the
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35 151 CIUSSS. Although we plan to extract data from reports ranging from 2012 to 2022, these
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37 152 stakeholders could not confirm that every report would be available for that 10-year range.
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39 153 Since we need several years of pre-implementation data for the synthetic control approach
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41 154 to be feasible, the precise choice of methods for the analyses at the FMG level will depend
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43 155 on how far back the data collected by the MSSS and the CIUSSS go.
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Table 1. Non-exhaustive list of FMG-level variables of interest

Variables of interest	Components	Sources
Year		
Id		
Size		MSSS's financial report of FMGs
Type	Private vs public	MSSS's financial report of FMGs
Number of hours worked for each type of healthcare worker	E.g., Nurses, physical therapists, nutritionist, psychologists	CIUSSS's payroll report
Full time equivalents (FTEs) for each type of healthcare worker	E.g., Nurses, physical therapists, nutritionist, psychologists	CIUSSS's payroll report
Enrollments	Total unweighted number of patient enrollments	MSSS's 8B report
Weighted enrollments	Weights include vulnerability, disadvantage, births, etc.	MSSS's 8B report
Number of physicians		MSSS's 8B report
Patient attendance rate		MSSS's financial report of FMGs
Visits	Subdivided into in-person visits and telemedicine. Further subdivided into visits from patients enrolled at the FMG, patients enrolled in another FMG, and patients enrolled in no FMG.	MSSS's 8C report
Funding	Total amount of government funding in CAD	MSSS's financial report of FMGs

161 In addition, to evaluate patients' service utilization outside of the FMG, and thus
 162 better understand the broader impact of *Archimède* on the public health system, we will
 163 use both generalized linear mixed-effects models and propensity score matching methods
 164 (28) to compare patients enrolled in the St-Vallier clinic to those enrolled in other FMGs.
 165 The outcomes will include metrics such as *number of urgent care admission events* and
 166 *length of hospitalization*. Confounding factors will include variables such as *age, gender,*
 167 *and pre-existing health conditions*. The database for this portion of the study will be built

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168 and anonymized by the *Institut de la Statistique du Québec* (ISQ). A short list of some of
 169 the variables we will be querying, as well as details about the source database from which
 170 they will be extracted by the ISQ, are presented in Table 2.

171 *Table 2. Public health system-level example variables of interest*

Variables of interest	Components	Sources database	Source database specifications
ID	Unique patient identifier provided by the ISQ	FIPA	FIPA contains information about patients covered by the public health insurance
Age		FIPA	
Gender		FIPA	
Partial postal code	First three digits	FIPA	
Urgent care admission event		BDCU	BDCU contains information about urgent care admissions
Length of hospitalization		MED-ECHO	MED-ECHO contains information about hospitalizations
Service request event		I-CLSC	I-CLSC contains information about frontline common health and social services

172 *Note.* FIPA = Fichier d'inscription des personnes assurées, BDCU = Banque de données
 173 commune des urgences. MED-ECHO = Maintenance et exploitation des données pour
 174 l'étude de la clientèle hospitalières, I-CLSC = Système d'information sur la clientèle et
 175 les services des CSSS – mission CLSC. A list of all available variables that the ISQ can
 176 provide can be found at:
 177 <https://statistique.quebec.ca/research/#/donnees/administratives/sante>.

178 The data will subsequently be transferred to us via a secured remote connection service
 179 offered by the ISQ. The final database will comprise upwards of 60 variables for 14,000
 180 randomly selected and uniquely identified patients; 3,500 (25%) will be patients enrolled
 181 in the St-Vallier FMG and 10,500 (75%) will be patients enrolled in other FMGs. The
 182 experimental population sample of 3,500 patients is based on the lowest number of

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3 183 enrollments in the St-Vallier clinic between 2018 and 2022 (3,924 patients). The 25-75%
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5 184 split was chosen to maximize the likelihood of successfully building synthetic control
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8 185 patients from weighted averages of patients enrolled in other FMGs to match the
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10 186 experimental group. To be included, patients will have to be over 18 years of age and will
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12 187 need to have been enrolled in the same single FMG between 2018 and 2022.
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189 **Qualitative approach**

190 We will conduct the qualitative research portion of this study using an interpretive
21
22 191 description methodology (29). This approach is appropriate for gaining a rich
23
24 192 understanding of service providers', stakeholders', and patients' experiences with the
25
26 193 *Archimède* model, and their links with meso and macro level factors that influence the
27
28 194 optimisation of roles, interprofessional collaboration and patient-centredness. To collect
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30 195 this data, we will conduct individual in-depth semi-structured interviews, which will be
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32 196 appropriate given the potentially sensitive data that participants will share, to permit us to
33
34 197 capture deeper understanding of the subjective work and patient experience.
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199 **Population: eligibility criteria and sampling strategy**

200 We will use a purposive sample (30) of healthcare providers (FPs, PHCNPs, RNs,
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202 201 various health and social services professionals), administrative staff and managers
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204 202 working in the St-Vallier FMG; stakeholders involved in the *Archimède* model
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206 203 implementation; and patients receiving services at the FMG. All employees from the St-
207
208 204 Vallier FMG will be eligible. We will recruit up to five stakeholders who played a key role
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210 205 in the implementation of the *Archimède* model (e.g., representatives from the MSSS,

206 clinical advisor on interprofessional collaboration), depending on the advisory committee's
207 suggestions. The sample of patients will be based on the main health problems for which
208 patients seek care, which we will determine during recruitment. We aim to include patients
209 with health problems such as chronic diseases, mental health problems, and loss of
210 autonomy. We believe that 20 patients will be sufficient for providing rich data, although
211 the final number will be determined by the attainment of data saturation (31). Patients will
212 be required to be ≥ 18 years old, enrolled with a FP, and considered able to provide
213 informed consent by healthcare providers. All patients enrolled in the study will be asked
214 to complete a socio-demographic form to provide information on their socio-economic
215 status.

217 Recruitment strategy

218 Participation in the individual interviews will be voluntary for all participants. For
219 the recruitment of healthcare providers, managers and administrative staff, we will conduct
220 an information session at the Saint-Vallier FMG to present the study and distribute
221 information leaflets. We will also send an email to these personnel categories with detailed
222 information about the study to inform employees who cannot attend the meeting.
223 Employees who are interested in participating in the interviews will be invited to contact
224 us. In addition, we will identify key stakeholders with the help of the advisory committee
225 and contact them directly via email or telephone. Recruitment will be facilitated by close
226 links between the research team and the actors in the field established through other
227 research activities. In addition, various strategies will be deployed to maximise

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3 228 recruitment, for example, meetings of the research team at clinic meetings, reminder
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5 229 emails, and participation of some members of the research team on strategic committees.
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8 230 For patient recruitment, we will ask healthcare providers to provide them with
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10 231 information leaflets. We will also leave leaflets in the waiting rooms of the FMG. These
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12 232 leaflets, which will inform patients about the entire study so that they have the choice to
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14 233 decline participation, will include a consent form and will inform patients about the \$30 to
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16 234 compensate participants for their time. Patients will have the option to contact the research
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18 235 team directly or leave their contact information in an online form if they are interested in
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20 236 participating in the interviews.
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26 238 Interviews

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29 239 The interviews will be conducted in participants' preferred setting (i.e., home, research
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31 240 centre, FMG, videoconference), albeit adhering as necessary to current public health
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33 241 guidelines. The individual interview guides, developed in collaboration with the advisory
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35 242 committee, capture the following elements: improved care and patient experience, and
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37 243 improved provider satisfaction (Quadruple aim framework); the micro, meso and macro
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39 244 dimension of the optimisation of scope of practice. See Table 3 for the specific interview
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41 245 themes. These interview guides will evolve iteratively in that analyses of the results of the
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43 246 first interviews will inform questions during subsequent interviews. The interviews will be
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45 247 audio-taped with participants' consent.
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Table 3. Interview themes

	Themes	Conceptual frameworks
Employees	Work organization and motives to work in the FMG Level of commitment to work in the FMG Experience and satisfaction with the new FMG's work organization	Quadruple aim: improved provider satisfaction
	Impact of <i>Archimède</i> on professional role and workload Interdisciplinary teamwork dynamics Obstacles to the implementation of the model (micro, meso, macro)	Optimisation of scope of practice
Stakeholders	Role in the implementation process Context of emergence and the implementation process Operation of the FMG Assessment of the <i>Archimède</i> model	Optimisation of scope of practice
Patients	Reasons for seeking care and healthcare providers seen Impact of <i>Archimède</i> on care and ability to get involved in one's own care (Saint-Vallier clinic) Satisfaction with care Likes and dislikes about the FMG's work organization Participation in care decision-making	Quadruple aim: improved care and patient experience

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253 Data analysis

254 Our analysis of the interview data will be facilitated by using Nvivo software (32).
 255 Data from professionals will be aggregated in such a way that each group is made up of a
 256 sufficiently large number of participants to preserve their anonymity. We will follow the
 257 stages of thematic analysis: initial coding according to our predefined interview themes
 258 and those that emerge during the analysis; categorization; consolidation of categories;
 259 linking of categories; and data integration and modeling (33). We will analyze data in light
 260 of factors that optimize scope of practice, at the micro, meso, and macro levels, as defined

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3 261 by the CAHS (22). We will give particular attention to the collaboration between healthcare
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5 262 providers, and collaboration between healthcare providers and administrative staff.
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8 263 Furthermore, we will characterize interactions between the micro, meso and macro levels.
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10 264 We will prepare comprehensive summaries of our results and discuss them with the
11
12 265 advisory committee group to enhance our interpretation of the results. Using the subsequent
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14 266 findings, we will (1) formulate recommendations for optimizing interprofessional
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16 267 collaborative and patient-centred practices and the role of healthcare providers, and (2)
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18 268 highlight the challenges and potential viable solutions related to the sustainability of the
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20 269 *Archimède* project and its potential scaling up in other settings.
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26 271 **PATIENT AND PUBLIC INVOLVEMENT**

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29 272 Patients and/or the public were involved in the design, or conduct, or reporting, or
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31 273 dissemination plans of this research. The user-partner played a key role from the very
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33 274 beginning of the pilot project through his participation in several meetings of the advisory
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35 275 committee. The governance of the project has been designed to ensure that user-partners
36
37 276 are involved in the decision-making processes, which will allow the advisory committee to
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39 277 remain responsive to user concerns throughout the implementation of the project. Refer to
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41 278 the Methods and analysis section for further details.
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47 280 **ETHICS AND DISSEMINATION**

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50 281 This project respects the ethics, integrity and responsible research conduct standards
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52 282 defined by the Fonds de recherche du Québec (FRQS) and the CIUSSS-CN. It has received
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54 283 ethical approval from the regional health organization with which the researchers are
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3 284 affiliated (# 2019-1503). Regarding ethical considerations specific to the participants in the
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5 285 interviews, we specified all their rights in accordance with the rules of the sectoral research
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7 286 ethics committee (CER-S) in population health and primary care (e.g., the right of
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9 287 participants to withdraw from the study at any time and to refuse to answer certain
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11 288 questions; the confidentiality obligations of the researchers; the confidentiality obligations
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13 289 of the focus group participants). The results of the investigation will be presented to the
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15 290 stakeholders involved in the advisory committee and at several scientific conferences.
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17 291 Manuscripts will be submitted to peer-reviewed journals.
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24 293 **DISCUSSION**

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26 294 Interprofessional teams are increasingly being established throughout Canada and
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28 295 elsewhere to improve the access, continuity and quality of services provided to individuals
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30 296 living with complex health problems (e.g., chronic diseases; mental health challenges;
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32 297 comorbidities) (6, 10, 15, 34-36). A variety of models exist, characterised both by the
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34 298 organization and degree of interprofessional collaboration, as well as the type of clients
35
36 299 served (37-39).
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40 300 This project will advance the understanding of the effects of a team-based model of
41
42 301 care within a FMG that is in a disadvantaged area and whose clientele presents complex
43
44 302 biopsychosocial problems. Various interprofessional primary care models have been
45
46 303 developed that are designed to address complex health problems in specific populations
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48 304 identified as vulnerable, for example, older adults, (40), individuals with HIV (41), and
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50 305 veterans (42). However, these models have frequently been presented as intervention
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52 306 programs composed of a predefined interprofessional continuum of care, a care manager,
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3 307 and/or case discussions. In comparison, the *Archimède* model is based on a uniform
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5 308 orientation to the optimisation of professional roles (seeing the right professional at the
6
7 309 right time), and the use of predefined pathways enacted by administrative staff when
8
9 310 making appointments. Furthermore, in this model, referrals are made between
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11 311 professionals, and the continuum of care is facilitated by having an interprofessional team
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13 312 in the same location. Access to this interprofessional approach is also facilitated because
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15 313 no fee is charged. In addition, compared to other reported primary care models (38, 43,
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17 314 44), there is no preselection of patients, with all patients being eligible for the appropriate
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19 315 professional services. Our research project seeks to understand the experience of users
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21 316 attending a clinic based on this model to assess the relevance of this model for this
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23 317 population.

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28 318 One of the strengths of our research includes the measure of efficiency with respect
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30 319 to operational performance at the FMG level and the use of health network resources (e.g.,
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32 320 emergency room visits) by *Archimède* users. This study will make an important
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34 321 contribution to the understanding of the efficiency of primary care models, thus responding
35
36 322 to the need to better evaluate primary care reforms (16, 36).

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40 323 The originality of our research lies in our focus on the interrelations between the
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42 324 micro, meso and macro levels to better identify the elements that facilitate or hinder the
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44 325 deployment of the model and the optimisation of interprofessional collaboration.
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46 326 Understanding the context of implementation, particularly in relation to the particularity of
47
48 327 the dual public and private organisational structures, is an important element in this
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50 328 research project. That is, although the model is deployed in a private clinic, it is publicly
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52 329 funded. As well, some staff are paid by the public health organization. Thus, our approach
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3 330 takes into account: 1) structural issues related to health policies in primary care, types of
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5 331 funding, and resource management; 2) issues related to the organization of the clinic (e.g.,
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7 332 dynamics of interprofessional collaboration and management practices); and 3) micro-level
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9 333 issues related to the subjective work experience of professionals and service users'
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11 334 experiences (22). Although our research evaluates only one FMG, the findings from this
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13 335 study could be relevant not only in Quebec but also for other jurisdictions looking to
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15 336 develop interprofessional primary care models that address the social determinants of
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17 337 health, and that optimize the use of health and social care providers' respective scopes of
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19 338 practice.
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26 340 Regarding the limitations of our investigation, there is a potential lack of generalisation in
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28 341 studying only one FMG. Nevertheless, conducting this project will permit us to both test
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30 342 our methodology to quantitatively assess the performance of the FMG, and to explore in
31
32 343 depth the influences of the implementation context on the deployment of the project. A
33
34 344 potential limitation of the type 2 effectiveness-implementation hybrid study approach
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36 345 concerns the difficulties that can arise if there is a problem in the implementation of the
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38 346 Archimède model in the FMG clinic with respect to the optimisation of professional roles
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40 347 and the close collaboration of the professionals; this difficulty can compromise the
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42 348 effectiveness trial field (25). In our study, the involvement of multiple actors in the
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44 349 advisory committee should help to mitigate this limitation by the fact that they will be
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46 350 informed quickly of the results along the way and by their ability to intervene directly
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48 351 within the team to make the necessary adjustments. A further possible limitation concerns
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50 352 the potential for generalisation to other areas with different demographic profiles, given
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3 353 that the FMG under study is in a disadvantaged area. However, it is unlikely that all patients
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5 354 attending the FMG are in a vulnerable situation; the use of a socio-demographic form will
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8 355 allow to establish a socioeconomic profile of the patients interviewed.
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11 12 357 **FUNDING STATEMENT**

13
14
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16
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18
19 360 number: NA
20
21

22 361 23 24 362 **AUTHORS CONTRIBUTION**

- 25
26
27 363 • Substantial contributions to the conception or design of the work (NC, YF, AF,
28
29 364 SCG, ML, MI, AD, J-LD, EJ and SB).
30
31 365 • Drafting the work or revising it critically for important intellectual content (NC,
32
33 366 YF, AF, SCG, ML, MI, AD, J-LD, EJ and SB).
34
35 367 • Final approval of the version to be published (NC, YF, AF, SCG, ML, MI, AD, J-
36
37 368 LD, EJ and SB).
38
39 369 • Agreement to be accountable for all aspects of the work in ensuring that questions
40
41 370 related to the accuracy or integrity of any part of the work are appropriately
42
43 371 investigated and resolved (NC, YF, AF, SCG, ML, MI, AD, J-LD, EJ and SB).
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50 373 **COMPETING INTERESTS**

51
52 374 None.
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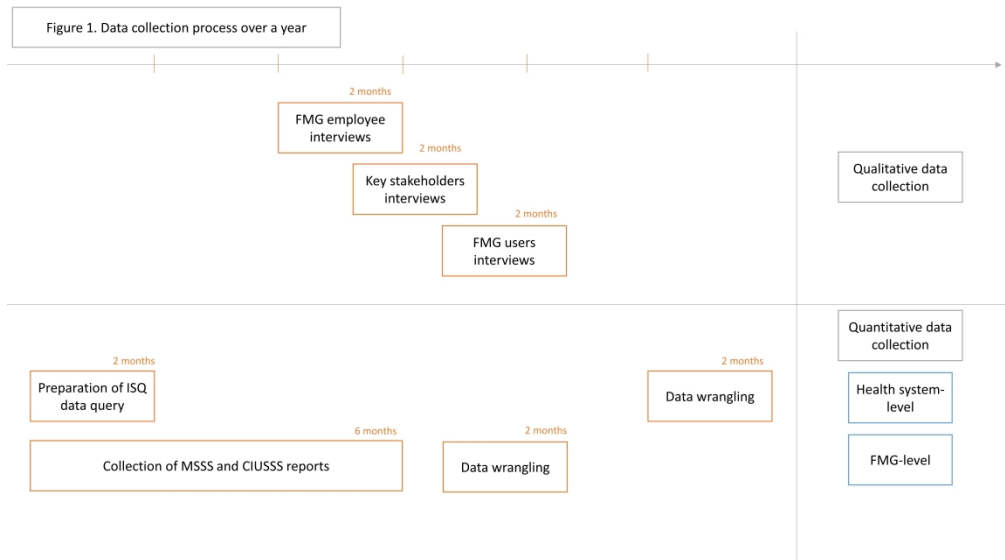
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**Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015**

Text Section and Item Name	Section or Item Description	
Notes to authors	<ul style="list-style-type: none"> • The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript. 	<p align="center">As you review the manuscript, place a checkmark in this column for each SQUIRE item that is appropriately addressed in the manuscript. Remember that not every item is necessary in every manuscript.</p>
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	p.1
2. Abstract	<ol style="list-style-type: none"> a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions 	pp.2-3

Introduction	<i>Why did you start?</i>	
3. Problem Description	Nature and significance of the local problem	p.5-6
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	p.5-6
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	p.8
6. Specific aims	Purpose of the project and of this report	p.7
Methods	<i>What did you do?</i>	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	p.7
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	a) p.7 b) p.7
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	a) p. 9
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	pp.10-13 (quantitative) pp. 13-15 (qualitative)
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	pp. 10-13 (quantitative) p.16 (qualitative)
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	p.17

Results	<i>What did you find?</i>	
13. Results	<ul style="list-style-type: none"> a. Initial steps of the intervention(s) and their evolution over time (<i>e.g.</i>, time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data 	Not appropriate; protocol article
Discussion	<i>What does it mean?</i>	
14. Summary	<ul style="list-style-type: none"> a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project 	<ul style="list-style-type: none"> a) N/A b) p.4 and pp.18-19
15. Interpretation	<ul style="list-style-type: none"> a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs 	N/A (protocol article)
16. Limitations	<ul style="list-style-type: none"> a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations 	pp.19-20
17. Conclusions	<ul style="list-style-type: none"> a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps 	pp.17-20
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	p.20

BMJ Open

An evaluation of an interprofessional primary healthcare team as a new model of primary care in Quebec: a protocol for a type 2 effectiveness-implementation hybrid study

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Manuscripts

Title page

An evaluation of an interprofessional primary healthcare team as a new model of primary care in Quebec: a protocol for a type 2 effectiveness-implementation hybrid study

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23
24 **Word count: 4140**
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27 **Keywords**

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29 Primary care, interprofessional team, advanced practice nursing, access, person-
30 centredness, efficiency
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34 **Abstract**

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37 **Introduction:** One Family Medicine Group (FMG) in Quebec has commenced a
38 five-year pilot project, which is herein referred to as the *Archimède* model, to implement a
39 patient-centred model based on interprofessional care and the optimal use of healthcare
40 providers' practice scopes. A research project will be conducted to: (1) assess this model's
41 effect on the FMG's operational performance, and its users' resource utilization at the
42 public health system level; (2) investigate its optimisation with respect to professional
43 roles, interprofessional teamwork, and patient-centredness; and (3) document users'
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3 experience with the model. The aim of this article is to describe the protocol that will be
4
5 used for this research.
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8 **Methods and analysis:** A hybrid implementation approach (type 2 model) will be
9
10 used. We will collect both quantitative and qualitative data. Regarding the quantitative
11
12 dimension, and because this is a single-unit intervention study, we will use either or both
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14 synthetic control methods and one-sample generalized linear models for analyses at the
15
16 FMG level. To evaluate the broader impact of *Archimède* on the public health system, we
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18 will use mixed-effects models and propensity score matching methods. Regarding the
19
20 qualitative research dimension, using an interpretative descriptive approach, we will
21
22 document users' experience and identify the factors that optimize professional scopes of
23
24 practice, collaborative practices, and patient-centredness. We will conduct individual in-
25
26 depth semi-structured interviews with healthcare providers, administrative staff,
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28 stakeholders involved in the *Archimède* model implementation, and patients.
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33 **Ethics and dissemination:** This study was approved by the Ethics Committee of the
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35 Sectoral Research in Population Health and Primary Care of the Centre intégré
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37 universitaire de santé et de services sociaux de la Capitale-Nationale (#2019-1503). The
38
39 results of the investigation will be presented to the stakeholders involved in the advisory
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41 committees and at several scientific conferences. Manuscripts will be submitted to peer-
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43 reviewed journals.
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Strengths and limitations of the study

- The measure of efficiency with respect to operational performance at the FMG level and the use of health network resources (e.g., emergency room visits) by Archimède users is a strength.
- The study's inclusion of the analysis of the interrelations between the micro, meso and macro levels to better identify the elements that facilitate or hinder the deployment of the Archimède model and the optimisation of professional roles and interprofessional collaboration is a strength.
- The possible lack of generalisation associated with studying only one FMG will be mitigated by the use of a methodology to quantitatively assess the performance of the FMG, and an in-depth exploration of the influences of the implementation context on the deployment of the project.
- The potential limitations of the Type 2 effectiveness-implementation hybrid study will be mitigated by the involvement of multiple actors on the advisory committee (e.g., able to be rapidly updated about the results; ability to intervene directly to make necessary adjustments).

INTRODUCTION

Context of the study

Primary care, which is patients' first point of contact with the health care system (1), provides early care for health problems, chronic disease management, and preventive services. Various models of interprofessional primary care are being created to address human resource shortages in health systems, control health care costs, and reduce overuse of emergency departments visits (2-4). These models are also designed to address the biopsychosocial needs of patients and improve access, continuity and quality of care (5-9). Various effects of these models have been reported for patients, for example : improved access and reduced stigma, especially for individuals with mental health problems (6, 10, 11); enhanced chronic disease management (12); better treatment adherence and follow-up (7, 13, 14); and improvement in symptoms or functioning (10, 13). Various positive impacts on providers have also been reported, including: upskilling (7, 11, 15); better job satisfaction (7, 8); and redistribution of workloads (8). However, although some organisational and cost savings benefits by ensuring more efficient practices have been reported (7), limited documentation of the cost-effectiveness of such models has been carried out.

In the early 2000s, in response to inconsistent primary care access, Canadian provinces and territories began developing various initiatives (16, 17), one of these being the creation of interprofessional primary care teams. The access to these teams remained for the most part centred on the family physician. In Quebec, these teams are called *Groupes de médecine familiale* [Family Medicine Groups (FMGs)], within some of which physicians, nurses, and other health and social services professionals collaborate to deliver

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2
3 health care based on contractual agreements with the provincial government (16). In
4
5 Quebec, some patients have a family doctor and others do not. Those who do have a family
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7 physician must be registered with one physician and ideally attend this clinic. However, if
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9 they are unable to get an appointment with their family physician, these patients can go to
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11 a walk-in clinic. Patients who do not have family physicians have to use walk-in clinics
12
13 only. Although the FMGs are private clinics (albeit financed within Quebec's public
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15 insurance system), they have direct collaborative links with the *Centres intégré*
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17 *universitaire de santé et de services sociaux (CIUSSS)*; many of the professionals who
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19 work in the FMGs are employees of the CIUSSS. The Ministry for Health and Social
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21 Services (MSSS) establishes the rules for the distribution of professional and
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23 administrative resources.
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29 In 2017, the Saint-Vallier FMG in Quebec City, situated within the CIUSSS-Capitale
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31 Nationale (CN) territory, commenced a five-year pilot project, titled *Archimède (18)*.
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33 Threatened with closure in 2015 due to the retirement of its physicians and the difficulties
34
35 of medical recruitment in this district, in which it has not always been easy to recruit
36
37 healthcare personnel, the pilot project enabled the FMG to maintain its activities, and to
38
39 continue to meet the complex and diversified needs of the population. Due to the COVID-
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41 19 pandemic, which necessitated significant changes in both how services could be
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43 provided and staff availability, the pilot project period was extended by two years. This
44
45 project, which was developed in collaboration with relevant stakeholders (e.g., MSSS,
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47 CIUSSS-CN), seeks to implement a patient-centred model based on interprofessional care
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49 and the optimal use of healthcare providers' scopes of practice.
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3 This model differs from the practices in many medical clinics in the sense that access
4 is not automatically through a family physician. Composed of several health and social
5 services professionals, the Archimède model works on the principle of the inverted
6 pyramid. That is, there are more nurses (primary health care nurse practitioners and
7 registered nurses) than physicians, and the clinic relies on the optimisation of professional
8 roles through the close collaborations between health and social professionals.
9

10
11 The *Archimède* project is anticipated to improve access to primary care and, given
12 the lower remuneration associated with the services provided by nurses and other health
13 and social services professionals compared to that of physicians, to reduce costs. Also,
14 arising partly from a more efficient allocation of patients across the various professions
15 within the clinic, the improved access is anticipated to reduce hospital utilization (e.g.,
16 emergency department visits), thus contributing to health system efficiency and improved
17 population health outcomes (1, 2).
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19
20 The aim of the protocol presented in this article is to evaluate the implementation of
21 this new model of primary care. Our investigation seeks to identify areas of improvement,
22 formulate recommendations to improve the model's functioning, ensure its utility to
23 stakeholders, and foster its sustainability and potential for scaling up. Specifically, this
24 study seeks to determine whether the *Archimède* model is efficient regarding patient and
25 clinic outcomes and teamwork (e.g., role optimisation) in relation to the resources invested.
26 Our objectives are: (1) to evaluate the impact of the *Archimède* model on operational
27 performance at the FMG level as well as user resource utilization at the public health
28 system level; (2) to identify the factors that foster or impede the optimisation of
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3 professional roles, interprofessional teamwork, and patient-centredness, and (3) to
4 document users' experience with the *Archimède* model.
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7 8 **Setting** 9

10 The St-Vallier FMG is in Quebec City's Saint-Sauveur district. This neighbourhood has
11 one of the highest rates of demographic fragility within the CIUSSS-CN territory (19).
12 Although the FMG serves a very broad clientele, a large proportion of its consultations are
13 conducted with users with chronic health problems or in vulnerable psychosocial
14 situations. The clinic's clientele is also characterized by a significant number of immigrants
15 and political refugees. Regarding the FMG's human resources, there are currently 27
16 employees, including six family physicians (FPs), four primary health care nurse
17 practitioners (PHCNPs), one mental health nurse practitioner (MHNP), five registered
18 nurses (RNs), six health and social services professionals (social worker, nutritionist,
19 physiotherapist, kinesiologist, psychologist, respiratory therapist), and five administrative
20 staff. All services are free of charge for the clinic's clients. Several elements have been put
21 in place to ensure the deployment and operation of the Archimède model. The use of the
22 right professional according to patients' health needs is facilitated by the use of referral
23 pathways by administrative personnel. The electronic medical record is used to facilitate
24 communication between professionals during the management of common patients. The
25 project manager, middle and senior managers of CIUSSS-CN provide ongoing support to
26 professionals to enhance interprofessional collaboration through training, personalised
27 coaching and frequent meetings. Visual aids for clarifying the roles of each are available
28 for professionals. The treatment of service users with complex problems is also facilitated
29 by joint consultations between professionals, or dyads, for example between RNs and
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3 PHCNPs. The team also contributes to facilitating access to various outreach services,
4 including in community resources and the various services offered by the CIUSSS-CN.
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7 8 **METHOD AND ANALYSIS**

9 10 **Conceptual framework**

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12
13 This study is based on two frameworks : the *Quadruple Aim* framework (20), which
14 is the Canadian framework used for health care transformation research (21); and the
15 optimisation of professional scopes of practice (22). The Quadruple Aim framework is
16 designed to foster change in health care systems through the achievement of four goals :
17 improved population health outcomes; improved care and patient experience; improved
18 provider satisfaction; and lower costs/better value (20, 21). Recently, a fifth aim has been
19 added that recognizes health equity as an important outcome to reduce health disparities
20 and address social determinants of health (23, 24). In primary care, the development of
21 interprofessional teams is a key factor in improving quality to achieve these goals (2).
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34 Regarding the optimisation of professional scopes of practice, the Canadian
35 Academy of Health Sciences (CAHS) identified factors of influence at the micro-, meso-
36 and macro-levels (22). Micro-level factors include professional hierarchies, professional
37 cultures, and communication among healthcare professionals. Meso-level factors include
38 communication across multiple care settings, professional protectionism, accountability,
39 and availability of evidence. Macro-level factors include legislation/regulations, payment
40 models, educational needs/requirements, and healthcare professional accountability.
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Design

The research on evidence-based interventions frequently favours a stepwise approach; one of the limitations of this approach is the significant time lag between the development of the interventions and its implementation in the field (25). To address this issue, we are using a hybrid implementation approach, specifically the type 2 model, which permits simultaneous testing or piloting of implementation strategies during an effectiveness trial (25). Specifically in this investigation, we will collect both quantitative and qualitative data to assess the effectiveness and implementation of the Archimède model, consistent with our specific objectives. See Table 1 for an overview of the type of data to be collected for the different outcomes. The overall data collection process (March 2023-February 2025) is presented in Figure 1.

Table 1 Overview of targeted outcomes and data types

Type of outcomes	Framework	Target population	Data type
Effectiveness	Quadruple aim: improved population health outcomes	Patients	Quantitative Qualitative
	Quadruple aim: improved care and patient experience	Patients	Qualitative
	Quadruple aim: improved provider satisfaction	FMG' employees (healthcare providers and administrative staff)	Qualitative
Implementation	Optimization of scopes of practice	FMG' employees (healthcare providers and administrative staff) Managers	Qualitative
	Quadruple aim: lower costs/better value	FMG/ public health system	Quantitative

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6 It is relevant to note that an advisory committee was established at the beginning of
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8 the development of the project, the objectives of which are to better understand the broader
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10 implementation context, monitor the progress of the research project, discuss
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12 methodological and fieldwork aspects and the emerging findings, and develop strategies
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14 for knowledge transfer to maximize the impact in the health care system. This committee
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16 is composed of members of the research team, and representatives from the management
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18 of the St-Vallier FMG, a user partner, and stakeholders from the CIUSSS-CN and the
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20 MSSS.
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26 *Insert Figure 1 here*
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28 **Figure 1. Data collection process over a year.**
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30 **Quantitative approach** 31

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34 Our quantitative approach aims to evaluate the impact of the *Archimède* model on
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36 operational performance at the FMG level as well as user resource utilization at the public
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38 health system level. In so doing, we will document the lower costs/better value dimension
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40 of the Quadruple aim.
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45 Because this is a single-unit intervention study, to quantitatively assess the
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47 performance of the *Archimède* model at the FMG level, we will use either or both synthetic
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49 control methods (26, 27) and one-sample generalized linear models. See Table 2 for a non-
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51 exhaustive list of outcomes (e.g., *number of patient visits* and *vulnerability-weighted*
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53 *enrollments*), their components, and their sources. Synthetic control methods are quasi-
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experimental and are commonly used in the policy evaluation literature. In the case of our study, this approach will consist of constructing a control counterfactual FMG from a weighted combination of other FMGs in the Quebec City region. On the other hand, one-sample generalized linear models, which will be informed by preliminary clustering analyses (such as principal component analysis) for control FMGs' selection, will allow for testing more streamlined outcome comparison either transversally or longitudinally.

The database for the FMG-level analyses will be built from different operational and financial reports of all FMGs in the Quebec City region, including the St-Vallier FMG. These reports are routinely compiled by and will be provided to us by the MSSS and the CIUSSS. Although we plan to extract data from reports ranging from 2012 to 2022, these stakeholders could not confirm that every report would be available for that 10-year range. Since we need several years of pre-implementation data for the synthetic control approach to be feasible, the precise choice of methods for the analyses at the FMG level will depend on how far back the data collected by the MSSS and the CIUSSS go.

Table 2. Non-exhaustive list of FMG-level variables of interest

Variables of interest	Components	Sources
Year		
Id		
Size		MSSS's financial report of FMGs
Type	Private vs public	MSSS's financial report of FMGs
Number of hours worked for each type of healthcare worker	E.g., Nurses, physical therapists, nutritionist, psychologists	CIUSSS's payroll report

Full time equivalents (FTEs) for each type of healthcare worker	E.g., Nurses, physical therapists, nutritionist, psychologists	CIUSSS's payroll report
Enrollments	Total unweighted number of patient enrollments	MSSS's 8B report
Weighted enrollments	Weights include vulnerability, disadvantage, births, etc.	MSSS's 8B report
Number of physicians		MSSS's 8B report
Patient attendance rate		MSSS's financial report of FMGs
Visits	Subdivided into in-person visits and telemedicine. Further subdivided into visits from patients enrolled at the FMG, patients enrolled in another FMG, and patients enrolled in no FMG.	MSSS's 8C report
Funding	Total amount of government funding in CAD	MSSS's financial report of FMGs

In addition, to evaluate patients' service utilization outside of the FMG, and thus better understand the broader impact of *Archimède* on the public health system, we will use both generalized linear mixed-effects models and propensity score matching methods (28) to compare patients enrolled in the St-Vallier clinic to those enrolled in other FMGs. The outcomes will include metrics such as *number of urgent care admission events* and *length of hospitalization*. Confounding factors will include variables such as *age*, *gender*, and pre-existing health conditions. The database for this portion of the study will be built and anonymized by the *Institut de la Statistique du Québec* (ISQ). A short list of some of the variables we will be querying, as well as details about the source database from which they will be extracted by the ISQ, are presented in Table 3.

Table 3. Public health system-level example variables of interest

Variables of interest	Components	Sources database	Source database specifications
ID	Unique patient identifier provided by the ISQ	FIPA	FIPA contains information about patients covered by the public health insurance
Age		FIPA	
Gender		FIPA	
Partial postal code	First three digits	FIPA	
Urgent care admission event		BDCU	BDCU contains information about urgent care admissions
Length of hospitalization		MED-ECHO	MED-ECHO contains information about hospitalizations
Service request event		I-CLSC	I-CLSC contains information about frontline common health and social services

Note. FIPA = Fichier d'inscription des personnes assurées, BDCU = Banque de données commune des urgences. MED-ECHO = Maintenance et exploitation des données pour l'étude de la clientèle hospitalières, I-CLSC = Système d'information sur la clientèle et les services des CSSS – mission CLSC. A list of all available variables that the ISQ can provide can be found at:

<https://statistique.quebec.ca/research/#/donnees/administratives/sante>.

The data will subsequently be transferred to us via a secured remote connection service offered by the ISQ. The final database will comprise upwards of 60 variables for 14,000 randomly selected and uniquely identified patients; 3,500 (25%) will be patients enrolled in the St-Vallier FMG and 10,500 (75%) will be patients enrolled in other FMGs. The experimental population sample of 3,500 patients is based on the lowest number of enrollments in the St-Vallier clinic between 2018 and 2022 (3,924 patients). The 25-75% split was chosen to maximize the likelihood of successfully building synthetic control patients from weighted averages of patients enrolled in other FMGs to match the

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3 experimental group. To be included, patients will have to be over 18 years of age and will
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5 need to have been enrolled in the same single FMG between 2018 and 2022.
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10 **Qualitative approach**

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12 We will conduct the qualitative research portion of this study using an interpretive
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14 description methodology (29). This approach is appropriate for gaining a rich
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16 understanding of service providers', stakeholders', and patients' experiences with the
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18 *Archimède* model, and their links with meso and macro level factors that influence the
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20 optimisation of roles, interprofessional collaboration and patient-centredness. To collect
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22 this data, we will conduct individual in-depth semi-structured interviews, which will be
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24 appropriate given the potentially sensitive data that participants will share, to permit us to
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26 capture deeper understanding of the subjective work and patient experience.
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33 **Population: eligibility criteria and sampling strategy**

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35 We will use a purposive sample (30) of healthcare providers (FPs, PHCNPs, RNs,
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37 various health and social services professionals), administrative staff and managers
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39 working in the St-Vallier FMG; stakeholders involved in the *Archimède* model
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41 implementation; and patients receiving services at the FMG. All employees from the St-
42
43 Vallier FMG will be eligible. We will recruit up to five stakeholders who played a key role
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45 in the implementation of the *Archimède* model (e.g., representatives from the MSSS,
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47 clinical advisor on interprofessional collaboration), depending on the advisory committee's
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49 suggestions. The sample of patients will be based on the main health problems for which
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51 patients seek care, which we will determine during recruitment. We aim to include patients
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3 with health problems such as chronic diseases, mental health problems, and loss of
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5 autonomy. We believe that 20 patients will be sufficient for providing rich data, although
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7 the final number will be determined by the attainment of data saturation (31). Patients will
8
9 be required to be ≥ 18 years old, enrolled with a FP, and considered able to provide
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11 informed consent by healthcare providers. All patients enrolled in the study will be asked
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13 to complete a socio-demographic form to provide information on their socio-economic
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15 status.
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22 Recruitment strategy

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24 Participation in the individual interviews will be voluntary for all participants. For
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26 the recruitment of healthcare providers, managers and administrative staff, we will conduct
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28 an information session at the Saint-Vallier FMG to present the study and distribute
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30 information leaflets. We will also send an email to these personnel categories with detailed
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32 information about the study to inform employees who cannot attend the meeting.
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34 Employees who are interested in participating in the interviews will be invited to contact
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36 us. In addition, we will identify key stakeholders with the help of the advisory committee
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38 and contact them directly via email or telephone. Recruitment will be facilitated by close
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40 links between the research team and the actors in the field established through other
41
42 research activities. In addition, various strategies will be deployed to maximise recruitment,
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44 for example, meetings of the research team at clinic meetings, reminder emails, and
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46 participation of some members of the research team on strategic committees.
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52 For patient recruitment, we will ask healthcare providers to provide them with
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54 information leaflets. We will also leave leaflets in the waiting rooms of the FMG. These
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leaflets, which will inform patients about the entire study so that they have the choice to decline participation, will include a consent form and will inform patients about the \$30 to compensate participants for their time. Patients will have the option to contact the research team directly or leave their contact information in an online form if they are interested in participating in the interviews.

Interviews

The interviews will be conducted in participants' preferred setting (i.e., home, research centre, FMG, videoconference), albeit adhering as necessary to current public health guidelines. The individual interview guides, developed in collaboration with the advisory committee, capture the following elements: improved care and patient experience, and improved provider satisfaction (Quadruple aim framework); the micro, meso and macro dimension of the optimisation of scope of practice. See Table 4 for the specific interview themes. These interview guides will evolve iteratively in that analyses of the results of the first interviews will inform questions during subsequent interviews. The interviews will be audio-taped with participants' consent.

Table 4. Interview themes

	Themes
Employees	Work organization and motives to work in the FMG Level of commitment to work in the FMG Experience and satisfaction with the new FMG's work organization
	Impact of <i>Archimède</i> on professional role and workload Interdisciplinary teamwork dynamics Obstacles to the implementation of the model (micro, meso, macro)
Stakeholders	Role in the implementation process

	Context of emergence and the implementation process Operation of the FMG Assessment of the <i>Archimède</i> model
Patients	Reasons for seeking care and healthcare providers seen Impact of <i>Archimède</i> on care and ability to get involved in one's own care (Saint-Vallier clinic) Satisfaction with care Likes and dislikes about the FMG's work organization Participation in care decision-making

Data analysis

Our analysis of the interview data will be facilitated by using Nvivo software (32). Data from professionals will be aggregated in such a way that each group is made up of a sufficiently large number of participants to preserve their anonymity. We will follow the stages of thematic analysis: initial coding according to our predefined interview themes and those that emerge during the analysis; categorization; consolidation of categories; linking of categories; and data integration and modeling (33). We will analyze data in light of factors that optimize scope of practice, at the micro, meso, and macro levels, as defined by the CAHS (22). We will give particular attention to the collaboration between healthcare providers, and collaboration between healthcare providers and administrative staff. Furthermore, we will characterize interactions between the micro, meso and macro levels. We will prepare comprehensive summaries of our results and discuss them with the advisory committee group to enhance our interpretation of the results. Using the subsequent findings, we will (1) formulate recommendations for optimizing interprofessional collaborative and patient-centred practices and the role of healthcare providers, and (2) highlight the challenges and potential viable solutions related to the sustainability of the *Archimède* project and its potential scaling up in other settings.

PATIENT AND PUBLIC INVOLVEMENT

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. The user-partner played a key role from the very beginning of the pilot project through his participation in several meetings of the advisory committee. The governance of the project has been designed to ensure that user-partners are involved in the decision-making processes, which will allow the advisory committee to remain responsive to user concerns throughout the implementation of the project. Refer to the Methods and analysis section for further details.

ETHICS AND DISSEMINATION

This project respects the ethics, integrity and responsible research conduct standards defined by the Fonds de recherche du Québec (FRQS) and the CIUSSS-CN. It has received ethical approval from the regional health organization with which the researchers are affiliated (# 2019-1503). Regarding ethical considerations specific to the participants in the interviews, we specified all their rights in accordance with the rules of the sectoral research ethics committee (CER-S) in population health and primary care (e.g., the right of participants to withdraw from the study at any time and to refuse to answer certain questions; the confidentiality obligations of the researchers; the confidentiality obligations of the focus group participants). The results of the investigation will be presented to the stakeholders involved in the advisory committee and at several scientific conferences. Manuscripts will be submitted to peer-reviewed journals.

DISCUSSION

Interprofessional teams are increasingly being established throughout Canada and elsewhere to improve the access, continuity and quality of services provided to individuals living with complex health problems (e.g., chronic diseases; mental health challenges; comorbidities) (6, 10, 15, 34-36). A variety of models exist, characterised both by the organization and degree of interprofessional collaboration, as well as the type of clients served (37-39).

This project will advance the understanding of the effects of a team-based model of care within a FMG that is in a disadvantaged area and whose clientele presents complex biopsychosocial problems. Various interprofessional primary care models have been developed that are designed to address complex health problems in specific populations identified as vulnerable, for example, older adults, (40), individuals with HIV (41), and veterans (42). However, these models have frequently been presented as intervention programs composed of a predefined interprofessional continuum of care, a care manager, and/or case discussions. In comparison, the *Archimède* model is based on a uniform orientation to the optimisation of professional roles (seeing the right professional at the right time), and the use of predefined pathways enacted by administrative staff when making appointments. Furthermore, in this model, referrals are made between professionals, and the continuum of care is facilitated by having an interprofessional team in the same location. Access to this interprofessional approach is also facilitated because no fee is charged. In addition, compared to other reported primary care models (38, 43, 44), there is no preselection of patients, with all patients being eligible for the appropriate professional services. Our research project seeks to understand the experience of users

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3 attending a clinic based on this model to assess the relevance of this model for this
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5 population.
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8 One of the strengths of our research includes the measure of efficiency with respect
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10 to operational performance at the FMG level and the use of health network resources (e.g.,
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12 emergency room visits) by *Archimède* users. This study will make an important
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14 contribution to the understanding of the efficiency of primary care models, thus responding
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16 to the need to better evaluate primary care reforms (16, 36).
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20 The originality of our research lies in our focus on the interrelations between the
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22 micro, meso and macro levels to better identify the elements that facilitate or hinder the
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24 deployment of the model and the optimisation of interprofessional collaboration.
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26 Understanding the context of implementation, particularly in relation to the particularity of
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28 the dual public and private organisational structures, is an important element in this
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30 research project. That is, although the model is deployed in a private clinic, it is publicly
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32 funded. As well, some staff are paid by the public health organization. Thus, our approach
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34 takes into account: 1) structural issues related to health policies in primary care, types of
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36 funding, and resource management; 2) issues related to the organization of the clinic (e.g.,
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38 dynamics of interprofessional collaboration and management practices); and 3) micro-level
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40 issues related to the subjective work experience of professionals and service users'
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42 experiences (22). Although our research evaluates only one FMG, the findings from this
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44 study could be relevant not only in Quebec but also for other jurisdictions looking to
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46 develop interprofessional primary care models that address the social determinants of
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48 health, and that optimize the use of health and social care providers' respective scopes of
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50 practice.
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6 Regarding the limitations of our investigation, there is a potential lack of generalisation in
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8 studying only one FMG. Nevertheless, conducting this project will permit us to both test
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10 our methodology to quantitatively assess the performance of the FMG, and to explore in
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12 depth the influences of the implementation context on the deployment of the project. A
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14 potential limitation of the type 2 effectiveness-implementation hybrid study approach
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16 concerns the difficulties that can arise if there is a problem in the implementation of the
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18 Archimède model in the FMG clinic with respect to the optimisation of professional roles
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20 and the close collaboration of the professionals; this difficulty can compromise the
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22 effectiveness trial field (25). In our study, the involvement of multiple actors in the advisory
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24 committee should help to mitigate this limitation by the fact that they will be informed
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26 quickly of the results along the way and by their ability to intervene directly within the
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28 team to make the necessary adjustments. A further possible limitation concerns the
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30 potential for generalisation to other areas with different demographic profiles, given that
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32 the FMG under study is in a disadvantaged area. However, it is unlikely that all patients
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34 attending the FMG are in a vulnerable situation; the use of a socio-demographic form will
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36 allow to establish a socioeconomic profile of the patients interviewed.
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AUTHORS CONTRIBUTION

- Substantial contributions to the conception or design of the work (NC, YF, AF, SCG, ML, MI, AD, J-LD, EJ and SB).
- Drafting the work or revising it critically for important intellectual content (NC, YF, AF, SCG, ML, MI, AD, J-LD, EJ and SB).
- Final approval of the version to be published (NC, YF, AF, SCG, ML, MI, AD, J-LD, EJ and SB).
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (NC, YF, AF, SCG, ML, MI, AD, J-LD, EJ and SB).

COMPETING INTERESTS

None.

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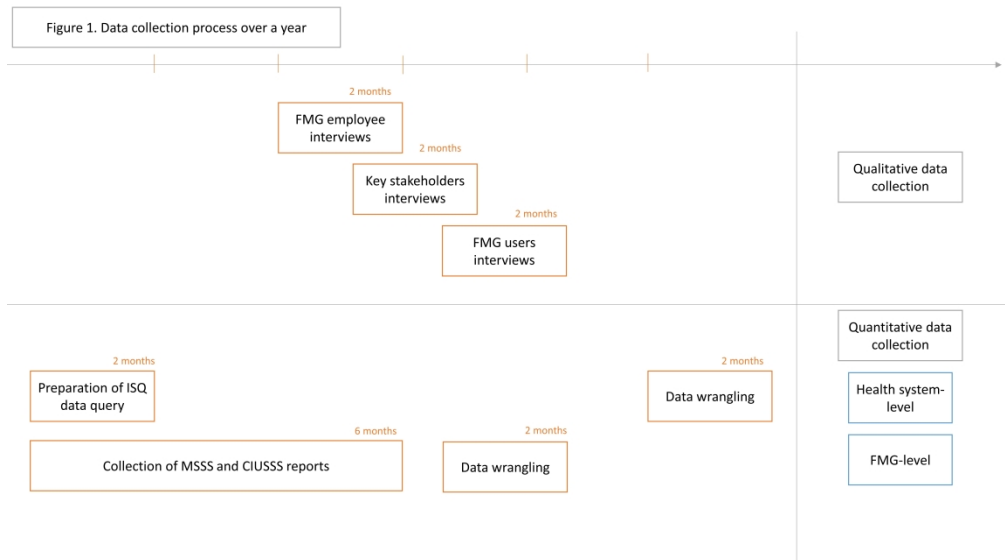
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**Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015**

Text Section and Item Name	Section or Item Description	
<p align="center">Notes to authors</p>	<ul style="list-style-type: none"> • The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript. 	<p align="center">As you review the manuscript, place a checkmark in this column for each SQUIRE item that is appropriately addressed in the manuscript. Remember that not every item is necessary in every manuscript.</p>
<p align="center">Title and Abstract</p>		
<p align="center">1. Title</p>	<p>Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)</p>	<p align="center">p.1</p>
<p align="center">2. Abstract</p>	<ol style="list-style-type: none"> a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions 	<p align="center">pp.2-3</p>

Introduction	<i>Why did you start?</i>	
3. Problem Description	Nature and significance of the local problem	p.5-6
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	p.5-6
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	p.8
6. Specific aims	Purpose of the project and of this report	p.7
Methods	<i>What did you do?</i>	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	p.7
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	a) p.7 b) p.7
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	a) p. 9
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	pp.10-13 (quantitative) pp. 13-15 (qualitative)
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	pp. 10-13 (quantitative) p.16 (qualitative)
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	p.17

Results	<i>What did you find?</i>	
13. Results	<ul style="list-style-type: none"> a. Initial steps of the intervention(s) and their evolution over time (<i>e.g.</i>, time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data 	Not appropriate; protocol article
Discussion	<i>What does it mean?</i>	
14. Summary	<ul style="list-style-type: none"> a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project 	<ul style="list-style-type: none"> a) N/A b) p.4 and pp.18-19
15. Interpretation	<ul style="list-style-type: none"> a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs 	N/A (protocol article)
16. Limitations	<ul style="list-style-type: none"> a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations 	pp.19-20
17. Conclusions	<ul style="list-style-type: none"> a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps 	pp.17-20
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	p.20



Standards for Reporting Implementation Studies: the StaRI checklist for completion



The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies ([StaRI](#)) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies ([StaRI](#)). [Explanation and Elaboration document](#). *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.
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The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item	Reported on page #	Implementation Strategy	Reported on page #	Intervention
		“Implementation strategy” refers to how the intervention was implemented		“Intervention” refers to the healthcare or public health intervention that is being implemented.
Title and abstract				
Title	1	p1		Identification as an implementation study, and description of the methodology in the title and/or keywords
Abstract	2	pp 2-3		Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.
Introduction				
Introduction	3	pp 5-7		Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.
Rationale	4	p9		The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

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Aims and objectives	5	pp7-8	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	6	P9	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	7	pp 5-8	The context in which the intervention was implemented. (Consider social, economic policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	8	pp8	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.		The population targeted by the intervention and any eligibility criteria.
Description	9	pp8-9	A description of the implementation strategy		A description of the intervention
Sub-groups	10	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	11	pp11-14 + pp15-18	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets		Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	12	P11	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	13	pp11-14	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy		Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	14	p12 + p14 + pp15-16	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	15	pp11-13 +p18	Methods of analysis (with reasons for that choice)		
Sub-group analyses	16	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	17	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy		Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	18	N/A	Primary and other outcome(s) of the implementation strategy		Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	19	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	20	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy		Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	21	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/adaptation	22	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences		Fidelity to delivering the core components of intervention (where measured)
Contextual changes	23	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	24	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	25	p4 + pp20-22	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	26	pp21-22	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)		Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	27	p19 + pp22-23	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		