ARC

Accès aux Ressources Communautaires
Access to Resources in the Community

December 27, 2017

1 LAY SUMMARY

Some people living with health problems require extra support to properly manage their conditions, as family doctors are only able to spend limited time in the office with these patients. There are many resources and programs in the community that can provide the necessary time and support for these patients, yet many patients are unaware that such resources exist. Patient navigators have been shown to be useful in helping patients with certain conditions (such as cancer) to get to the resources they need, especially when they have social challenges that make it difficult for them to reach these programs (for example, language or transportation barriers, poverty, or poor social support). This study will look at how helpful Navigators are to link patients at family doctors' offices to community resources. To do this, family doctors' offices in Ottawa and Sudbury will be recruited. All offices will receive training on directing patients to CRs and will be assigned a patient navigator to support patients access CRs. Half of the patients referred to CRs by their providers will have access to the navigator (intervention) assigned to the practice. This study will assess whether access to a navigator increases patients' access to community health and social services compared to usual standard of care. In addition, the study aims to understand whether English and French speaking individuals are as likely to benefit from a navigator in accessing community resources in the language of their choice.

2 BACKGROUND

2.1 WORK CONDUCTED IN PREPARATION FOR THIS PROJECT

The proposed project builds on work conducted between 2013 and today.

The Canadian Institutes of Health Research's Community Based Primary Health Care Team Grant SPOR initiative funded a five-year program of research (known as IMPACT: Innovative Models Promoting Access-to-Care Transformation, http://www.impactresearchprogram.com/). The goal of the IMPACT Project is to increase access to community-based primary health care for vulnerable populations. The lead for the Ontario arm of the IMPACT project, Simone Dahrouge, has undertaken a community engagement initiative within the Champlain Local Health Integration Network (LHIN) to understand the barriers patients face to adequately access community based health and social resources (CRs) and how these can be overcome. Under that funding, the team undertook an extensive consultation process to identify a regional priority gap, select and adapt an intervention, and implement and evaluate a single arm intervention. We are currently in the last phase of that project, which is serving as a feasibility phase for the randomized controlled trial. The feasibility study is evaluating the acceptability, demand, implementation, adaption, integration, and practicality of the study intervention and related activities to optimize appropriate access to CRs for primary care patients. Enrolment for that project will be completed by March 2018. This study received ethics approval from the OHSN Research Ethics Board (Protocol #20160914-01H), Bruyère Continuing Care Research Ethics Board (Protocol #M16-1616-055), Hôpital Montfort Research Ethics Board (Protocol # SD-DP-27-02-17), and the University of Ottawa Research Ethics Board (Protocol # A05-17-04).That trial is a registered clinical trial: NCT03105635.

During the feasibility phase the team established a regional stakeholder advisory group (Champlain LHIN). The composition of the advisory group has been adapted to meet the needs of the study. In the initial phase the composition was broad until the region identified the priority area and approach to addressing the gap. The committee is now composed of patients of various minority communities who contribute their lived experience, primary care providers from different care models and leaders from organizations responsible for community services (Community Care Access Centres and Community Health Centres) who inform the feasibility of the approach for each context, and best approach to integrating of the two sectors, health planners (the LHIN Primary Care Lead, senior integration specialist and others) who bring their broader context health services knowledge as well as resources (such as practice transformation facilitation services) to the project, as well as other stakeholders that inform specific components of the intervention (Ontario 211, Champlain Healthline). That Committee meets regularly and contributes directly to the direction of the study design, implementation, evaluation and dissemination (See Additional information: 1 Champlain Advisory Committee) for additional information. Because the committee fundamentally represents the interests of the region, it is often referred to in this document as 'the region".

The initial consultative phase identified poor access to CRs as a priority access gap. Examples of these include self-management, smoking cessation, care giver support, and falls prevention programs. The research team relied on a scoping review conducted for the IMPACT program and conducted several interviews and focus groups with community stakeholders to inform the best approach addressing this gap. The region selected to implement a patient navigator who can assist patients for whom the use of a community service is recommended by their primary care provider achieve access to that service. Primary care providers rarely make specific recommendations to access CRs; largely because they are unaware of these. They make general recommendations to improve healthy behaviours, but do not refer to specific types of services. Two realist reviews have been commissioned and completed by a team of experts to help us understand the critical success factors and shape our intervention. One review is focused on "community navigators" and the other on "primary care referral to community services" to help the team understand the factors that support us. This information was used to develop the ARC intervention. A number of themes identified in these reviews including training for clinical staff to identify and refer to relevant CRs to address patients' social barriers; implementing a champion within practice to integrate referral into usual care; use of electronic health records to prompt provider referral and share information between provider and the community; and developing a screening process and promotional material to prompt referral.

As a result, the region developed the Access to Resources in the Community/Accès aux Resources Communautaires (ARC) intervention. The ARC project will build on this work by focussing on improving access to community resources in patients' language of choice and emphasizing access to French-language resources for Francophones in Ontario.

2.2 PRIMARY HEALTH CARE

Primary care provides essential services that help prevent the onset of disease and the deterioration of existing ones. Primary health care is a broader approach to health that also includes supporting patients to overcome the challenges posed by their social context.

In the current primary care context, with the exception of team based practices (e.g. Family Health Teams and Community Health Centres), the primary care providers' role in promoting healthy lifestyles or addressing challenges associated with the social determinants of health, which contribute to the risk of developing an acute illness or a chronic disease, are usually limited to brief health promotion counseling. However, patients require additional support to achieve their habit changing goals or improve their social situation.

Ontario jurisdictions have invested heavily in CRs that can support patients to achieve good health through education and by assisting them in their healthy choices (e.g. self-management, nutritional counseling, falls prevention) (1-4) and services that help patients overcome barriers to adequate access and address social determinants of health (5;6) (e.g. translation services, transportation, advocacy, financial assistance, housing). But these are critically underused (7), especially by those with the greatest needs,(6) and as such, opportunities to achieve better health are missed. A sub group of Francophones living in minority situations face not only language barriers, but also further amplified health disparities resulting from social risk factors such as poverty, unemployment, and low education.(8)

The recent work conducted by Price and colleagues to inform Ontario's restructuring of the primary health care system, suggests that primary care practices will need to rely increasingly on CRs within specific geographic areas to provide the necessary interprofessional care required to meet the needs of their patients.(9) Our work to date has demonstrated that, with the exception of the home care services offered by the Community Care Access Centres, primary care providers are largely unaware of the resources available to their patients within their community and this situation could be worse concerning the social and health care services in the Francophone community. Linkages between these two sectors need to be strengthened.

2.3 COMMUNITY RESOURCES

CRs play an important role in supporting individuals to achieve health goals. The U.S. Preventive Services Task Force Recommendation Statement strongly recommends that individuals with known cardiovascular disease risk factors be provided education and support to overcome risks associated with poor dietary and sedentary lifestyle.(10) A scientific statement from the American Heart Association makes strong recommendations in support of community based wellness programs.(11) Similarly National Guidelines for Diabetes Management highlight the role self-management education and support programs provided in the community in achieving healthy outcomes.(12) Several review studies have concluded that community resources' target population and approaches vary, including educational group programs,(13;14) group visits,(13) interventions targeted at high risk population,(15) including the elderly,(16;17) and other approaches.(18;19) Another review stresses the benefit of an integrated approach to addressing health determinants.(20)

Primary Care providers address the health needs of all patients throughout the lifespan. They are the first point of contact with the healthcare system, provide patient centered care that includes health promotion, chronic disease management, and palliative services, and are best suited to coordinate patient care across these sectors. To achieve better access to CRs, primary care practices must be oriented to these services and the navigation tools that can help them identify the ones that meet the need of their patients in order to improve referral.

The Change Foundation identifies poor integration within an increasingly complex healthcare system as a growing concern of the healthcare sustainability: "Ontario's healthcare community has begun to fully absorb the consequences of an unintegrated healthcare system. Individuals seeking care can get lost as they move among different healthcare providers who are not connected to one another. At times, this can have a serious effect on clinical outcomes, and it frequently duplicates efforts, wastes everyone's time and increases costs."(21)

Without additional support, the likelihood that patients with social barriers realize access to the recommended service is low. This challenge is compounded when more than one obstacle is faced such as for Francophones living in minority situations and who experience constraints related to poverty, poor literacy, or social isolation. For these individuals, linkage between primary care and CRs is especially important. (16) Community Resources in each Region

There are numerous CRs that exist in each region, to which primary care patients could be referred. The tables contained in Additional information: 2 Examples of Health Related Resources provide examples of resources based on the areas identified by our stakeholder consultations as most relevant, which include cardiovascular disease and diabetes prevention and management (such as smoking cessation and nutrition), mental health, falls prevention and pain management. Additional information: 3 Examples of Social Resources also provides examples of CRs that can help address social barriers to utilization of CRs such as transportation and translation services.

2.3.1 Access

The concept of access to primary health care is complex, as barriers can be manifest at the individual/patient or provider/organizational level and are dependent upon where and when access is sought. The conceptual framework of access to health care proposed by Levesque et al. (22) suggests five dimensions of accessibility that pertain to available healthcare service: 1) approachability, 2) acceptability, 3) availability and accommodation, 4) affordability, and 5) appropriateness. These dimensions are corollaries to individuals' abilities which vary based on individuals' knowledge, culture, and available resources, including 1) ability to perceive the need for care, 2) ability to seek care, 3) ability to reach care, 4) ability to pay for care, and 5) ability to engage in care. The framework (see: Additional information: 4 Access Framework) depicts these dimensions on a continuum that ranges from the early stages of health care access (understanding one's health care needs, perceiving that there is care available, and seeking that care), to later stages of access (getting an appointment, managing the direct and indirect costs of participation, and receiving care that is appropriate for the individual). True access then, is only achieved if barriers are overcome at each stage.

It is important to understand and address system-level barriers, like lack of services in geographical regions, or poor integration between health care organizations, to reduce barriers to access. These changes, however, are often controlled by health authorities and involve collaboration among multiple stakeholders to affect change. Addressing individual-level barriers may be more feasible to affect improvements in access, as it has been demonstrated with interventions such as patient navigation, which has been shown to increase individuals' abilities to seek and reach needed services. Equitable access can also be improved by patient navigation services targeted at individuals facing social barriers to accessing care. (23) Additionally, this approach has been demonstrated acceptable and feasible to link primary care providers and CRs to address lifestyle risk factors. (24)

2.3.1.1 Francophones living in Minority situations

Linguistic barriers limit Franco-Ontarians' ability to access needed services. The impact of these barriers is especially evident for preventive and social services because these rely more heavily on communication. This includes mental health care, health promoting services such as falls prevention, diet, as well as services that address the social determinants of health. These gaps in Francophone care result in an increased use of emergency services and unnecessary tests.(8)

Despite considerable evidence demonstrating the importance of language consideration in care delivery, disparities in care for Franco-Ontarians persist. This is in part because there remain significant gaps in our understanding of how to overcome these challenges.(25) It is well documented that linguistic concordance between patient and care provider is associated with better care.(26) Awareness of the barriers and attempts to better respond to the patients' needs, including offering appropriate accommodations (such as translations), help reduce the mental health care gaps, but does not eliminate disparities.(27)

In fact, a study relying on the Ontario sample from the Survey on Vitality of Official-Language Minorities (SVOLM) which assesses the experience of Canadians of either official language living in a minority situation has documented that only 33% of Francophones in Ontario receive primary care services in French.(28)

2.3.2 Utilization

The likelihood of individuals utilizing a service they have been referred to varies considerably across studies, and is related to the service to which the individual is referred, and the support provided to enhance utilization (e.g. patient navigation, resource staff contact patients, etc.).

The literature on uptake of smoking cessation services demonstrates very low utilization (0.3%-2.3% of patients achieve contact with the resource) when no measures are implemented to support access. (29) (30) Interventions solely targeted at providers are generally ineffective, (30) or increase only marginally (3.9%).(29) Significantly increased utilization is achieved when interventions involve individual(s) reaching out to patients after the referral is given rather than relying on patients' initiative. For example, when practices employed the 'Ask, Advise, Connect' approach 11.4% of smokers talked with someone from the Quitline (the Quitline called them), compared to 0.6% of smokers in a practice with the 'Ask, Advise, Refer' approach that relied on patients calling the Quitline (OR for reach = 17.38; 95% CI=8.08-37.36). (31)

Even greater utilization of resources is achieved when interventions target high-risk patients (29), or particularly vulnerable populations such as women experiencing partner violence (4.4% contacted the intended resource), (32) or mothers with high socioeconomic need (39% enrol in a resource).(33)

2.3.3 Navigation

The challenge faced by many initiatives intended to support individuals to achieve better health is the inequities in their utilization,(34;35) and more intensive support is recommended for individuals with social complexities.(36)

2.3.3.1 Electronic and Telephone Navigation Resources

Navigation tools such as the Healthline and Ontario 211 (37;38) catalogue existing CRs and offer on-line directories and telephone support services to assist Ontarians identify the services and programs they require.

Ontario 211 is a non-profit agency that helps Ontarians connect to a variety of resources in their community through an online directory of available health and social resources and a telephone helpline.

The Healthline provides a similar online directory of community based programs across Ontario including the Champlain region and North East region.

Individuals can obtain information on services available in their community and details on the specific programs offered (e.g., location, cost, etc.) by searching the Healthline and 211 online directories, or by speaking with a 211 representative for additional assistance. These navigation tools act as information channels that help individuals identify programs of interest located in their community and in turn, aim to address an important barrier to access: individuals' lack of information on available CRs.

Unfortunately, our interviews and focus groups with primary care healthcare providers (PHCPs) and community members have demonstrated limited awareness of these navigation tools. In addition, while these tools provide information on the types of services available in the community, they are limited in their ability to consider individual barriers to access and support people to overcome these barriers and reach the service that is most appropriate for them.

2.3.3.2 Patient Navigation

Despite increased knowledge and awareness of available community health and social resources, many individuals face additional barriers that limit their access to these resources and require additional support to achieve their health goals and overcome difficulties in obtaining needed services.

Patient navigation has been conceptualized as an approach to empower individuals, promote patient engagement, and address health disparities among underserved and vulnerable populations. A Patient Navigator is an individual who supports and guides patients in overcoming barriers to access health and social care and achieve \service utilization. These individuals are also sometimes called Community Health Workers/aides/brokers/etc., lay health workers, promotoras, and other similar terms. Common to these is the role the individual plays in assisting the patient to navigate the health care system. This involves helping patients identify the services that could respond to their health priorities and assist them in overcoming barriers to access required services. This includes harnessing existing services (e.g. translation, transportation, and financial), advocating for the patient, supporting self-management, and generally helping the patient overcome access barriers. The second aspect of this role that has emerged as essential is the trust that develops between the patient and the Navigator, an aspect of the relationship that is strengthened when the Navigator and patient share common profiles. This aspect is particularly applicable for Francophone patients where there will be a shared language spoken (French).

The navigator role has been developed in the context of cancer patients. Recent review on the subject underlines the usefulness of the patient navigation in the integration of a fragmented health care system, and its importance for those more vulnerable either because of their medical (39) or social status. (23)

Several jurisdictions, including Vancouver, Saskatchewan, and Manitoba have had significant success using patient navigators (referred to herein as Navigators), (40) although most do not have formal evaluations. Navigators that have addressed challenges experienced in cultural and linguistic minorities have been successfully employed in many regions. A recent systematic review of the literature concluded that "Several studies reported significant improvements in participants' chronic disease prevention and self-management outcomes and meta-analyses identified a positive trend associated with multi-cultural health worker intervention." (41) Community health workers (CHWs) have been employed throughout Canadian regions most commonly to support access to health care, health promotion and education care, and the determinants of health. Similarly another 2015 scoping review on the subject concluded that CHWs can improve a wide range of health issues, can reduce disparities across social groups, including linguistic groups, and that those that focused on primary health care and health promotion "have demonstrated both actual and potential control of high costs of medical services and inappropriate use of emergency services when and if CHWs and their interventions are integrated into the health care systems." (18) A 2017 scoping review of patient navigation in primary care reported a number of positive outcomes including improved patient health and wellness, self-efficacy, increased access to care, and improved follow-up with primary care providers and care coordination (42).

The authors conclude that additional research is required to better understand the potential for these Navigators to increase access to care, reduce health care costs and address social determinants of health, and that the role of the Navigator needs to be better defined.

Willis et al. have developed a framework to describe the similarities and differences across navigator types with a focus on clarifying the unique roles and responsibilities of patient navigators in different settings ranging from the community to healthcare institutions (Additional information: 5 Navigator Framework) (43). This framework delineates the similarities and differences across three navigator types: community health workers, patient navigators, and clinically licensed navigators. Patient navigation, situated within primary care is described in this framework as a 'patient navigator.'

3 PURPOSE

The purpose of this project is to optimize appropriate access to community based services for socially complex primary care patients, including Franco-Ontarians living in minority situations, and promote the continuity of information across primary and community care.

4 OBJECTIVES AND DELIVERABLES

Objective A: Optimize equitable utilization of community based resources

Deliverable 1: Effectiveness of a patient navigator on utilization of CRs

Deliverable 2: Make policy recommendations to address remaining gaps

Deliverable 3: Establish a model of navigation that is transferable and scalable.

Objective B: Support continuity of information across Primary and Community Care

Deliverable 4: Establish a process that support appropriate exchange of information across the two sectors

5 CONTEXT

The intervention is set in primary care practices. The intent is to integrate primary care and CRs to optimize appropriate access to CRs by individual patients. Within Ontario, 96% of residents have a primary care provider. (44)

There are four predominant types of primary care practices in Ontario. 1) The majority (approximately 50%) of individuals receive care in practices in which family physicians' remuneration is derived principally by the fee they earn for each service they deliver. These are called Fee-For-Service, and include the Family Health Groups and Comprehensive Care Models. 2) Approximately 40% of Ontarians receive care in practices in which family physicians' remuneration is based principally on capitation, which is based on the number (age and sex adjusted) of patients enrolled under their care. These are called Family Health Networks and Family Health Organizations. These practices, like the Family Health Groups and Comprehensive Care Model have a traditional team composition made up of a group of family physicians working with some nurses and front staff. 3) Approximately half the capitation practices are also Family Health Teams. Family Health Teams have a larger and more varied team. In addition to the family physicians, nurses, and front staff, these practices host ministry-funded allied health professionals such as nurse practitioners, pharmacists, and social workers. These professionals work alongside family physicians to provide patients with comprehensive primary care. 4) The last model is the Community Health Centre. Community Health Centres are also an interprofessional model. In these practices all professionals, physicians included, are salaried. The model's principal mandate is to provide better care for vulnerable populations (e.g. individuals of low-socioeconomic status, immigrants and refugees). (45)

The context in which Franco-Ontarians reside can influence the barriers to adequate access to social and health care services in their mother tongue. The breadth of existing CRs, the number available in French, the extent to which social services that help individuals overcome barriers to access vary considerably by regions and are largely influenced by population density. For this reason, to better understand the issues Francophones living in minority situations face, we will conduct ARC in two contexts: Ottawa (central and eastern regions of Champlain Local Health Integration Network -LHIN) and Sudbury within the North East LHIN. These regions have a sufficient Francophone population to allow us to understand how access to community health and social resources in the patient's language of choice may be different between Anglophone and Francophone patients. We are recruiting practices in regions with at least 20-25% of Francophone residents.

The Champlain LHIN is a large, geographically-delineated health jurisdiction spanning nearly 18,000km$^{2.}$ (46) The most urban region of the Champlain LHIN (downtown Ottawa) is designated Health Link Area 5[*], which spans over 173 km^2, and has a population of over 354,022 residents. (47) Across the Champlain LHIN, about 20% of residents are Francophone, 18% are immigrants, 15% are visible minorities, 11% live below the poverty cut off, and about 3% are Aboriginal. (46) It is estimated that 38% of the population aged 12 years and up have a chronic condition, and 15% have multiple chronic conditions. 16% of residents in the Champlain LHIN have a mental health or substance abuse disorder; these rates are higher among youth and young

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[*] Health Link Area 5 - The Ottawa central Ottawa region including Nepean, Glebe, Old Ottawa South, Industrial East, Riverview, Playfair Park and Huntclub. It excludes Vanier and Overbrooke. The region is bounded by the Ottawa River to the north, Conroy and Leitrim to the east, Earl Armstrong and Crestway to the south and Woodroffe to the west.

adults.(48). Compared to the Champlain region, in Health Link 5 about 13% of residents are Francophone, 1.7% have no knowledge of English or French, 26% are immigrants, 24% are visible minorities, 18% live below the poverty cut off, and about 1.5% are Aboriginal.(46) The eastern region of Ottawa (Champlain LHIN) is an urban community with ethnically diverse populations. Ensuring access to quality health services for Francophones in this region is a key priority, as 18.8% of its 1.32 million residents report French as their first language.

The North East LHIN is the second largest LHIN in Ontario with a population of over 564,000 residents. The North East LHIN has the largest proportion of Francophone residents (23%) in the province, as well as a large Aboriginal population (11%). Compared to provincial averages, residents of the North East LHIN are older, have a shorter life expectancy, have lower levels of education and are more likely to be unemployed, and report poor health practices and a higher prevalence of chronic diseases. (49) 28% of residents of the North East LHIN are limited in their activities due to a chronic physical or mental condition or health problem. (50) North-eastern Ontarians have also expressed difficulties accessing health care services and a desire for increased home a community based services (49) The City of Greater Sudbury is Northern Ontario's largest urban center with a population of 160,770, nearly 27% of which are francophone (51) and 8.2% self-identifying as Aboriginal. (52) Furthermore, compared to provincial averages, Sudburians have higher rates of cardiovascular disease and certain types of cancer, have higher rates of smoking, alcohol consumption and obesity and are more likely to be hospitalised or visit an emergency department. (53) Considering the linguistic diversity of the region and its poor health outcomes, Sudbury was chosen to join ARC as an effort to improve access to linguistically appropriate CRs.

6 INTERVENTION

All practices will have access to the intervention. Practices will receive the practice changes to promote patient referrals to CRs. Patients referred to CRs will be randomized to either the intervention or the control arm.

Patients allocated to the control arm will receive information on Ontario 211, an electronic and telephone navigation service. Patients allocated to the intervention arm will be offered the services of the Patient Navigator. The fundamental role of the Navigator is to provide appropriate support to primary care patients to overcome barriers to accessing CRs (e.g. assisting the patient in identifying the most appropriate resource, providing the patient with transportation services, etc.) and reach and utilize these services.

6.1 PRACTICE CHANGES

All practices participating in the study will receive the following support to facilitate the implementation of the intervention in the practice:

6.1.1 Practices/Providers

*6.1.1.1 To increase providers' **awareness** of CRs (Objective A)*

All practices will receive an orientation on the breadth of available community based health and social resources.

Approach: Participating providers will receive information on the breadth of available resources, including the benefit of these resources to their patients and their practice. Because providers are hesitant to recommend the use of health promoting CRs to individuals with social barriers because they are unlikely to utilize the resources, the orientation will include information on resources that address social barriers (e.g. no transportation, low health literacy, social isolation, language barrier) to demonstrate that even more socially complex patients can access support services to overcome their barriers and utilize health promoting resources to which they were referred.

6.1.1.2 *To support practices **streamline the process of referring** patients to CRs into their existing structures (Objective A)*

To better integrate the referral process into usual practice, we will work with each participating practice to implement the referral approach best suited for them.

Approach: Assess the practice/providers 'current referral practices and determine their preferred approach to referring patients to CR. The research team will work with PHCPS and practice staff to determine the optimal process to prompt provider referral and adapt the process based on PHCPs' needs and preferences.

The referral process will require the PHCP to record the necessary information regarding the patient's needs relating to the CR. A referral form (see form: Appendix: A – Draft Referral Form) has been created for the feasibility study and will be used as a starting point for this study. This form may be adapted to better suit the needs of the practice relating to communication. We anticipate most practices to integrate the referral process directly into their EMR (where one exists). The practice may use the referral form provided to them or adapt an existing form they currently use for the purpose of this study. A paper copy of the referral form given to patients will serve as a tangible reminder to access the resource and increase the likelihood of compliance.

Once this process is established, we will train all participating PHCPs on how to use the referral form and support the practice to establish a process to integrate the use of the referral form into their daily routine. The research team created an infographic outlining the study process and an instructional video explaining the details of the referral process to share with participating providers (See Additional Information: 6 Instructional Information).

Note that Objective B of this study is to establish a best communication strategy that enhances information continuity between primary health care and CRs. The referral form will necessarily be part of the information exchange, and will therefore be adapted as we learn about the preferred communication approach (See section 6.1.1.5)

6.1.1.3 *To increase **patients' awareness of CR** and to encourage a discussion regarding these resources with their provider (Objective A)*

Practices will receive promotional material (e.g., posters, flyers, videos) to promote the breadth of existing community based health and social resources and the process by which navigation services can support individuals access these resources.

Approach: The ARC promotional poster (see poster: Appendix: B – Promotional Material) and the ARC promotional video (see link: Appendix: B –Promotional Material) will be displayed in the waiting room and patient examining rooms (where feasible) of all participating practices. The ARC promotional material will highlight the breadth of available CR and navigation support via the ARC study. Patients will be encouraged to discuss the benefits of these resources with their primary care provider.

6.1.1.4 To facilitate the integration of the patient navigator in the practice (Objective A)

A patient navigator will be attached to each primary care practice participating in the study. The research coordinator will work with the practices to determine the most optimal strategy for integrating the navigator into each practice.

Approach: Consideration will be given to practice/providers' expectations relating to the days and times when the navigator would be expected to be on site, including regular "office hours" to schedule appointments with patients and/or PHCPs, and any internal meetings that would be beneficial for the navigator to attend (e.g., staff and/or physician meetings).

Practice staff will be asked to establish a time (usually one half day a week) where the navigator can use a designated space in the practice to meet with the patients referred to the CRs. The research coordinator will also be aware of existing resources within the practices for which external referrals should not be encouraged. This is especially relevant for interprofessional practices (FHTs) since these offer a number of services internally (e.g. dietitian services) which they may wish to prioritize for their patients.

6.1.1.5 To support continuity of information between Primary and Community Care (Objective B)

The research coordinator will work with each practice to establish a communication strategy best suited for that practice. This will cover information needs between PHCPs and the navigator as well as information needs between PHCPs and CRs.

PHCP ←→ Navigator:

The approach through which the navigator and practice staff will communicate about patient needs to overcome barriers to accessing care, and experience using that community resource will be established by the research coordinator according to the practice/providers' needs and preferences. The approach to and extent of communication between the navigator and practice staff, including meeting times, frequency of meetings, communication medium, etc. will be determined individually for each practice.

Approach: We will begin by implementing the approach adopted during the feasibility study for the exchange of information between PHCPs and the navigator. The first point of communication begins with PHCPs completing a brief referral form (Appendix: A – Draft Referral Form) for each patient they direct to a CR. This form captures standardized information that is required by the navigator (e.g., patient's language, needs, contact information), and serves as a reminder for the patient about their discussion with their PHCP. During the feasibility phase, all participating practices integrated this form into their EMR. PHCPs completed the form in each patient's medical record so that a record of the referral is maintained in the chart. They provided patients with a printed copy of the form and faxed a copy to the ARC research team. The content of that referral form was sufficient for the purpose of navigation.

Once the patient was enrolled in the study and met with the navigator, PHCPs received updates from the navigator and a final report on the status of their patient's access to the CR via a standardized reporting form (Appendix: C – Navigator Feedback Form).Practices were asked to establish their preferred method for receiving this reporting form such as, for example, integrating the form into their EMR. Because the navigator is not a member of the clinical care team, the practices participating in the feasibility study opted to receive these communications by fax. This will be proposed to the participants in this study.

The communication between PHCPs and the navigator was tailored according to PHCP needs and preferences. All PHCPs agreed to receive information from the navigator about the status of their patients by fax at least twice: once after the initial encounter between the patient and the navigator and a second time after the navigator discharged the patient and closed their file. Any interim communication would occur only as needed (e.g., if the patient identifies a health care need that cannot be addressed by the navigator). After the first meeting with the patient, the navigator would forward information to the PHCP about the priority needs identified by the patient and information on available resources identified by the navigator. A final report was faxed to the PHCP once the navigator had determined that the patient had accessed the resource, or when the appropriate level of support was provided and the patient felt empowered to access the resource. Information on the recommended resource and the next steps (e.g., appointment made, wait list, etc.) to take was also shared with the PHCP. The information shared between the navigator and the PHCP is limited to the services provided by the navigator to support patients overcome barriers to accessing the service recommended by their PHCP, as well as other services identified by the patient. Any additional information on the patient's utilization of these services was not included.

To achieve Objective B, we will determine whether this communication approach is appropriate or whether it can be improved. We will evaluate the feasibility, acceptability and utility of the approach used.

PHCP ←→ CRs:

In the feasibility study, no standard information was transmitted to the CRs to which patients were referred. Only relevant information to determine the appropriate resource for the patient (e.g. eligibility for services, location and cost) was shared by the navigator verbally when required. Similarly, neither the CR nor the navigator provided the PHCP with information relating to the patient's experience accessing the CR.

In this study, each participating practice and the CRs they prioritize will be consulted to develop a standardized/generic communication approach that can be tailored to individual practices' context and needs. We will assess the information needs of CRs to which the patients are most often referred in order to determine what information would be required to best inform the care of the patients they serve. We will determine whether that information need can be met by the PHCPs.

Factors to be considered include: CR information needs (e.g., content of the generic referral form); PHCP information needs regarding patient access to the CR; and means, frequency and confidentiality of communications across the sectors.

We will determine whether such information is required and test the feasibility, acceptability and utility of any new approach proposed.

Approach: Establish a standardized communication approach across the sectors through the Navigator. The referral form (Appendix: A – Draft Referral Form) will serve as means of for PHCPs to communicate information about the patient to the navigator. The navigator will share this information and any additional information they obtain with the CR.

The navigator will provide the PHCP with updates and a final report on the status of their patient's access to the CR through a standardized reporting form (Appendix: C – Navigator Feedback Form). The means of communication (e.g. through EMR, by fax, …) will be tailored to each practice's preference. We will assess whether that communication strategy remains feasible, acceptable and useful to the practices participating in the RCT.

Because the CRs do not provide information on the patient's encounters with them, and the contact with the navigator will be terminated before the patient has completed the utilization of the community resource, that information will not be available to us, and will not be included in any communication.

6.1.2 Patients

6.1.2.1 Control arm

Patients allocated to the control arm will be directed to the Ontario 211 services (see section Electronic and Telephone Navigation Resources). After consenting to participate in the study and completing the first telephone survey, the research assistant will inform these patients of the navigation services provided by Ontario 211 to help them access the CR recommended to them by their PHCP. Patients requesting information about the nature of the service will be informed that it is free, bilingual and available 24hours 7 days/week. The research assistant will instruct patients to dial 2-1-1 if they wish obtain additional information on the nature of this service.

6.1.2.1 Intervention arm

Patients allocated to the intervention arm will be offered the services of the ARC Patient Navigator. After consenting to participate in the study and completing the telephone survey, the research assistant will inform these patients that they can use the services offered by the ARC patient navigator to help them access the CR referred to them by their PHCP. Following a brief description of the services provided by the navigator (e.g., arrange transportation, make appointments, fill out forms, etc.), patients will be offered to be contacted by the navigator by telephone or to meet with the navigator in person on a day and time that is most convenient for them.

The profile and qualifications of the navigator are described in Additional Information 7 – Profile and Qualifications of the Navigator.

Role of the Navigator

Practices will receive support from a Navigator to assist patients to access CRs identified by their PHCP on the referral form (Appendix: A – Draft Referral Form). The navigator will help patients identify their priority needs and support them in accessing the CRs that can help address these needs. Navigators can support patients to access resources that were not identified by their PHCP, unless these are medical services that require a physician referral, or that are outside the scope of practice of the lay navigator.

The Navigator links patients, primary care, and community care by acting as an informational channel, champion, and advocate for patients. Navigators are intended to act as an integral member of the primary care practice team, and are defined by a clear scope of practice that is non-clinical and distinguishes their role and responsibilities from that of care providers. Navigators will develop effective interpersonal skills and communication skills with the PC team, patients and community program staff to assist patients to reach the appropriate CR, and address social barriers to care. Navigators will be assigned and paid to work with a specific practice to ensure timely meetings with patients and to act as a central liaison with providers, practices, and community resources.

Navigation will be provided by fully bilingual individuals. Specific attention will be paid to meeting the language needs of Francophones. The "Active Offer" of services in the language of the individual's choice will be prioritized. That is, the Navigator will actively identify that their service is available in French and English. If the patient speaks neither, the Navigator will seek the services of a cultural interpreter/translator, preferably a family member. The Navigator will also actively encourage individuals to use services in their language and seek the language appropriate services for the individual, where these are available, or offer the services of a translator.

The Navigator role and activities are described in more details in Additional Information 8: Role and Activities of the Navigator.

7 METHOD

7.1 DESIGN

This is a prospective, mixed method (patient) randomized controlled trial of navigation services provided by Ontario 211 vs. navigation services provided by a lay Patient Navigator. Randomization is 1:1 control:intervention.

The protocol is the second phase of a single arm study involving a lay Patient Navigator intervention (BRI-REB # M16-16-055,055,OHSN REB #201609014-01H20160914, Hôpital Montfort REB # SD-DP-27-02-17, and the University of Ottawa REB # A05-17-04). The mixed method design is a sequential, explanatory design in which the collection and analysis (at least partial) of quantitative data is followed by the collection of qualitative data that will aim to explore the findings emerging from the quantitative data so as to gain a more in depth understanding of the results.

7.2 RANDOMIZATION

Patients having consented to participate in the study will complete a survey, after which their random assignment to one of two arms (intervention or control) will be revealed.

The randomization schedule will be blocked at the practice level to ensure a balance of control and intervention patients for each practice, including all providers. The randomization schedule will be developed by an independent statistician and arm allocation will be concealed.

Patients randomized to the intervention arm will have access to services provided by the ARC Patient Navigator, whereas patients randomized to the control arm will be directed to the Ontario 211 navigation service.

7.3 PARTICIPANTS AND ELIGIBILITY

7.3.1 Primary care practices

Primary care practices that meet the following criteria are eligible to participate in the study:

7.3.1.1 Inclusion

- Any practice providing comprehensive primary care services (i.e. excludes practices that provide walk in services only), except for Community Health Centres.

This includes Reformed Fee For Service (Family Health Groups, Comprehensive Care Model), Capitation based models (Family Health Networks, Family Health Organizations), and interprofessional models (Family Health Teams)

- Located in a neighbourhood of the Champlain (Ottawa area) or North East (Sudbury area) LHIN that has a francophone population of 20% of greater, as identified in the Ottawa Neighbourhood Study and in custom neighbourhoods created by the city of Greater Sudbury for city planning purposes, both linked to Statistics Canada's 2011 Population Census, respectively.
- Having at least one primary care provider agreeing to participate in the study

7.3.1.2 Exclusion

- A Community Health Centre or clinics providing walk-in services only
- Practices that are under the traditional fee for service remuneration
- Located in a neighbourhood with less than 20% Francophone residents

7.3.2 Primary care providers

Providers care providers that meet the following criteria are eligible to participate in the study:

7.3.2.1 Inclusion

- Work in a practice that meets the eligibility criteria participating practice will be invited to participate in the study.
- Is a Primary Health Care Provider: A health professional that may refer patients to CRs such as physicians, nurses, and social workers.

For the purpose of simplicity all these are referred to as Primary Health Care Providers in the document.

7.3.2.1 Exclusion

There are no exclusion criteria for primary care health care providers

7.3.2.2 Qualitative Interviews

We will use a purposeful sampling approach to identify PHCPs who will be invited for the interview. The selection criteria will aim to get maximum variation while guided by the summary findings from the provider surveys that might show differences in responses across provider/practice profile. We will recruit PHCPs to maximize variation in profession and experience with the intervention, while also ensuring a good representation of males and females and PHCPs of different age groups.

7.3.3 Primary care patients

Primary care patients are eligible to participate if they meet the following criteria:

7.3.3.1 Inclusion

- Patient identifies a primary care provider participating in the study as their main primary care provider
- Has received a recommendation for a CR from their PHCP
- Is able to communicate in English or French, or is willing to be served via a cultural interpreter/translator, preferably a family member.

- Is able to provide consent for the study (18 years of age or older), or has parental/guardian proxy to provide consent (minor patients, patients with cognitive deficits)

7.3.3.2 Exclusion

- Unable to provide consent and does not have a family member/guardian who can provide proxy consent

There is no age, language or other requirements for patient eligibility.

7.3.3.3 Qualitative Interviews

We will use a purposeful sampling approach to identify patients who will be invited for the interview. The selection criteria will aim to get maximum variation while guided by the summary findings from the patient surveys that might show differences in responses across provider/practice profile. We will recruit patients to maximize variation in social complexity and experience with the intervention, while also ensuring a good representation of males and females and different age groups.

8 RECRUITMENT

8.1 PRACTICES/PROVIDERS

A practice is defined as a clinic site where providers share a common charting system and at least one staff resource. Sites where solo practitioners share a common waiting room and front staff but do not share the charting system are considered to have multiple practices, each one representing the solo practitioner. Also, in Ontario several practice sites have come together under a common primary care organization for administrative purposes. These organizations have more than one practice site, each with a different physical address, and each of these sites are considered a distinct practice.

The pool of potentially eligible practices will be identified via established lists (held by the Champlain and North East LHINs), online searches, and telephone inquiries for each of the two study regions. A list of all practices in the two regions within neighbourhoods having at least 20% francophone population will be established. To the extent feasible, the list will identify the practice address and neighbourhood, practice model, manager, lead physician (if applicable), and contact information (clinic telephone number, mailing and email address).

8.1.1 Prioritizing neighbourhoods

Neighbourhoods with a higher proportion of francophone population will be prioritized. For examples, practices in neighbourhoods that have a 50% francophone population will be targeted for recruitment before practices that have a 30% francophone population.

8.1.2 Identifying practices

Within a neighbourhood, practices will be randomly ordered using a random number generator, and recruitment will proceed down the list beginning with the neighbourhood of highest francophone populations.

8.1.3 Practice Recruitment Approach

Invitations to participate will be sent to the number of practices required in each region to meet its sample size requirement in the order described above. When a practice refuses, the next practice will be sent an invitation. Recruitment will proceed with that approach until the sample size requirement is reached.

We will use the Dillman Tailored Design Method(54) to recruit practices (Appendix: D – Practice/Provider Recruitment Package). Using that method, eligible practices are contacted up to three times to encourage participation. Firstly, an invitation letter will be emailed (or mailed if no email is available) to the individual we identify as most likely to be the practice lead. An information brochure (Appendix: D – Practice/Provider Recruitment Package) will be included (i.e., as an attachment) with the invitation letter. Secondly, a reminder email will be sent after two weeks. Finally, we will follow up these email contacts (three weeks after the initial email invitation) with a telephone call to the practice manager, lead physician or other primary care provider to offer practice members additional information about the study.

8.1.4 Provider Recruitment Approach

After obtaining an interest from a practice member to whom the invitation email was sent, we will offer all practice members (PHCPs) eligible for the study an information session during which the study is described and participation offered. The Practice Information and Consent Form and information on Navigation Services (Appendix: D—Practice/Provider Recruitment Package) will be provided to all PHCPs prior to or during the information session. All PHCPs will be encouraged to participate. At least one PHCP is required to participate to include the practice in the study.

A practice “champion” (practice clinical or administrative staff) will be identified in each practice, and will be the liaison between the practice and the research team and the main person responsible for overseeing the study implementation in the practice. Each practice Champion will receive a letter (see Appendix: D—Practice/Provider Recruitment Package) providing information on the nature of the study and their role as practice Champion.

8.1.4.1 Recruitment for Interviews

After completing the post-intervention survey, PHCPs will be informed that they may be asked to participate in an interview, and their permission to be contacted for their consent should they be selected to participate will be requested. Those who agree will make up our pool of potential participants.

All providers who complete the post-intervention survey and agree to be contacted will be invited to participate in an individual in-person interview. A conscious effort will be made to recruit a variety of providers (e.g. physicians, nurses and other participating health care providers) which reflect the provider profiles of the practices in the study.

8.1.5 Patient Recruitment Approach

PHCPs participating in the study will be encouraged to refer their patients who could benefit from CRs to these services. PHCPs will be asked complete the study referral form (Appendix: A – Draft Referral Form) for all patients for whom they identify a need that can be addressed by accessing a CR, briefly mention the study to these patients, and ask for their verbal consent to be contacted by a member of the research team to learn more about the study. Patients who agree will receive a copy of the completed referral form and a sealed package containing two copies of the patient study information sheet and consent form (see Appendix: E – Patient Information and Consent Forms) and a pre-paid envelop to mail their written consent to the study team.

PHCPs will fax completed patient referrals to the study team. Upon receiving a copy of the patient referral, a member of the research team (i.e. Research Assistant) will contact the patient by telephone to explain the study and obtain their verbal consent to participate. They will also instruct the patient to mail a copy of their signed consent form (see Appendix: E – Patient Information and Consent Forms) to the research team using the pre-paid envelope in their patient study information package.

Upon receiving the patient's verbal consent, the research assistant will administer a survey, after which they will reveal the concealed arm allocation and inform the patient of the arm to which they are randomized (control or intervention) (see Section 6.1.2).

A more detailed description of the consenting process is provided in section 12.2: Obtaining consent.

8.1.5.1 *Recruitment for Interviews*

After completing the post-intervention survey, patients will be informed that they may be asked to participate in an interview, and their permission to be contacted at that time for their consent should they be selected to participate will be requested. Those who agree will make up our pool of potential participants. Patients may also be invited to participate in an interview at the end of the survey. The interview would then be scheduled at the respondent's convenience.

9 TOOLS AND MEASUREMENTS

Quantitative data will be obtained principally from surveys, although study personnel notes, including the navigator documentation of interactions with the patient, providers and CRs will be used for the process evaluation. A diagram showing the schedule for these measurements is found in Additional Information: 6 – Instructional Information

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Additional Info 6A - English RCT Study Process (2017-Dec-28)

Additional Info 6B – English ARC Referral Form RCT video (2017-Dec-27)
https://www.powtoon.com/online-presentation/fUFWyTAINPD/rct-arc-referral-form/?mode=movie

Additional information: 7 – Timeline.

9.1 QUANTITATIVE TOOLS AND MEASUREMENTS

9.1.1 Referral assessment:

A baseline referral rate will be calculated using a method for collecting observational data (i.e., card study) (55). For a period of 1 week prior to the study implementation, participating PHCPs will be asked to indicate (on a designated card) each patient that he or she referred/recommended to attend a community program.

In addition to completing referral forms for all patients directed to a CR during the 12 month study period, post-study implementation referral rates will be calculated using a similar method for observational data collection (i.e., card study). Since we anticipate seasonal variation in referral rates, a post-intervention referral rate will be measured for a period of 1 week exactly 12 months after the initial assessment to eliminate the impact of that variation.

9.1.2 Practice Survey:

This survey tool (see Appendix: G – Practice Survey) captures general information on the practice profile, services offered, equity orientation, and collaboration with other healthcare providers and organizations.

This survey will be given to the practice "Champion" who will be instructed to get the assistance of any other practice member to complete it at baseline only.

9.1.3 Provider Survey:

A survey tool (Appendix: H – Provider Survey) will capture the profile of participating PHCPs, their confidence in managing complex patients, as well as several dimensions of work that will help us understand in which context the intervention is most effective. These dimensions are:

Section A: Knowledge, attitudes, & practice, with reference to vulnerable populations

Section B: Contextual factors

Section C: Change valence

Section D: Climate

Section E: Organization readiness for change

Section F: Implementation effectiveness

Section G: Experience with Navigator

All participating PHCPs will complete the survey at baseline before patient enrolment begins, as well as near the end of the intervention period, but before the intervention is removed so as to not contaminate the responses by the effect of removing the intervention.

9.1.4 Patient Survey:

This survey tool (Appendix: K – Rapid Cycle Evaluation) captures the attributes listed below. Items in red will be administered to patients in allocated to the intervention arm only.

Section A: First Contact Access
Section B: Needs/Difficulties/Use of healthcare
Section C: Ability to engage
Section D: Risk assessment score
Section E: Health/Chronic condition
Section F: Quality of Life VR-12
Section G: Social support
Section H: Social vulnerability index questions
Section I: Socio demographic
Section J: Pre-Intervention Community Resource Referral
Section K: Pre-Intervention Experience with other Community Resources
Section L: Health Action Process Approach

Section M: Patient Activation Measure
Section N: Post-Intervention Main Outcome
Section O: Post-Intervention Community Service Evaluation
Section P: Post-Intervention Navigator assessment

This survey will be administered at patient enrolment (i.e., pre-intervention) and at the end of the patient three month intervention period (i.e., post-intervention). Some questions are only asked at baseline (pre-intervention), and others are only asked after the three month intervention period (post-intervention).

9.1.5 Health Administrative Data:

Health administrative data housed at the Institute for Clinical Evaluative Sciences (ICES) will be used to understand the impact of the intervention on the utilization of health care services. These include measures of physician visits, emergency room utilization, and hospitalization. Data from participating patients and practices will be uploaded to ICES and linked to their corresponding profiles within ICES databases. Consent for this linkage is included in the practice and patient information and consent sheet.

9.1.6 Navigator Training Assessment

The Navigator will complete a survey about their training which assesses their motivation to learn (before the training), motivation to transfer learning (completed immediately after the training), use of knowledge and skills in their everyday work, and an evaluation of the training program (Appendix: J – Navigator Training Assessment). Assessment is also incorporated throughout the online learning modules with multiple choice tests, case studies and reflective exercises.

The Patient Navigator Training website also includes a Navigator Workbook and a Discussion Board which provide a means of self-assessment and ongoing learning. The Navigator Workbook is designed to help the Navigator reflect on their learning, integrate their knowledge with previous experience, and think about how to apply this information in their Navigator role. Navigators will respond to guided questions about educational content.

The Discussion Board is a community forum that is used during the online training, and prior to and after each of the face-to-face (F2F) sessions. Navigators can post questions about topics and learning materials, view videos, respond to case studies, and share learning resources. This space will also help Navigators prepare for the F2F sessions and support their ongoing learning through dialogue following the training program.

9.1.7 Rapid Cycle Evaluation:

This tool (Appendix: K – Rapid Cycle Evaluation) will allow the researchers to determine whether the processes established in that practice meet the expectation of the practice and how these need to be adapted to respond to the practice’s need. This tool may be modified by information we collect as the progresses. Its intent is to allow us to document the fidelity of the intervention, and adapt the implementation based on practice feedback. Any adaptation of the implementation will be limited to the aspects described in this protocol. Such adaptation may include changing the type of flyers available in the waiting room or eliminating the waiting room stand entirely; adapting the referral form to facilitate referral or capture information the practice deems essential. This will also be an opportunity to address problems that had not been brought to our attention earlier.

The Rapid Cycle Evaluation (RCE) will be conducted as followed:

1. A first evaluation survey will be administered near the end of the "implementation phase" of the study (1 month period) to help the research team understand the success of the study set up in the practice. This survey will be completed by a member of the practice once. It may be administered a second time depending on the answers provided in the initial survey.

2. A second evaluation survey will be administered during the "study phase" (12 month period) to help inform the research team on the integration of study activities in the practice. This survey will be completed by a member of the practice monthly, or more or less frequently depending on the status of the previous assessment.

The RCE will be completed by a member of the practice either by phone (administered by the Research Assistant or Research Coordinator) or electronically (i.e., email).

9.2 QUALITATIVE TOOLS AND MEASUREMENTS

The questions in the following three Appendices are a template for the interviews that will be carried out with the providers, patients and navigators (Appendix: L – Provider Qualitative Themes**,**

Appendix: M – Patient Qualitative Themes**,** Appendix: N – Navigator Qualitative Assessment **)**.

A mix of exploratory and predominantly explanatory questions will be used for provider (Appendix: L – Provider Qualitative Themes) and patient (

Appendix: M – Patient Qualitative Themes) interviews. Exploratory questions capture patient or provider's perspectives about access to primary care, patient vulnerability and navigation. Explanatory questions are specific to each of the study objectives. The qualitative assessment is intended to be explanatory to the quantitative assessment. As such, the qualitative assessment will always follow the quantitative assessment. The explanatory questions will be based on survey results and will vary from one study condition to the next. As such, the qualitative tools are grounded in the quantitative findings. (56) The qualitative data collection from patients will emulate the staggered approached initiated with the quantitative data collection. Thus, at this point in time, we can only anticipate that the line of questioning will be based on broad constructs from the surveys, and more specific interview guides will be developed once the quantitative analyses are completed. Thus, the interview questions may change as the findings from the quantitative data will be used to inform these questions.

9.2.1 Timing

Provider interviews (Appendix: L – Provider Qualitative Themes**)** will be conducted on a purposefully recruited sample (see Section 8.1.4.1) within 2 months after they have completed the follow-up (post-intervention) survey but before the intervention is removed so as to not contaminate the responses by the effect of removing the intervention.

A member of the practice (i.e., the practice "Champion") will answer a series of questions pertaining to the activities carried out throughout the study (i.e., practice wrap-up assessment).

Patient interviews (

Appendix: M – Patient Qualitative Themes) will be conducted on a purposefully recruited sample (see Section 8.1.5.1) at the end of the three months intervention period (Post-intervention). Patient interviews will be conducted within two-months after having completed the intervention period, as soon as possible after having completed the Post-Intervention survey.

Navigator interviews (Appendix: N – Navigator Qualitative Assessment) will take place at the end of study period to help us understand the strengths and challenges of the navigation approach.

9.3 STUDY DOCUMENTATION

9.3.1 Practice Set-Up Log

The Research Coordinator will document all encounters with the practice to keep track of the implementation of study activities in the practice (e.g., referral process, promotional material, navigator integration), practice/provider needs and preferences, and required adaptations to facilitate the implementation of the intervention in the practice. The type of documentations to be captured is shown in Appendix: O – Practice Set Up Log. Note that this log may be adapted as required.

9.3.2 Navigator Log

The navigator will document encounters with patients, primary care practice personnel and CRs. The type of documentations to be captured in the Navigator log is shown in Appendix: O – Practice Set Up Log

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Appendix P - Practice Set-Up Log (2017-Dec-27)

Appendix: P – Navigator Log. Note that this log may be adapted as required.

10 DATA ANALYSES

10.1 DEFINITIONS

10.1.1 Primary Outcome: Access

The primary outcome measure is **access** to CRs amongst the patients participating in the study. This outcome reflects the ability of the navigator to help patients overcome barriers to access and reach the CR. We will assess this outcome in both arms (control and intervention) three months after enrolment in the study through a patient survey (Appendix: I – Patient Survey). The outcome will be a count of the CRs accessed (as a patient may access more than one CR).

A **community resource** is defined as: A service, a resource, a program that is offered in the community and that addresses social or health needs. **Access** is defined as: the use of a community resource. “Use” includes having attended the program; received the service; obtained the resource. The goal of the navigator is to support the patient obtain the resource they need. If the patient attends the resource at least once, it will be considered a positive outcome. Therefore, even if the patient decides that the resource does not meet their needs and discontinues utilization, utilization will be considered achieved. Information available about the extent of utilization and whether the patient discontinued the service and the reason for discontinuing will be captured.

Many resources have a waiting period before the individual can make use of the service. Being on a waiting list does not constitute utilization as it is not given that all individuals on a wait list eventually utilize the service. Our patient partners felt that in cases where the desired resource has a lengthy waiting period, the navigator should connect the patient with another resource that can help address the need to at least some extent. However, being on a wait list for a service and having had an “intake” visit for that service (contact of any sort, telephone, face to face or other) should be considered utilization.

Therefore, **Access** is achieved if:

- The patient accesses the resource at least once
- The patient is on the waiting list AND has had an intake visit for that service.

10.1.2 Secondary outcomes

10.1.2.1 Patient survey

Patients’ social barriers captured in the Navigator log (Appendix: O – Practice Set Up Log

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Appendix P - Practice Set-Up Log (2017-Dec-27)

Appendix: P – Navigator Log) and patient characteristics captured in the patient survey (Appendix: I – Patient Survey) will be used to assess the abibility of the intervention to address equity:

Section I: Social vulnerability index questions
Section J: Socio demographic

The patient survey captures a number of outcome measures that reflect the following dimensions (Appendix: I – Patient Survey):

Section B: Needs/Difficulties/Use of healthcare - *Multiple questions, including two scales (ability to pay and enduring relationship)*
Section C: Ability to engage – *One scale (including three concepts)*
Section F: Quality of Life VR-12 - *One scale*
Section L: Health Action Process Approach - *One scale (including eight concepts)*
Section M: Patient Activation Measure - *One scale*

Section O: Community service evaluation

Section P: Navigator assessment (intervention arm only)

10.1.2.2 Provider surveys

Measures captured in the provider survey will allow us to understand the impact of the intervention at that level. These measures include:

Provider (Appendix: H – Provider Survey)

Section A: Knowledge, attitudes, & practice, with reference to vulnerable populations

Section B: Contextual factors (e.g., organizational structure)

Section C: Change valence

Section D: Climate

Section E: Organizational readiness for change

Section F: Implementation effectiveness

Section G: Experience with the Navigator

10.1.2.3 *Health administrative data*

In addition, health administrative data housed at the Institute for Clinical Evaluative Sciences (ICES) will be used to understand the impact of the intervention on the utilization of health care services. These include measures of physician visits, emergency room utilization, and hospitalization. ICES captures all health care services that are covered through the Ontario Health Insurance Plan (OHIP). It is hypothesized that better access to community health and social resources (the majority of which are not covered by OHIP) would reduce the need for visit to primary care practices, and reduce the risk of poor outcomes, such as emergency room visits and hospitalizations. The following measures exemplify the type of data that will be analyzed

- Visits to primary care physicians (OHIP)
- Visits to specialists (OHIP)
- Emergency room visits (National Ambulatory Care Reporting System [NACRS])
- Hospitalizations (Discharge Abstract Database [DAD])

The analyses of ICES data will be conducted under the section 45 of PHIPA. "Section 45 of PHIPA is designed to enable the work of organizations like ICES that conduct analysis and compile statistics about the management and effectiveness of health care." http://www.ices.on.ca/Data-and-Privacy/Privacy%20at%20ICES.

10.2 QUANTITATIVE ANALYSES

All analyses will be performed using an intent-to-treat approach.

10.2.1 Descriptive

Quantitative measures will be reported descriptively, with measures of central tendencies and dispersion. Descriptive analyses will also be used to represent the profile of the practices, providers, and the profile of patients in the two study arms to allow a visual assessment of potential differences.

Provider scales of effectiveness (Knowledge, attitudes, & practice, with reference to vulnerable populations) at Pre-intervention, post-intervention, as well as the difference between these two scores will be reported using summary measures and measures of dispersion.

10.2.2 Comparative

The main analysis to address **Objective A, Deliverable 1** will be a comparison of total number of CRs accessed by the patients in the Control and Intervention arms.

Because the primary outcome is a count, we will use a Poisson regression to compare the two arms. Other measures will be analyzed using chi Square or t-tests and linear, as appropriate.

10.2.3 Regression analyses

The unit of analysis for all regression analyses will be the individual patient.

For the outcome measures obtained from data collected during the study, we will conduct regression analyses where the dependent variable will be, in turn, the measures of effectiveness identified above, while the independent variables will be practice, provider, and patient level co-variates that may help us under what attributes are associated with better outcome.

10.2.3.1 Patient Level Outcomes

For outcomes measured at the patient level, the following regressions will be carried out

- Unit of analysis: Patient
- Type of analysis: Linear for continuous scales, Logistic for dichotomous outcomes, Poisson for count data.
- Dependent variable: In turn: each outcome measurement
- Moderator: Arm (control vs intervention)
- Other independent variables: Some measures of patient, provider and practice characteristics that could help explain the impact of the outcome

The regressions aim to compare the effectiveness of the intervention accounting for potential differences in confounders in the two arms, as well as understand the factors that are predictive of better outcomes. In the latter, variables having a p value smaller than 0.10 will be retained.

10.2.3.2 Provider Level Outcomes

Bootstrap moderated mediation analyses will be carried out to test associations between change readiness predictors and outcomes predicted by the theory. Results will be considered statistically significant based on *p* values equal or smaller than 0.10.

- Unit of analysis: Practice (and individual when theoretically justified)
- Type of analysis: Linear bootstrap
- Predictors: Psychological safety, Satisfaction with operational procedures, Psychological uncertainty, Change fatigue, Supporting infrastructure, Team type
- Moderator: Arm (control vs intervention)
- Mediators: Appropriateness, Personnel benefit, Role overload, ambiguity and conflict, Impact empowerment, Interprofessional conflict, Climate support for innovation, Commitment to change, Task interdependence, Quality of idea implemented
- Outcome: Implementation effectiveness + Provider survey scales measuring effectiveness

10.2.4 Multivariable analyses to assess equity

The main analysis will include all patients enrolled in the trial, regardless of language preference. Secondary analyses will assess separately and compare the impact of the intervention on individuals' ability to access health or social resources in their language of choice for French speaking and English speaking participants. In these analyses, the language variable will be used as an effect modifier.

10.2.5 Health Administrative Data

Patients participating in the study were asked to provide their Ontario Health Insurance Program (OHIP) number, and providers participating in the study were asked to provide their OHIP billing code. We will link the study data to health administrative data housed at the Institute for Clinical Evaluative Sciences using the patient OHIP number and provider billing code.

10.2.5.1 Representativeness

We will compare the profile of providers participating in the study to others in their practice and in the region. We will also compare the profile of patients having participated in the study to all patients of participating providers. This will allow us to understand the profile of patients who are more likely to be referred to navigation services.

10.2.5.2 Outcome data

Some outcome measures will be obtained from health administrative data housed at the Institute for Clinical Evaluative Sciences. For these analyses, the date of patient enrolment is the start of year 1. The two years that follow the start of the intervention are years 1 and 2. Year 0 is the 12 month interval preceding the enrolment date.

The mean difference in Visits to primary care physicians (OHIP) and Visits to specialists (OHIP) measures between year 1 (ramp up year) and year 0, and year 2 (full effect) and year 0 will be assessed and compared in the intervention and control arm.

The rate of Emergency room visits (National Ambulatory Care Reporting System [NACRS]) and Hospitalizations (Discharge Abstract Database [DAD]) in year 1 and year 2 in the control and intervention arm will be compared.

10.3 QUALITATIVE ANALYSES

Consistent with principles of an explanatory sequential design of a phenomenological tradition, we will begin by collecting and analyzing the patient and provider surveys, the results of which will guide the qualitative line of questioning which will seek to further explore survey findings.

The interviews with providers will be used to further contextualize survey results, while patient interviews will allow us to explain certain differences experienced by the intervention and control groups while also accounting for the regional context (Ottawa vs. Sudbury). Preliminary questions for the patient interview guide and provider interview guide were developed from the ARC project objectives. These questions were aligned with elements of the study's conceptual framework including the Access Framework and the Health Action Process Approach to provide a theoretical underpinning for the qualitative analysis. The interview questions will be further developed based on the quantitative results from the first participating providers and patients. As further quantitative data is gathered, interview guides will evolve based on a combination of the quantitative and qualitative results stemming from the surveys and interviews respectively.

The overarching research question guiding this qualitative phase is: *What is the provider and patient experience with the navigation to CRs?* Data will be analysed inductively, including an in-depth within-case analysis (e.g. data of patient participants in the control arm) and an in-depth between-case analysis (e.g. data of patient participants in the control arm compared to data of the participants in the intervention arm(s). A between region analysis will be conducted to explore the different ways in which Ottawa and Sudbury contexts understood and experienced access to CR and navigation. Data collection, coding and analysis will follow a sequential iterative process.

These interpretative thematic analyses will be completed using an iterative process. (57;58) Data analyses will be completed in six phases as described by Braun and Clarke (2006). **Phase 1**: Interviews will be audio recorded and then transcribed verbatim. As data continues to be gathered, the research assistants and researchers will independently read the entire transcripts repeatedly to immerse themselves in the data. These transcripts will be entered into NVivo 11 (computer software program) for subsequent coding and analysis. **Phase 2:** Research assistants will do the initial coding of the data by identifying individual segments of text. Individual segments of text with similar codes will be collated. A process of inter-rater reliability will be followed for the first 3-4 transcripts. Independently coded transcripts will be compared to identify similarities and differences in the coding process. Discrepancies will be addressed by coding or recoding. Discrepant interpretations may identify areas for further exploration with a subset of participants to enrich the analysis by including multiple interpretations. (59) **Phase 3:** Members of the research team will work through the rest of the analyses: Phases 3-6. As the researchers assemble similar codes they will identify preliminary themes with illustrative examples from the data, including any recurring, converging, and contradictory patterns, or any linkages to theory. As more data are collected and reviewed, coded themes will be revised and refined. **Phase 4**: Identified themes will be reviewed in relation to the coded extracts and the entire data set followed by producing a thematic map to represent the entire analysis. **Phase 5**: Each theme will then be defined and named accordingly. **Phase 6:** Examples from coded extract for each final theme (quotes) will be retrieved and used as supportive evidence for final reporting. Throughout this process, researchers will maintain a reflexive journal.

Within this research study, several of Guba and Lincoln's (60) trustworthiness criteria will be adopted. Specifically, the study's rigor will be ensured by applying methods of credibility, transferability, dependability and confirmability. For credibility, several members of the research team will be involved in the analyses. As such we will work collectively to come to our conclusions by using a process of negotiation and consensus. (61;62) Therefore, multiple perspectives on the study will be considered. (62) This will be instrumental in establishing that the findings of the proposed research inquiry are authentic and credible. (63) Further, member checks will also be incorporated within the protocol to ensure accuracy of the findings by presenting the analyses and findings back to a select number of patients and providers (members) who contributed to the data. The purpose of member-checking is to confirm that the interpretation and understanding of the researchers is what was intended by the participants. (63) For transferability, thick descriptions will be compiled and developed to elucidate all of the research processes (methodological choices, purposeful sampling, data collection, data analyses) that were completed within this study. (63) This will allow the researchers to make sure that this study can be applied to different settings with the same potential for different populations. (62) For dependability, a detailed audit trail will be kept to ensure that the processes used throughout the collection of data and analyses are consistent for the duration of the study. (63) For instance, a detailed account of the research activities and decisions that are made will be kept in order to detail how the data obtained were collected, documented and examined. For confirmability, through the process of reflexive journaling, the researchers will identify their assumptions, conceptions, and experiences and how this might impact upon their analysis of the data. The journals will enable researchers to explore this subjective element and allow them to discuss these as part of the coding and interpretation process. (61) The investigators will use 'bracketing' to set aside personal biases, knowledge and perspectives. (64)

11 SAMPLE SIZE CALCULATIONS

We established the minimally clinically important difference at 20% absolute, and 50% relative. A total sample size of 368 patients (184 in each arm) is required to detect an absolute difference in 20% from 40%-60% (relative difference of 50%), given a type I error or 5% and type II error of 10%, accounting for continuity correction and a dropout rate of 25%.

Assuming an average practice size of 3 participating providers, an annual referral rate of 68 patients per practice, a 60% participation rate, recruiting 9 practices will achieve a sample size of 365. Assuming 25% drop out rate for the practices, we will recruit 12 practices, 8 practices in the Champlain LHIN and 4 in the North East LIHN to ensure we are adequately powered.

Referral Assumptions: Three physicians per practice, each with a panel size of 1500 patients of which half will have a condition for which a community resource could be beneficial, of whom 60% 1350 will have at least one encounter during the 12 month study period (4500 x 50% x 60% = 1350). Assuming a 5% referral rate, and a participation rate of 60%, we estimate 41 participants per practice.

We assumed a relatively low referral rate of 5%, based on physician self-reported measures of the likelihood of referring patients to CRs to address **health risk factors**, which suggest that this is not a commonly used practice. One study indicates that 17% usually or always provide referrals to smoking cessation programs, 4% to physical activity, 7% for management of alcohol consumption, and 6% for nutrition.(65) Yet another study suggested that 42% of physicians refer patients to physical activity. (66;66) Referrals for the management of chronic conditions are higher. A study conducted in Canada reported that 50% of physicians referred to diabetes education programs (67) but it remains unclear what proportion of their patients these physicians refer. Another Canadian statistic suggest that approximately 25% of individuals with chronic condition who could benefit from accessing CRs are referred to these services.(68) The statistics on referrals vary considerably, and are related to the type of CRs sought.(29;65-67;69-79) There is no documentation on the actual referral rates to a community resource of any kind available in the community by primary care provider; the target of this study.

Control Access Rate Assumption: Previous studies reported broadly different access rates to community resources, ranging between 2.5% and 70%, depending on the resource.(29-33;80) We powered the study to detect a change from 40% to 60% because these estimates produced the largest sample size requirements.

11.1 QUALITATIVE SAMPLE

11.1.1 Providers

Given the potential participation of group practices with large number of providers, a limit of 2 providers per practice will be invited to participate in an individual interview. Selection criteria will be applied to ensure an even distribution of providers based on number of vulnerable patients within the practice and level of difficulty in providing care to individuals with social vulnerability. Further selection criteria (gender, language, years worked in primary care) will be applied to achieve a sample which is representative of providers. We anticipate 12-15 providers will be required to reach saturation.(81) Providers will continue to be recruited until response saturation has been achieved, likely 8-10 in Ottawa and 4-5 in Sudbury.

11.1.2 Patients

We will recruit approximately 35-40 patients to participate in an interview. We will seek an even distribution of respondents by regions based on the number of participating practices in the region (see patient selection flow chart below). For instance, we are expecting 8-10 practices to participate in the Ottawa region and between 4-5 in Greater Sudbury region, or a ratio of 2:1. Patient recruitment will follow this 2:1 ratio.
Participants will be recruited from all study conditions; 1) those in the intervention group who contacted and utilized the Patient Navigator, 2) those in the intervention group who did not utilize the Patient Navigator, 3) those in the control group who utilize the 211 services, and 4) those in the control group who did not utilize the 211 services. Patients will also be purposefully selected to language of choice, and to represent both those who accessed a community resource and those who did not.

Selection criteria will be applied at the regional level to ensure an even distribution of patients based on language and barriers to access (low to high number based on post-intervention patient survey). Further selection criteria (age, gender, the percentage of patients who accessed a CR during the study period) will be applied to achieve a sample which is representative of patients who participated in the quantitative portion of the study (based on descriptive results from the surveys). We will then recruit patients for interviews accordingly. Recruitment will continue until saturation within each subgroup has been achieved.

12 ETHICAL CONSIDERATIONS

12.1 OBTAINING CONSENT

12.1.1 Practice and provider consent

Details of practice and provider recruitment are provided in section 8.1 Practice and Provider Recruitment.

A diagram representing the different consent points is shown in Appendix: Q – Consent Pathways. Following the presentation delivered at the practice, if at least one PHCP is interested in participating in the study, the practice invitation letter and study information sheet and consent form (Appendix: D – Practice/Provider Package) as well as selected promotional material will be left with the practice to be circulated by a person designated by the practice to all practice members (they see fit to invite), and encouraging individuals desiring more information will contact the study team. Those agreeing to participate will affix their signature on the consent form.

12.1.1.1 Post intervention interviews

At the end of the provider's second survey (near the end of the intervention), some purposely selected providers will be invited to participate in the study interviews. Signed consent will be obtained at the time of the interview.

12.1.2 Patient consent

The steps in the patient consenting pathway are depicted in Appendix: Q – Consent Pathways. In all practices, when the PHCP wishes to direct a patient to a community resource that could benefit them, and feels that the patient could benefit from navigation services, the PHCP and patient will have a discussion about the need for that resource and its potential benefit, introduce the ARC navigation study using a brief scripted explanation, and request the patient's permission to provide their name to the study team so they can explain further what is involved.

Patients consenting to be contacted by the research team, will receive a copy of the referral form required for the study and a study information and consent package. They will be told that a member of the research team will follow up with them with more information. The study information and consent package contains two copies of the Study Information Sheet and Consent Form (Appendix: E– Patient Information Sheets and Consent forms) as well as a stamped envelope addressed to the research study office.

The referral form will be faxed to the research team or otherwise provided through a standard secure practice process to trigger the recruitment process. A research assistant will telephone patients, review the Study Information Sheet and Consent Form, and seek their verbal consent to participate in the study. The consent covers participating in the navigation service to which will be randomized, completing a telephone baseline and post intervention survey, and providing their OHIP # to allow it to be linked to health administrative databases (via ICES) to conduct analyses related to the study intervention. Agreeing to provide their OHIP # is not a requirement for participating in the study and receiving the navigation services. Patients will then also informed that approximately one in 10 patients will be invited to an interview at the end of the study period, and that if they were to be selected, their consent for that component of the study would be sought at that time. The research assistant then asks if this is an appropriate time to administer the baseline patient survey. If not, a separate meeting is scheduled for that.

Consenting patients will be asked to sign the study consent forms and mail one copy to the research office using the stamped envelope. The consent form will separately indicate patients' consent/non-consent for study participation and to have their OHIP# linked to health administrative databases. Following the baseline survey, the research assistant will enter the patient study information in a program provided by the statistician that will reveal the treatment allocation for that patient.

12.1.2.1 Post intervention interviews

Patients selected to participate in the post intervention interview will be identified during the post-intervention survey (3 months after recruitment) based, in part, on their response to that survey. These patients will be invited to participate in the interview at that time and the interview process will be explained. Consenting patients will be asked to sign separate consent form (see Appendix: E– Patient Information Sheets and Consent forms). Interviews will take place in person (preferably) or by telephone. Participants will be asked to sign signed separate consent form at the time of the face to face interview or provided with a consent form to complete and return by mail if the interview is done by telephone.

12.2 PARTICIPANT COMPENSATION

12.2.1 Practice/Providers

Some study related requirements may cost the practice time. These include the time spent by front staff requesting patient consent to be contacted by the study team or time spent by primary care providers to complete a survey. To offset the opportunity costs associated with the practices' participation in this study, we offer $400 per practice, plus $200 per primary care provider (up to $800) (physician/nurse practitioner who refers patients) for their participation in the study.

13 POTENTIAL RISKS AND BENEFITS

13.1 RISKS

13.1.1 Practices/Providers

The participation in this study could be disruptive to practices and/or providers regular work flow as such resulting in potential physical or psychological risk (i.e., fatigue, stress). The study team will work collaboratively with practices and providers to define necessary research tasks, determine reasonable expectations, and minimize potential disruption to all. There is also potential for social risk whereas some providers within a participating practice who prefer not to participate may be viewed negatively by their peers, thus compromising their professional relationships or a provider may feel obligated to participate if they are part of a participating practice. A clear statement outlining such social risks is included in the letter of information and it is stated that employers/colleagues will not be made aware of who is participating and who is not.

13.1.2 Patients

There is minimal risk for patients involved in this study. There is the risk that patients' personal identifying information and OHIP# used for study purposes could be accessed by unauthorized individuals. To mitigate against this risk, all reasonable steps will be taken to secure this data, including using a secure online database (SSL) that is maintained in Canada, encrypted and password protected, and only accessible to the Navigators/Coordinator assigned to the patient (personal identifying information, but not OHIP#) and study staff (personal identifying information and OHIP#).

Completing the survey and participating in the interview can cause a burden to the patients. To minimize this burden, we will conduct all surveys by telephone at a time of the patient's choosing (removing the need for patients to complete the survey themselves and eliminating the need for further travel). . Interaction with the Navigator or with the Ontario 211 services could cause unexpected stress potentially as social barriers are discussed or as the Navigator helps the patient learn how to navigate the system. The Navigator will take all possible steps to overcome such social barriers when assisting the patients to access the community resource which they were referred to. Ontario 211 is a publically available service that uses trained respondents.

13.2 BENEFITS

13.2.1 Practices/Providers:

Participation could benefit the provider because they will learn about existing CRs that can help meet their patients' needs, and this may allow them to provide more comprehensive care to their patients. Also, when their patients receive navigation services to access CR, they may be more likely to utilize these services and this may result in reduced number of visits or duration of visits time with their PHCP provider for concerns that may be addressed by these resources.

Patients who participate in the study may be more resourceful at identifying and accessing services that they need, thereby potentially reducing the level of support required for them by the practice members.

13.2.2 Patients

All patients may benefit from participation by learning through Ontario 211 or the patient navigator about CRs available to them to address their primary health care needs and may be more likely to use them, thereby reducing unmet needs. Patients randomized to the intervention arm, the Patient Navigator, may receive additional support to address social barriers, which we postulate will increase their ability to utilize the necessary CRs.

14 PRIVACY AND SECURITY OF STUDY DATA

All data collected will be securely stored in the study database using all reasonable protection steps (encryption, secure network, limited access, password protection). Only members of the study team will have access to the entire dataset. For the purpose of analyses, all data will be stripped of the respondent's (practice, provider, and patient) identifiable information and will be identified by an undecipherable study code. A separate Microsoft Access database will be used to track patient participation (e.g., completion of study activities) and allow the participants' study code to be linked to their information for the purpose of communication between the research team and study participants. This tracking database will be password protected and will be stored securely and separately from the study data.

Information on the referral form will be securely transmitted from the practice to the research team. The current plan is for communication between the research team and the practice to take place through fax. The research team will use a fax number dedicated to the study, and store the fax machine securely in a locked filing cabinet. Only members of the research team will have access to these documents. The Research Assistant will enter the information provided on the faxed referral form and patients' OHIP # with specific consent electronically in the tracking database containing identifiable patient information and a corresponding patient ID.

Should a participating practice chose a different method of communicating patient information with the research team, we will ensure that the approach meets the TCPS-2 privacy confidentiality requirements.

Qualitative study data will be audiotaped and transcribed verbatim with consent, and transcripts will be securely stored in locked filing cabinets and/or on a password-protected, encrypted server in the investigator's office at the Bruyère Research Institute or at Laurentian University. Data collected in the Sudbury region will be stored on a secure server maintains and backed up by the IT department at Laurentian University conforming to industry standards for security. Data sharing between the Sudbury and Chaplain regions will be conducted using secure methods.

Patient survey data will be securely transmitted to a secure, encrypted, password-protected online database. The server for this database (https://www.qualtrics.com/) is maintained in Canada and conforms to industry standards for security (https://www.qualtrics.com/security-statement/). The flow of data from the patient-provider encounter to the study personnel, storage of data, and transfer of data from study to the Institute of Clinical and Evaluative Sciences (ICES) for linking to health administrative data will be performed according to ICES procedures. ICES applies a variety of measures to protect the information entrusted to it. Physical security measures, technological safeguards like encryption and a robust framework of policies and procedures work together to protect information.

These data are securely held in encoded form and analyzed at the Institute for Clinical Evaluative Sciences (ICES, www.ices.on.ca). All relevant datasets were linked using unique, encoded identifiers and analyzed at ICES.

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15 RESEARCH TEAM

The team is composed of a good mix of senior and junior researchers with expertise in health service delivery and equity in primary care (Dahrouge), project management, teamwork and collaboration (Chiocchio), rural and northern health (Gauthier), access to French health care services and equity (Lemonde), chronic diseases, women’s health and health of Francophone populations living in a minority situation (Prud’homme).

Simone Dahrouge, PhD (Nominated-PI) is the Director of the C.T. Lamont Primary Health Care Research Centre, the research arm of the Department of Family Medicine for the University of Ottawa. Dr. Dahrouge’s work focuses on optimizing equity and access to primary care, and understanding the impact of interventions in primary care reform on quality of care and patient outcomes. Dr. Dahrouge is an Adjunct Scientist with the Institute of Clinical Evaluative Sciences (Primary Care and Population Health Research Program) and will lead all analyses related to health administrative data.

François Chiocchio, PhD (Co-Principal Investigator)

François Chiocchio is Professor of Organisational Behaviour and Human Resource Management at University of Ottawa's Telfer School of Management. His research focuses on projects, teamwork, and collaboration in various organizational environments, including health care organizations in Canada and Africa. A measure and assessment specialist, he developed several instruments for selection purposes or that provide feedback on competency development; work for which he was praised with national (i.e., Canada) and provincial (i.e., Québec) awards. Dr. Chiocchio is one of the only academics specialized in industrial-organizational psychology certified as a Project Management Professional by the Project Management Institute and as a Certified Human Resources Professional (CHRP) by the Canadian Council of Human Resources Associations.

Alain Gauthier, PhD (Co-Principal Investigator)

Alain Gauthier is an Associate Professor with the School of Human Kinetics and Faculty Investigator at the Centre for Rural and Northern Health Research (CRaNHR) at Laurentian University. Dr. Gauthier is primarily interested in research related to the health of sociolinguistic minorities, with a particular emphasis on rural and northern areas. He currently leads the Francophones Health research program at CRaNHR related to the access to, and quality of, French Language Health Services for persons residing in northern Ontario. He is a member of the Board of Directors of the Centre de santé communautaire du Grand Sudbury and of the Club Richelieu Les Patriotes du Sudbury.

Justin Presseau, PhD (Investigator)

Dr. Presseau is a Scientist and health psychologist at the Ottawa Hospital Research Institute and Assistant Professor in the School of Epidemiology, Public Health and Preventive Medicine at the University of Ottawa. His research draws upon theories and approaches from health psychology and behavioural medicine to develop and evaluate interventions focused on changing healthcare professional behaviours and health behaviours of patients and the public. He has expertise in the use of theories of behaviour and behaviour change to inform the development and evaluation of interventions designed to change the behaviour of healthcare professionals, patients and the public.

Manon Lemonde, RN, PhD (Investigator)

Manon Lemonde is an Associate Professor in the Faculty of Health Sciences, at the University of Ontario Institute of Technology (UOIT). She is also an Instructor at Laurentian University in Sudbury. Dr. Lemonde's research areas of specialty include chronic disease management and seniors' health. She is investigating how francophone seniors are able to access French health-care services in Ontario, as well as the barriers and facilitators for obtaining these services. She is also investigating self-management options for seniors dealing with chronic diseases.

Claire Kendall, MD, PhD (Investigator)

Dr. Claire Kendall is an Associate Professor with the Department of Family Medicine, University of Ottawa; Clinician Investigator at the C.T. Lamont Primary Health Care Research Centre, Bruyère Research Institute; and practicing family physician with the Bruyère Family Health Team. She is an Adjunct Scientist at the Institute for Clinical Evaluative Sciences (ICES) and in the Clinical Epidemiology Program at The Ottawa Hospital Research Institute. Dr. Kendall has established a program of research aimed at improving the delivery of primary health care for populations with or at risk for HIV. Dr. Kendall is Principal Investigator on the Participatory Research in Ottawa: Understanding Drug Use (the PROUD) study, a community-based participatory research cohort study which aims to prioritize community engagement and involvement in understanding HIV risk among people who use drugs in Ottawa. Her research relies on multiple methodologies, including secondary analysis of the health administrative data held at ICES, primary collected cohort survey data, qualitative methods, and the meaningful involvement of patients and people with lived experience.

Rose-Ann Devlin, PhD (Investigator)

Earning her Ph.D. in economics from the University of Toronto, Rose Anne Devlin has been a professor in the Department of Economics, University of Ottawa, since 1991. Dr. Devlin is currently the vice-dean of research for the Faculty of Social Sciences. Professor Devlin has published work on a broad range of topics, including: the incentive effects of physician remuneration schemes, the structure of primary-care practices (including decisions to collaborate with other health-care professionals), and how supplemental insurance affects health care usage. Recently, she has been working on issues associated with accessing regular primary care physicians and the role of social supports.

Denis Prud'homme, MD, MSc (Investigator)
Denis Prud'homme is the Associate vice-president Research and the Scientific director of the Institut de recherche de l'Hôpital Montfort. He obtained a medical degree and a Specialist's Certificate in Family Medicine as well as a bachelor degree in kinesiology and a master degree in exercise physiology at Laval University. He is a Full Professor at the School of Human Kinetics and he was Dean of the Faculty of Health Sciences from 2002 to 2012. He is also an active clinician at the Sports Medicine Clinic Outaouais. Dr. Prud'homme is involved in research on the effects of exercise in patients with health problems such as obesity, diabetes, and metabolic syndrome.

Monica Taljaard, PhD (Investigator)
Dr. Taljaard is a Senior Scientist with the Clinical Epidemiology Program, Ottawa Hospital Research Institute and an Associate Professor in Epidemiology and Community Medicine at the University of Ottawa. Dr. Taljaard is biostatistician and member of the Ottawa Methods Center, where she works with researchers and clinicians from a variety of backgrounds to design and analyze cluster randomized trials, standard clinical trials, and observational studies. She has co-authored more than 100 publications in peer-reviewed journals and more than 100 research presentations at national and international conferences. Dr. Taljaard has established successful and productive collaborations with many clinicians and scientists and she has been a co-applicant, statistical advisor and collaborator on over 50 funded clinical and health services research projects.

16 RELEVANCE

This project is grounded in primary care, the foundational pillar of our healthcare system, a sector that is arguably the most efficient at achieving population health and reducing disparities. (31) It builds on existing provincial investments (211, CRs, the Healthline) and aligns with upcoming primary care reforms which are anticipated to promote a better integration between primary care and CRs. It is patient centered and directly addresses three Ministry and Long Term Care's 2015 strategic objectives: Access to the right care, Integration and coordination of community care, and supporting patients achieve health goals through information and education. (34-36;39;82;83)

The program will assess the implementation and subsequent use of a Francophone navigation strategy to optimize access to care received by Francophone living in minority situations. It will support Franco-Ontarians overcome barriers to care across the various access dimensions. Finally, it will also provide a better understanding of the gaps in resources serving the Francophone population.

The results of this project will also support decision makers regarding the objectives cited in the recent Price report(9), specifically the objectives 18 and 19 regarding "System Collaboration, Coordination and Scale Economies".

2. REFERENCES

(1) Pennant M, Davenport C, Bayliss S, Greenheld W, Marshall T, Hyde C. Community programs for the prevention of cardiovascular disease: a systematic review. Am J Epidemiol 2010 Sep 1;172(5):501-16.

(2) March S, Torres E, Ramos M, Ripoll J, Garcia A, Bulilete O, et al. Adult community health-promoting interventions in primary health care: A systematic review. Prev Med 2015 Jan 1;76(0):94-104.

(3) Canadian Medical Association. CMA Position Statement:Ensuring Equitable Access to Care: Strategies for Governments, Health System Planners, and the Medical Profession Health System Planners, and the Medical Profession. https://www cma ca/Assets/assets-library/document/en/advocacy/PD14-04-e pdf 2013

(4) Public Health Agency of Canada. Creating a Healthier Canada: Making Prevention a Priority. http://www phac-aspc gc ca/hp-ps/hl-mvs/declaration/pdf/dpp-eng pdf 2010

(5) Furler J, Young D. Prevention and socioeconomic disadvantage. Aust Fam Physician 2005 Oct;34(10):821-4.

(6) Fiscella K, Shin P. The inverse care law: implications for healthcare of vulnerable populations. J Ambul Care Manage 2005 Oct;28(4):304-12.

(7) Office of the Auditor General of Ontario. 2012 Annual Report. http://www auditor on ca/en/reports_2012_en htm 2012

(8) Bouchard L, Gaboury I, Chomienne MHln, Gilbert A, Dubois L. La santé en situation linguistique minoritaire. Healthc Policy 2009 May;4(4):36-42.

(9) Price D, Baker E, Golden B, Golden B, Hannam R. Patient Care Groups: A new model of population based primary health care for Ontario A report on behalf of the Primary Health Care Expert Advisory Committee. 2015.
Ref Type: Online Source

(10) LeFevre ML, U.S.Preventive Services Task Force. Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors: U.S. Preventive Services Task Force Recommendation Statement.[Summary for patients in Ann Intern Med. 2014 Oct 21;161(8):I-36; PMID: 25155276]. Ann Intern Med 2014 Oct 21;161(8):587-93.

(11) Mozaffarian D, Afshin A, Benowitz NL, Bittner V, Daniels SR, Franch HA, et al. Population approaches to improve diet, physical activity, and smoking habits: a scientific statement from the American Heart Association. Circulation 2012 Sep 18;126(12):1514-63.

(12) Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Hess FA, et al. Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement

of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Care 2015 Jul;38(7):1372-82.

(13) Quinones AR, Richardson J, Freeman M, Fu R, O'Neil ME, Motu'apuaka M, et al. Educational group visits for the management of chronic health conditions: a systematic review. [Review]. Patient Educ Couns 2014 Apr;95(1):3-29.

(14) Dunneram Y, Jeewon R. Healthy Diet and Nutrition Education Program among Women of Reproductive Age: A Necessity of Multilevel Strategies or Community Responsibility. [Review]. Health Promotion Perspectives 2015;5(2):116-27.

(15) Kaczorowski J, Del GC, Nadeau-Grenier V. Community-based programs to improve prevention and management of hypertension: recent Canadian experiences, challenges, and opportunities. [Review]. Canadian Journal of Cardiology 2013 May;29(5):571-8.

(16) Anuruang S, Hickman LD, Jackson D, Dharmendra T, Van BJ, Davidson PM. Community-based interventions to promote management for older people: an integrative review. [Review]. J Clin Nurs 2014 Aug;23(15-16):2110-20.

(17) Fields NL, Anderson KA, Dabelko-Schoeny H. The effectiveness of adult day services for older adults: a review of the literature from 2000 to 2011. [Review]. Journal of Applied Gerontology 2014 Mar;33(2):130-63.

(18) Smalls BL, Walker RJ, Bonilha HS, Campbell JA, Egede LE. Community Interventions to Improve Glycemic Control in African Americans with Type 2 Diabetes: A Systemic Review. [Review]. Global Journal of Health Science 2015;7(5):171-82.

(19) Pennant M, Davenport C, Bayliss S, Greenheld W, Marshall T, Hyde C. Community programs for the prevention of cardiovascular disease: a systematic review. [Review] [56 refs]. Am J Epidemiol 2010 Sep 1;172(5):501-16.

(20) Croisant SP, Scott L. Community-based interventions in asthma. [Review]. Advances in Experimental Medicine & Biology 2014;795:105-15.

(21) The Change Foundation. Health System Navigators: Band-Aid or Cure? A primer with reflections from The Change Foundation's Panorama Panel. Toronto; 2013.

(22) Levesque JF, Harris M, Russell G. Patient-centred access to health care: conceptualising access at the interface of health systems and populations. International Journal for Equity in He 2013 Mar 11;11:12-8.

(23) Paskett ED, Harrop JP, Wells KJ. Patient navigation: An update on the state of the science. CA: a Cancer Journal for Clinicians 2011 Jul 1;61(4):237-49.

(24) Loskutova NY, Tsai AG, Fisher EB, LaCruz DM, Cherrington AL, Harrington TM, et al. Patient Navigators Connecting Patients to Community Resources to Improve Diabetes Outcomes. The Journal of the American Board of Family Medicine 2016 Jan 1;29(1):78-89.

(25) Sanchez K, Ybarra R, Chapa T, Martinez ON. Eliminating Behavioral Health Disparities and Improving Outcomes for Racial and Ethnic Minority Populations. Psychiatr Serv 2015.

(26) Napoles AM, Gregorich SE, Santoyo-Olsson J, O'Brien H, Stewart AL. Interpersonal Processes of Care and Patient Satisfaction: Do Associations Differ by Race, Ethnicity, and Language? Health Serv Res 2009 Aug;44(4):1326-44.

(27) Miranda J, Duan N, Sherbourne C, Schoenbaum M, Lagomasino I, Jackson-Triche M, et al. Improving Care for Minorities: Can Quality Improvement Interventions Improve Care and Outcomes For Depressed Minorities? Results of a Randomized, Controlled Trial. Health Serv Res 2003 Apr;38(2):613-30.

(28) Gagnon-Arpin I, Bouchard L. *Les Services de Santé en Français en Ontario: Offre, Demande, Utilisation*. 2015.
Ref Type: Online Source

(29) Linder JA, Rigotti NA, Schneider LI, Kelley JH, Brawarsky P, Haas JS. An electronic health record-based intervention to improve tobacco treatment in primary care: a cluster-randomized controlled trial. Arch Intern Med 2009 Apr 27;169(8):781-7.

(30) Bentz CJ, Bayley KB, Bonin KE, Fleming L, Hollis JF, Hunt JS, et al. Provider feedback to improve 5A's tobacco cessation in primary care: a cluster randomized clinical trial. Nicotine Tob Res 2007 Mar;9(3):341-9.

(31) Vidrine JI, Shete S, Li Y, Cao Y, Alford MH, Galindo-Talton M, et al. The Ask-Advise-Connect approach for smokers in a safety net healthcare system: a group-randomized trial. Am J Prev Med 2013 Dec;45(6):737-41.

(32) Klevens J, Kee R, Trick W, Garcia D, Angulo FR, Jones R, et al. Effect of screening for partner violence on women's quality of life: a randomized controlled trial. JAMA 2012 Aug 15;308(7):681-9.

(33) Garg A, Toy S, Tripodis Y, Silverstein M, Freeman E. Addressing social determinants of health at well child care visits: a cluster RCT. Pediatrics 2015 Feb;135(2):e296-e304.

(34) Hillier-Brown FC, Bambra CL, Cairns JM, Kasim A, Moore HJ, Summerbell CD. A systematic review of the effectiveness of individual, community and societal level interventions at reducing socioeconomic inequalities in obesity amongst children. [Review]. BMC Public Health 2014;14:834.

(35) Pearson TA, Wall S, Lewis C, Jenkins PL, Nafziger A, Weinehall L. Dissecting the``black box"of community intervention: Lessons from community-wide cardiovascular disease prevention programs in the US and Sweden. Scand J Public Health 2001;29(56 suppl):69-78.

(36) Vanstone M, Giacomini M, Smith A, Brundisini F, DeJean D, Winsor S. How diet modification challenges are magnified in vulnerable or marginalized people with diabetes

and heart disease: a systematic review and qualitative meta-synthesis. [Review]. Ontario Health Technology Assessment Series 2013;13(14):1-40.

(37) Champlain Community Care Access Centre. The Champlain Health Line. http://www champlainhealthline ca/ 2015

(38) United Way Canada. Ontario 211. http://www 211ontario ca/ 2015

(39) Freeman HP. The Origin, Evolution, and Principles of Patient Navigation. Cancer Epidemiology Biomarkers & Prevention 2012 Oct 1;21(10):1614-7.

(40) Fayerman P. Patient Navigators: the greatest service in health care you've never heard of – until now. The Vancouver Sun 2011 Feb 24.

(41) Goris J, Komaric N, Guandalini A, Francis D, Hawes E. Effectiveness of multicultural health workers in chronic disease prevention and self-management in culturally and linguistically diverse populations: a systematic literature review. Aust J Prim Health 2013;19(1):14-37.

(42) Valaitis RK, Carter N, Lam A, Nicholl J, Feather J, Cleghorn L. Implementation and maintenance of patient navigation programs linking primary care with community-based health and social services: a scoping literature review. BMC Health Serv Res 2017;17(1):116.

(43) Willis A, Reed E, Pratt-Chapman M, Kapp H, Hatcher E, Vaitones V, et al. Development of a Framework for Patient Navigation: Delineating Roles Across Navigator Types. Journal of Oncology Navigation and Survivorship 2013;4(6):20-6.

(44) Health Quality Ontario. Quality in Primary Care: Setting a foundation for monitoring and reporting in Ontario. Toronto: Queen's Printer for Ontario; 2015.

(45) Ministry of Health and Long-Term Care. Community Health Centre. 2012. Queen's Printer for Canada. 10-11-2013.
Ref Type: Online Source

(46) Champlain LHIN. Population Characteristics for Champlain Health Link Areas. Ottawa: Government of Ontario; 2013.

(47) Champlain LHIN. Preliminary Data for Champlain Health Link Areas. Ottawa: Government of Ontario; 2013.

(48) Health Systems Intelligence Project, Ministry of Health and Long-Term Care. Population Health Profile: Champlain LHIN. http://www health gov on ca/transformation/providers/information/resources/profiles/profile_champlain pdf 2013 [cited 2013 Apr 10];Available from: URL: http://www.health.gov.on.ca/transformation/providers/information/resources/profiles/profile_champlain.pdf

(49) North East Local Health Integration Network. Integrated Health Service Plan 2016-2019: A plan for the health and well-being of Northerners living in Northeastern Ontario communities. 2016.

(50) Bains N, Dall K, Hay C, Pacey M, Sarkella J, Ward M. Population Health Profile: North East LHIN. 2005.

(51) Statistics Canada. Focus on Geography Series, 2011 Census - Census metropolitan area of Greater Sudbury / Grand Sudbury. 2012.

(52) Statistics Canada. NHS Focus on Geography Series - Greater Sudbury / Grand Sudbury. 2016.
Ref Type: Online Source

(53) Sudbury & District Health Unit. SDHU Population Health Profile: Summary Report. Sudbury, ON; 2016.

(54) Dillman DA. Mail and telephone surveys: the total design method. New York: Wiley; 1978.

(55) Westfall JM, Zittleman L, Staton EW, Parnes B, Smith PC, Niebauer LJ, et al. Card studies for observational research in practice. The Annals of Family Medicine 2011;9(1):63-8.

(56) Ivankova NV, Creswell JW, Stick SL. Using Mixed-Methods Sequential Explanatory Design: From Theory to Practice. Field Methods 2006 Feb 1;18(1):3-20.

(57) Sandelowski M. Qualitative analysis: What it is and how to begin. Res Nurs Health 1995 Aug 1;18(4):371-5.

(58) Thorne S. *Interpretive Description*. [2]. 2008.
Ref Type: Serial (Book,Monograph)

(59) Anderson J, Perry J, Blue C, Browne A, Henderson A, Khan KB, et al. "Rewriting" Cultural Safety Within the Postcolonial and Postnational Feminist Project: Toward New Epistemologies of Healing. Advances in Nursing Science 2003;26(3):196-214.

(60) Guba EG, Lincoln YS. Competing paradigms in qualitative research. Handbook of qualitative research. 163-194. 1994.
Ref Type: Serial (Book,Monograph)

(61) Anney V. Ensuring the quality of the findings of qualitative research: looking at Trustworthiness Criteria. Journal of Emerging Trends in Educational Research and Policy Studies 2014;5(2):272-81.

(62) Shenton AK. Strategies for ensuring trustworthiness in qualitative research projects. Education for information 2004;22(2):63-75.

(63) Guba EG. Criteria for assessing the trustworthiness of naturalistic inquiries. ECTJ 1981;29(2):75-91.

(64) Lopez KA, Willis DG. Descriptive versus interpretive phenomenology: Their contributions to nursing knowledge. Qual Health Res 2004;14(5):726-35.

(65) Denney-Wilson E, Fanaian M, Wan Q, Vagholkar S, Schutze H, Mark M. Lifestyle risk factors in general practice - routine assessment and management. Aust Fam Physician 2010 Dec;39(12):950-3.

(66) Harrison RA, McNair F, Dugdill L. Access to exercise referral schemes -- a population based analysis. J Public Health (Oxf) 2005 Dec;27(4):326-30.

(67) Gucciardi E, Wing-Sheung Chan V, Fortugno M, Khan S, Horodezny S, Swartzack SJ. Primary Care Physician Referral Patterns to Diabetes Education Programs in Southern Ontario, Canada. Canadian Journal of Diabetes 35, 262-268. 2011.
Ref Type: Journal (Full)

(68) Health Council of Canada. Helping Patients Help Themselves: Are Canadians with Chronic Conditions Getting the Support They Need to Manage Their Health? 2010.

(69) Holtrop JS, Dosh SA, Torres T, Thum YM. The community health educator referral liaison (CHERL): a primary care practice role for promoting healthy behaviors. Am J Prev Med 2008 Nov;35(5:Suppl):Suppl-72.

(70) Hooks-Anderson DR, Crannage EF, Salas J, Scherrer JF. Race and referral to diabetes education in primary care patients with prediabetes and diabetes. Diabetes Educator 2015 Jun;41(3):281-9.

(71) Evans L, Green S, Sharma K, Marinho F, Thomas P. Improving access to primary mental health services: are link workers the answer? London Journal of Primary Care 2014;6(2):23-8.

(72) Calkins LE, Michelson IR, Corso AS. Provider proximity as a predictor of referral rate and success. Psychological Services 2013 Nov;10(4):395-400.

(73) Morgan CL, Currie CJ, Hunt J, Evans JD, Rogers C, Stott NC, et al. Relative activity and referral patterns for diabetes and non-diabetes in general practice. Diabet Med 2000 Mar;17(3):230-5.

(74) Wolf HJ, Dwyer A, Ahnen DJ, Pray SL, Rein SM, Morwood KD, et al. Colon cancer screening for Colorado's underserved: a community clinic/academic partnership. Am J Prev Med 2015 Mar;48(3):264-70.

(75) Waterworth S, Gott M, Raphael D, Parsons J, Arroll B. Working with older people with multiple long-term conditions: a qualitative exploration of nurses' experiences. J Adv Nurs 2015 Jan;71(1):90-9.

(76) Harris MF, Jayasinghe UW, Chan BC, Proudfoot J, Crookes P, Zwar N, et al. Patient and practice characteristics predict the frequency of general practice multidisciplinary referrals of patients with chronic diseases: a multilevel study. Health Policy (Amsterdam, Netherlands) 2011 Jul;101(2):140-5.

(77) Elley CR, Dawes D, Dawes M, Price M, Draper H, Goodyear-Smith F. Screening for lifestyle and mental health risk factors in the waiting room: feasibility study of the Case-finding Health Assessment Tool. Can Fam Physician 2014 Nov;60(11):e527-e534.

(78) Rosen R. *Transforming general practice: what are the levers for change?* The Nurse Practitioner 2015.

(79) Bennett WL, Gudzune KA, Appel LJ, Clark JM. Insights from the POWER practice-based weight loss trial: a focus group study on the PCP's role in weight management. J Gen Intern Med 2014 Jan;29(1):50-8.

(80) Le V, Syed S, Vega KJ, Sharma T, Madhoun MF, Srinivasan N, et al. Patient prompting of their physician resulted in increased colon cancer screening referrals. World J Gastrointest Oncol 2014 Jul 15;6(7):257-62.

(81) Guest G, Bunce A, Johnson L. How Many Interviews Are Enough? Field Methods 2006 Feb 1;18(1):59-82.

(82) Ontario Ministry of Health and Long-Term Care. Patients First: Action Plan for Health Care. 2015.

(83) Pearson TA, Lewis C, Wall S, Jenkins PL, Nafziger A, Weinehall L. Dissecting the "black box" of community intervention: background and rationale. [Review] [40 refs]. Scandinavian Journal of Public Health Supplement 2001;56:5-12.

(84) Mayer MK, Urlaub DM, Guzman-Corrales LM, Kowitt SD, Shea CM, Fisher EB. "They're Doing Something That Actually No One Else Can Do": A Qualitative Study of Peer Support and Primary Care Integration. J Ambul Care Manage 2016 Jan;39(1):76-86.

(85) Kangovi S, Grande D, Carter T, Barg FK, Rogers M, Glanz K, et al. The use of participatory action research to design a patient-centered community health worker care transitions intervention. Healthc (Amst) 2014 Jul;2(2):136-44.

(86) Calhoun EA, Whitley EM, Esparza A, Ness E, Greene A, Garcia R, et al. A National Patient Navigator Training Program. Health Promot Pract 2010 Mar 1;11(2):205-15.

(87) Najafizada SA, Bourgeault IL, Labonte R, Packer C, Torres S. Community health workers in Canada and other high-income countries: A scoping review and research gaps. Can J Public Health 2015;106(3):157-64.

(88) Ustjanauskas AE, Bredice M, Nuhaily S, Kath L, Wells KJ. Training in Patient Navigation: A Review of the Research Literature. Health Promot Pract 2015 Dec 8.

(89) Howard MB, Freund KM, Battaglia TA. Caseload for patient navigation: What is keeping navigators busy? Cancer Epidemiol Biomarkers Prev 19[Suppl 10], A26. 2010.
Ref Type: Abstract

ADDITIONAL INFORMATION

3. ADDITIONAL INFORMATION: 1 CHAMPLAIN ADVISORY COMMITTEE

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Additional Information

Additional Info 1 - Champlain Advisory Committee

4. ADDITIONAL INFORMATION: 2 EXAMPLES OF HEALTH RELATED RESOURCES

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Additional Information

Additional Info 2 – Examples of Health Related Resources

5. ADDITIONAL INFORMATION: 3 EXAMPLES OF SOCIAL RESOURCES

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Additional Information

Additional Info 3-Examples of Social Resources

6. ADDITIONAL INFORMATION: 4 ACCESS FRAMEWORK

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Additional Information

Additional Info 4-Conceptual framework of access to health care

7. ADDITIONAL INFORMATION: 5 NAVIGATOR FRAMEWORK

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Additional Information

Additional Info 5-Navigator Framework

8. ADDITIONAL INFORMATION: 6 – INSTRUCTIONAL INFORMATION

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Additional Info 6A - English RCT Study Process (2017-Dec-28)

Additional Info 6B – English ARC Referral Form RCT video (2017-Dec-27)
https://www.powtoon.com/online-presentation/fUFWyTAINPD/rct-arc-referral-form/?mode=movie

9. ADDITIONAL INFORMATION: 7 – PROFILE AND QUALIFICATIONS OF THE NAVIGATOR

Lay navigators will be recruited based on their language skills, interpersonal skills, ability to adapt to different situations as well as their personal experience or knowledge of a) navigating the health care system or community resources, b) overcoming social barriers, and/or c) living with and effectively managing health conditions, so as to reflect the primary care population that they will work with. (41;84) Bilingual Navigators will be selected, recognizing the importance of shared culture and language on optimizing access to community based services for Franco-Ontarian primary care patients. No previous health professional experience is required of the navigators.

Navigators will complete a period of training organized by the research team to develop the knowledge, skills and abilities to assist patients with social complexities identify appropriate community resources and support them in overcoming barriers to adequate access. This training program was successfully piloted during the Feasibility study.

The training curriculum for the navigators is based on the literature and similar evidence-informed navigator training programs including the Colorado Patient Navigator Training Collaborative, Individualized Management for Patient-Centered Targets (IMPaCT) Training Manual (85) and the McMaster University Health TAPESTRY Health Connector Training Program (http://healthtapestry.ca). The core training content includes the principles and scope of navigation (communication, cultural competency, developing trust relationships), identifying patient goals and prioritizing, overcoming barriers to care (e.g. financial, transportation), providing psychosocial support, empowering patients to participate in wellness behaviours, self-management, and health promotion; record-keeping, and working as a member of a primary care team. Participants will gain knowledge about, and practice in navigating community resources and services for the priority health programs targeted by ARC: mental health, healthy living, chronic disease management, and seniors' health. This may evolve depending on the health programs identified as most pertinent to the primary care practices' in the study.

Three training formats will be used to address the scope and complexity of the navigation role: online learning, face-to-face sessions, and community mentorship to support navigators as they carry out their role. Online modules and learning resources including a discussion board and a reflective workbook are housed on a Patient Navigator Training website for the project. This format and related content will be guided by adult learning theory and leverage collaboration among navigators to enable them to act as a resource for each other in their navigation role. (85;86) The training is consistent with the literature which identifies that navigators are trained for specific roles and services in the community, most commonly by the organizations that hire them. (41;87;88)

Several relevant organizations and their staff will be engaged to participate in the training of navigators based on their expertise with information and referral to community services, self-management support, and/or providing culturally competent care. These organizations include, but are not limited to the following: navigation tools (e.g. 211-finding community resources), Active Offer (e.g. Le Réseau des services de santé en francais Somerset West Community Health Centre Multicultural Health Navigators (learning from experienced navigators), social workers from Community Health Centres/Family Health Teams (identifying and addressing social barriers to health); self-management programs, motivational interviewing); and mental health services (e.g. Royal Ottawa Mental Health Centre and Montfort Renaissance (peer support for mental health and addictions).

10. ADDITIONAL INFORMATION: 8 – ROLE AND ACTIVITIES OF THE NAVIGATOR

Navigators will support patients to access community based resources for healthy living and self-management, rather than providing specific information about health issues.(41;43) Navigators will empower patients to seek and use community resources by teaching them how to identify available and relevant programs to meet their health-related goals, in their language of choice. Navigators may also provide social support, , arrange appointments or accompaniment to resources, assist with completing forms, explain the purpose and components of community programs, and advocate on patients' behalf to support access to resources.

The Navigator will meet patients at the primary care practice or in a location acceptable to the practice and patient (e.g. community health centre) or by telephone.

- At the initial encounter:
  - The navigator will ensure that the individual understands the reason for referral, potential benefits, and what is involved to participate in the resource(s) to which they were referred
  - Discuss social barriers potentially affecting patients' access to community health resources
  - Assist patients to prioritize their health goals and relevant resources to achieve these
- The navigator will then assist patients to access the community-based services in the language of their choice to which they have been referred. The navigator may assist the patient in making appointments, coordinating transportation, and/or accompaniment to resources as required).

The navigator will work with the practices to

- Optimize communication and understanding between providers and patients by demonstrating linguistic sensitivity, interpreting cultural norms, roles or beliefs that may affect their understanding of needed care, and seeking of resources
- Document patient encounters, maintain accurate and complete records of navigation services provided
- Provide information and feedback to facilitate informational continuity between primary care providers and patients

These activities are based upon previously defined functional domains of patient navigation, (43) online repositories of patient navigator job descriptions, and detailed manuals for implementing community health workers within community settings. <u>Navigators will not be involved in activities that are clinically oriented</u>, such as promoting medication adherence, referring to treatment or specialist services, or providing individuals with coping strategies to manage their illness or disease. In these situations the Navigator will inform the the primary care provider about the patient's health care needs.

All navigators will have access to their peer Navigators, and/or the Navigation Coordinator for debriefing about their interactions with patients, learning, and for social support for their navigation role. Patients with very complex needs and those requiring activities beyond the scope of the Navigator, will be referred to their primary care physician for follow-up. In the Champlain region, the Executive Director of the Somerset West Community Health Centre has agreed to support the ARC project by providing access to peer support for Navigators and space for Navigators to meet with each other, and with patients if needed. Navigators may be able to refer patients with complex needs for other CHC services as appropriate and upon agreement by their primary care provider (see Appendix: R – Statement of Relationship with SWCHC). Similar support will be sought from the CHC in Sudbury within the North East LHIN.

The Navigators will also be invited to act as co-researchers throughout the study. All Navigators will be supplied with a series of self-reflection questions in relation to their experience and will be asked to keep a weekly journal of their activities. The Navigators, with selected members of the research team, will be invited to co-author a manuscript based on their firsthand account of their experience.

Patients assigned to the intervention arm will be offered the services of the Navigator. Patients that accept the services will be scheduled to meet with the Navigator by telephone or in person on at a time and place (e.g., at their practice, at a CHC) that is most convenient for them. They will meet with the Navigator for up to one hour to allow sufficient time to establish rapport, identify potential barriers, and set patient-led priorities.

It is expected that patients' needs will vary, and some patients will receive sufficient support during the initial encounter, while others may require multiple contacts. Patients will be able to access the Navigator after the initial meeting, by phone or in-person, to address any relevant questions or issues arising from the referral to the community resource. If required, subsequent meetings will be scheduled for 30 minutes. As the potential caseload for a navigator varies considerably depending on the extent of their roles and responsibilities, (89) we anticipate that the Navigator will have time-limited contact with each patient, that ends three months from the initial meeting, or when access to the appropriate resource is achieved, whichever comes first.

The Navigator will follow-up with patients by phone within the 1-2 weeks following their meeting where recommendations were made so as to assess community resource utilization and address barriers encountered.

Patients that meet with the Navigator may identify additional needs and/or resources of interest that were not indicated by their PHCP on the referral form (Appendix: A – Draft Referral Form). Consent will be obtained from participating PHCPs (see Appendix: D—Practice/Provider Recruitment Package) to allow the Navigator to support patients access resources that they did not recommend. The Navigator can support the patient access services that can help address additional needs, unless these are of a medical nature. Patients that identify health needs that are clinically relevant and fall outside the Navigator's scope of practice cannot be addressed by the Navigator. The Navigator will follow-up with PHCPs after the initial encounter with the patient to inform the PHCP of the patient's priority needs and resources identified. Any additional need identified by the patient, including those that can and cannot be addressed by the Navigator, will be shared with their PHCP.

APPENDICES

11. APPENDIX: A – DRAFT REFERRAL FORM

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix A-Draft Refferal Form

Appendix A1 - English ARC Referral Form RCT (2017-Dec-11)

12. APPENDIX: B – PROMOTIONAL MATERIAL

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix B-Promotional Material

Appendix B1 - ARC Bilingual Promotional Poster (2017-Dec-22)

Appendix B2 - ARC RCT English Promotional Video (2017-Dec-21): https://www.powtoon.com/online-presentation/dQWHRiqDLTZ/rct-promotional-video/

13. APPENDIX: C – NAVIGATOR FEEDBACK FORM

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix C-Navigator Feedback Form

Appendix C - English ARC Navigator Feedback Form

14. APPENDIX: D – PRACTICE/PROVIDER RECRUITMENT PACKAGE

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix D-Practice_Provider Recruitment Package

Appendix D1 - English Practice Invitation letter (2017-Dec-12)

Appendix D2 – English Practice and Provider Information and Consent Form (2017-Dec-12)

Appendix D3 - English Provider Information and Consent Form- Interview - (2017-Dec-12)

Appendix D4 - English Practice Reminder Email (2017-Dec-12)

Appendix D5 - English Practice Reminder Phone Call (2017-Nov-21)

Appendix D6 – English Information Brochure (2017-Dec-27)

Appendix D7 – English Navigation Services (2017-Mar-20)

Appendix D8 – English Letter to Champion (2017-Dec-12)

15. APPENDIX: E– PATIENT INFORMATION SHEETS AND CONSENT FORMS

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix E-Patient Information and Consent Forms

Appendix E1 – English Participant Information Consent Form (2017-Dec-27)

Appendix E2 - English Participant Interview Consent Form (2017-Dec-27)

Appendix E3 - English Patient Instructions (2017-Nov-10)

16.APPENDIX: F – STUDY TIMELINE

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix F-Study Timeline

Appendix F – Study Timeline (2017-Dec-27)

17.APPENDIX: G – PRACTICE SURVEY

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix G-Practice Survey

Appendix H – English Practice Survey _Baseline only (2017-Dec-27)

18.APPENDIX: H – PROVIDER SURVEY

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix H-Provider Survey

Appendix H - English Practitioner Survey (2017-Dec-27)

19.APPENDIX: I – PATIENT SURVEY

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix I - Patient Survey Appendix I - English Patient Survey (2017-Dec-27)

20.APPENDIX: J – NAVIGATOR TRAINING ASSESSMENT

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix J-Navigator Training Assessment

Appendix J - English Navigator Training Assessment (2017-Mar-20)

21.APPENDIX: K – RAPID CYCLE EVALUATION

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix K-Rapid Cycle Evaluation

Appendix K - English Rapid Cycle Evaluation (2017-Dec-27)

22.APPENDIX: L – PROVIDER QUALITATIVE THEMES

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix L-Provider Interview Guide

Appendix L – English Provider Interview Guide (2017-Dec-27)

23. APPENDIX: M – PATIENT QUALITATIVE THEMES

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix M-Patient Interview Guide

Appendix M – English Patient Interview Guide (2017-Nov-16)

24. APPENDIX: N – NAVIGATOR QUALITATIVE ASSESSMENT

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix N-Navigator Interview Guide

Appendix N – English Navigator Interview (2017-Nov-16)

25. APPENDIX: O – PRACTICE SET UP LOG

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix O-Practice Set Up Log

Appendix P - Practice Set-Up Log (2017-Dec-27)

26. APPENDIX: P – NAVIGATOR LOG

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix P-Navigator Log

Appendix P - Navigator Log (2017-Nov-23)

27. APPENDIX: Q – CONSENT PATHWAYS

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix Q-Consent Pathways

Appendix Q - Consent Pathways RCT (2017-Dec-27)

28. APPENDIX: R– STATEMENT OF RELATIONSHIP WITH SWCHC

S:\CTLC-Investigators\Dahrouge\2. Projects\1.2 ARC RCT\1. Protocol and Appendices\Appendices\Appendix R - Statement of Relationship with SWCHC

Appendix R – Statement of Relationship with SWCHC (2017-May-18)