Access to Resources in the Community (ARC) through Navigation – A Feasibility Study Protocol

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ABSTRACT

**Background:** Community based health and social resources can help individuals with complex health and social needs. However, there is often a discontinuation of patient care between primary care practices and community resources due to: a lack of physician or patient awareness of available resources; the presence of social barriers; the paucity of means to facilitate patients’ trajectory along the continuum of care; and more broadly, to the difficulties implementing organizational changes in primary care practices already busy providing health care services. Navigation services – where a person is tasked with helping connect patients to community resources – can strengthen continuity of care for patients. The implementation and study of the navigators’ impact is complex and warrants further investigation.

**Objective:** Assess whether the ARC Model is feasible, including its potential to achieve its intended outcomes, and the viability of the evaluation approach.

**Methods:** Describe the protocol of a single arm, prospective, explanatory mixed methods, pre-post design feasibility study, focusing on primary care practice settings with vulnerable populations. Participants include primary care providers, and patients.

**Results:** Enrollment is closed with 82 patients. Navigation services have ended for 69 patients.

**Conclusions:** Multilayered complex issues contribute to a high risk of failing to sustainably implement navigation services, thwarting randomized control trials’ effectiveness at assessing their impact. Undertaking a feasibility study from a conceptually clear and methodologically solid protocol will inform on the acceptability, ease of implementation, quality of integration, practicality and adaptation needs prior to initiating a randomized control trial.

**Trial registration:** ClinicalTrials.gov, NCT03105635. Registered 10 April 2017

**Key words:** Feasibility study, primary health care, access, community resources, navigation
INTRODUCTION

Equitable access to primary health care (PHC) plays an important role in reducing health inequities. (1) Despite significant efforts to strengthen that sector in Canada, (2) disparities in access to these services continue to affect several populations, including immigrants, Indigenous peoples, individuals of lower socio-economic status, those living in rural regions, and cultural minorities, including Francophones living in minority situations. (3-10) This problem is compounded by the fact that these social factors are also determinants of health that contribute significantly to the risk of poor health. (11) and adequate access to PHC, including health enabling resources available in the community, remains a priority strategy to mitigating these inequities. (12)

Community resources such as smoking cessation, falls prevention, and chronic disease self-management programs can play an important role in supporting individuals achieve their health goals. Primary care providers (PCPs) may offer lifestyle counseling and preventive care support to promote positive health behaviours, but this is often insufficient for individuals to meet their intended goals because the path to healthy behaviour is fraught with barriers that thwart their intent and capacity to act. (13) The work done by PCPs in supporting individuals to develop self-efficacy can be complemented by health enabling community resources, which encompass a broad range of health and social services. Several reviews report positive outcomes with community based services that aim to reduce the risk of cardiovascular disease, (14-16) promote secondary prevention of various chronic diseases, (17-19) and improve health promoting behaviours. (20;21) Such resources are recommended by the U.S. Preventive Services Task Force. (22) and the American Heart Association. (20) Similarly, National Guidelines for Diabetes Management highlight the role self-management education and community support programs play in achieving healthy outcomes. (23) Many of these resources have been shown to be useful in meeting the health needs of individuals with complex social profiles, (16;24) and some have highlighted their role in reducing health inequities experienced by certain populations. (25;26) Unfortunately, these services remain underused, (27) especially by individuals with social disadvantages, (28) resulting in the propagation of inequities and unmet health needs.

One response to this multifaceted issue is to facilitate access to health enabling community resources by way of embedding navigation services within PCPs. Navigators are non-clinical individuals who assist patients in identifying the appropriate community resources and support them in overcoming access barriers and achieving service utilization. (29) However, the navigator role has been almost exclusively studied in disease- or population-specific contexts. (31) In that latter role, they are often called community health workers. Two recent meta-analyses focused on medical conditions, the majority of which were cancer related studies, showed that patients assigned to navigation services had significantly better outcomes across a number of measures, including appropriate health care utilization, disease control, and clinical outcomes, such as mortality. (30). Another review reported similar benefits of navigation services for immigrants and ethnic communities. (32)

The current models of navigation services and their implementation have significant limitations. Models targeting individuals with specific medical conditions do not address the breadth of potential navigation needs individuals may have, and may be contributing to a fragmented delivery of care. Population specific programs only target a subset of the population and, by definition, cannot be applied to the general population. Implementing changes in the way PCPs operate – even when there is agreement within PCPs on the need for the change – is challenging as well. Very few studies have implemented navigation services within primary care, integrating these services within the breadth of care they coordinate(33-38) and supporting the PCPs’ efforts to engage patients in self-care. We found a single
study that evaluated the role of a patient navigator in providing system navigation support to more complex primary care patients. However, in that study, the navigation services were provided by a social worker. (39)

In consultation with stakeholders, we developed a novel approach to enhancing equitable Access to Resources in the Community (ARC) - the ARC Model where a lay navigator is integrated within primary care practices to support primary care patients access resources that are available in their community to help address one or multiple needs.

This feasibility study will assess whether the ARC Model is feasible, including its potential to achieve its intended outcomes, and the viability of the evaluation approach. Ultimately, this feasibility study will strengthen a subsequent RCT study, which in turn will increase the likelihood of collecting reliable and relevant data and produce valid conclusions on the implementation and impact of our navigator program.

Specifically, we will evaluate eight areas of feasibility: **Acceptability, Demand, Implementation, Adaptation, Integration, Practicality, and Efficacy** of the ARC Model, and **Appropriateness** of the intervention evaluation approach to study participants. (40)

**METHODS**

This section follows the SPIRIT guidelines for reporting on protocols (41).

This is a single arm, prospective, explanatory mixed method, pre-post design feasibility study.

**Setting**

The study is set in central Ottawa (Ontario, Canada), a region with broad socio-economic diversity, including Francophones (13%), immigrants (26%), visible minorities (24%), and individuals living in low income housing (18%). (42)

**Study Participants**

The ARC model was implemented in two practice contexts to understand the different levers and barriers to implementing the ARC Model: 1) the traditional primary care practice which consists of family physicians, nurses and administrative staff, and 2) in the interprofessional practice model in which patients have access to various allied health professionals such as nurse practitioners, pharmacists, and social workers, as well as some in-house health programs. Participating PCPs are required to provide comprehensive primary care services to the general population.

Patients of participating PCPs are eligible to participate if a need that may be addressed by services offered in the community is identified during an encounter with their PCP, they are able to communicate in English or French or willing to be served by a cultural interpreter/translator, and have no significant cognitive deficiencies or have a family member that can provide proxy consent and participate in the study with the patient.

**Intervention**

We established a **Collaborative Partnership** of key stakeholders who can inform the development, implementation and evaluation of the ARC Model. The partnership includes policy makers, members from community organizations, healthcare providers, and people with lived experience.
The intent of the ARC intervention is to promote equitable access to health enabling resources by engaging PCPs in identifying their patients’ needs that could be addressed by a community resource and directing them to such services, and subsequently supporting the patients’ access to these resources through navigation. The ARC intervention is described in Appendix A (TIDieR Checklist (43)), and details of the ARC navigation model are provided in Appendix B. Briefly, the patient navigator will meet with each patient to whom a service was recommended to understand their needs, expectations and priorities, identify anticipated barriers in accessing the resource (e.g. knowledge, health literacy, transportation, completing forms caregiving responsibilities, financial, motivation), support patients in overcoming these barriers, and facilitate access to the most appropriate resource for the patient. The navigator reports back to the PCP on the plan developed after the first encounter, and again at the end of services. Navigation services are discontinued when the patient has accessed the appropriate service or no longer wants or requires navigation assistance. Navigation services are offered to patients for up to 3 months.

Timelines
The patient recruitment period was 9 months, and individual patient participation will be approximately 3 months.

Sample size
We estimated that 80 patients would be required to adequately assess the ARC Model feasibility. In the region where the study is conducted, over 60% of the population has insufficient consumption of fruits and vegetables, 28% are obese, 19% drink heavily, 12% smoke, and 22% report feeling stressed “quite a lot”(44). Community resources offer services that target all of these health related issues. Assuming conservatively that 30% of patients at the practice could potentially benefit from a community resource, that 5% of these would be referred over a 9-month period, and that half would agree to participate, recruiting four to six practices with at least three PCPs in each (minimum 12 PCPs) with a panel size of 1,500 patients each, 135 of these patients could be enrolled, providing an adequate assessment of the feasibility of the ARC Model. We also interviewed a minimum of one provider and one patient per practice.

Recruitment
The study was promoted among stakeholders. Providers expressing an interest were sent a practice/provider study information and consent package, and a study information/recruitment session was scheduled with all interested PCPs at the practice.

During encounters with patients, when a participating PCP and their patient identified a need that could be addressed by a community resource, the PCP completed a standardized community resource referral form, briefly introduced the study and requested the patient’s agreement to be contacted by a member of the research team. Patients that agreed to be contacted received a study information and consent package and a copy of the completed referral form identifying their need(s). A copy of that form was faxed to the study team who then contacted the patient and provided detailed information about the study. Patients who provided verbal consent to participate in the study were asked to sign and mail in the consent form included in their study information and consent package.

A subsample of PCPs and patients were invited to participate in a qualitative interview at the beginning and end of their participation in the study. All participating PCPs were invited, and at least one PCP from
each practice was interviewed. Patients were purposefully selected to participate in the interviews, with the aim to maximize variation across age and gender, and from each practice.

Data collection methods

Table 1 provides a summary of the data collection tools, the dimensions measured, the population targeted, as well as how and when the tools are to be administered.

Table 1: Data collection tools

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Dimension</th>
<th>Target population</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>How</td>
<td>When</td>
<td></td>
</tr>
<tr>
<td><strong>Quantitative data</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referral form</td>
<td>Referral rate</td>
<td>PCPs</td>
<td>Completed by PCPs, Completed for each referral beginning 1 month prior to intervention and continuing throughout study</td>
</tr>
<tr>
<td>Practice survey</td>
<td>Organization, services provided,</td>
<td>One/practice</td>
<td>Self-administered by one PCP per practice, Baseline and end of study</td>
</tr>
<tr>
<td>Provider survey</td>
<td>Equity orientation, Climate, Organizational</td>
<td>All PCPs</td>
<td>Self-administered by PCPs, Baseline</td>
</tr>
<tr>
<td></td>
<td>structure, Change readiness</td>
<td></td>
<td>End of study (before intervention is removed)</td>
</tr>
<tr>
<td></td>
<td>Experience with intervention</td>
<td>All PCPs</td>
<td>Self-administered by PCPs</td>
</tr>
<tr>
<td>Patient survey</td>
<td>Experience with healthcare, self-efficacy,</td>
<td>All patients</td>
<td>Administered via telephone by research team, Baseline</td>
</tr>
<tr>
<td></td>
<td>social vulnerability, experience with CRs,</td>
<td>referred</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Experience with intervention, utilization of</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>referred CR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qualitative data</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Participant data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider interview</td>
<td>Background (PCP and practice profile)</td>
<td>2 PCPs/practice</td>
<td>Administered in-person or Pre-intervention</td>
</tr>
</tbody>
</table>
One practice member, referred to as the practice champion, is the main contact for the practice. The practice champion completes the practice level survey and each participating PCP completes the provider survey. These surveys are completed at baseline before the introduction of the patient navigator in the practice, and again immediately prior to ending the navigation services. These surveys assess the practice's organization and PCPs' knowledge, attitudes, and experience with reference to vulnerable populations, as well as factors that can influence the success of the intervention, and its implementation from a change management perspective. The organizational structure, climate of their work environment, as well as readiness and commitment to change. The post-intervention survey also includes questions relating to their experience with the patient navigator.

Patients complete a baseline survey immediately after providing consent, and prior to meeting with the navigator, and a post-intervention survey at 3 months. These surveys assess various dimensions of access, measures of self-efficacy, and their experience with the ARC services.

Selected patients and PCPs are also invited to participate in an interview following the completion of the baseline survey and the post-intervention survey. These interviews will explore patients' access to
primary health care services and providers’ experience providing care to more vulnerable patient populations. Patients and PCPs are also asked about their experience with the patient navigator.

Conforming to a rapid cycle evaluation (RCE) approach, the designated practice champion completes regular assessments of the study progress to inform the need for adapting the intervention to meet the needs of the practice. RCE will also inform on levers and barriers to the changes within PCPs that the introduction of an additional layer of services imposes. The first assessment was conducted immediately following the initial implementation phase and evaluated the practices’ experience with the introduction of the ARC Model components. Subsequent evaluations were conducted monthly to evaluate their impressions of study progress.(49)

The patient navigator maintains a log of activities relating to patient support, including encounters with patients, their PCPs, and staff from the recommended community resource. The patient navigator also maintains a reflective journal on their thoughts related to day-to-day activities to promote deeper understanding of the skills required as part of their navigator role. PCPs' and patients' interviews will be used to understand and build upon the survey results.(50)

**Outcomes**

The feasibility study will assess eight areas of focus: Acceptability of the ARC Model, Demand for the navigation service, Implementation approach viability, Adaptation required, Integration of the navigation service within the practice, Practicality of the ARC Model to the practice/providers and patients, the potential for the intervention Efficacy, and Appropriateness of the intervention evaluation approach to study participants.(40) Table 2 provides the operational definition of the areas and their data source.

<table>
<thead>
<tr>
<th>Area of Focus</th>
<th>Outcome Measure</th>
<th>Measurement Tool</th>
<th>Method of analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptability</td>
<td>- PCP satisfaction with study activities</td>
<td>- Rapid cycle evaluation (implementation stage)</td>
<td>- Level of satisfaction with study activities</td>
</tr>
<tr>
<td></td>
<td>- PCP commitment to change</td>
<td></td>
<td>- Descriptive statistics</td>
</tr>
<tr>
<td></td>
<td>- PCP and patient experience with the Navigator</td>
<td>- Post PCP and patient surveys and interviews</td>
<td>- Descriptive statistics and content analysis</td>
</tr>
<tr>
<td>Demand</td>
<td>- Referral forms completed by PCPs</td>
<td>- Referral form</td>
<td>- Rate of referrals</td>
</tr>
<tr>
<td></td>
<td>- Patient acceptance of navigation services</td>
<td>- Navigator Log</td>
<td>- Proportion of patients using navigation services</td>
</tr>
<tr>
<td></td>
<td>- Navigator-patient encounters</td>
<td></td>
<td>- Number of navigator-patient encounters</td>
</tr>
<tr>
<td>Implementation</td>
<td>- PCP readiness to change to accept the ARC navigation Model</td>
<td>- Pre and post PCP survey</td>
<td>- Descriptive statistics</td>
</tr>
<tr>
<td></td>
<td>- Mode of delivery of navigation services</td>
<td>- Navigator Log</td>
<td>- Number of telephone vs. in person</td>
</tr>
</tbody>
</table>
## Encounters
- Patient satisfaction with ARC navigation Model
- Rate of patient access to CR
- Descriptive statistics and content analysis

## Adaptation
- Changes in planned process to accommodate practices
- Rapid cycle evaluation (intervention stage)
- Frequency of adaptation of study activities
- Changes in method of navigation services delivery to accommodate patient expectations
- Navigator Log
- Proportion of phone vs. in-person encounters
- Proportion of in-person encounters at the practice vs. elsewhere

## Integration
- PCP satisfaction with study activities
- Pre and post practice survey
- Comparison across practice models
- PCP Satisfaction with intervention activities
- Rapid cycle evaluation (intervention stage)
- Descriptive statistics and content analysis
- Appropriateness of Navigator service delivery
- Navigator Log
- Frequency of encounters at the practice site

## Practicality
- PCP ability to perform study activities
- Rapid cycle evaluation (intervention stage)
- Descriptive statistics and content analysis
- Patient ability to use navigator services
- Post patient survey and interview

## Efficacy
- Ability of patients to access CR that meet their needs
- Characteristics of patients and needs according to ability to access CR
- Post patient survey and interview
- Descriptive statistics and content analysis

## Appropriateness of Evaluation
- Completeness of surveys (and individual components) by PCPs and patients and participants’ comments on these (e.g. content, clarity, length)
- Participation of PCP and patients in interviews
- N/A
- Proportion of survey completeness
- Number of interviews completed
**Data management**

Procedures developed by the ARC team and captured in various training and "how to" guides contributed to the standardized implementation of study activities related to data collection, coding, entry and storage. Quantitative data is inscribed directly into Qualtrics, a centralized data collection tool, and transferred to IBM SPSS™ for analyses. For qualitative data, interview notes or transcripts and open-ended answers to survey questions are entered into (NVivo™), a software that facilitates content analysis.

**Analyses**

Table 2 provides a summary of the analytical approach to each of the outcome measures related to eight areas of focus of a feasibility study. Consistent with principles of an explanatory sequential design of a phenomenological tradition, we will begin by 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.

**RESULTS**

Participant recruitment has ended and data collection is still in progress. 35 PCPs consented to participate in the study, 29 of which referred at least one patient. 131 referrals were received by the research team across the 9 month intervention period. Patient enrollment is closed with 82 patients (63% response rate). The research team was unable to make direct contact with 34 (26%) patients, and 15 (11%) patients declined to participate in the study; 3 (4%) patients withdrew from the study after completing the baseline survey. 78 (99%) patients accepted navigation services, and 69 (87%) patients completed these services to date. Post-intervention data collection is ongoing. Results informing the feasibility of the ARC-navigation model according to the eight areas of focus described above will be made available.

**DISCUSSION**

There is a need to implement measures that will foster a better use of community resources especially for vulnerable populations. There is also a need to assess the extent to which such measures actually meet their objectives. We identified navigation services integrated within primary care as an innovative means by which patients' trajectories from practices to community resources can be facilitated. We also recognize that both the need to implement navigation services in primary care and the need to assess their impact are complex conceptually and operationally. As such, it is sensible and logical to first assess the acceptability, implementation, integration, practicality and potential adaptation of both the intervention and research process by way of a feasibility study. This feasibility study will strengthen a subsequent RCT study, which in turn will increase the likelihood of collecting reliable and relevant data and produce valid conclusions on the implementation and impact of our navigator program.
ACKNOWLEDGEMENTS

All authors contributed to the conception and design of the ARC feasibility study protocol. SD oversaw the study design and implementation plan. SD and FC provided expertise in the development of quantitative data collection tools and analyses plan. AG, DTS, and ML provided expertise in the development of qualitative data collection tools and analyses plan. CK, DP, and MHC provided expertise about primary care context and vulnerable patient needs. JP and MT provided expertise in research methods and statistical analyses. All authors read and approved the final manuscript.

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The aforementioned funding bodies do not have a role in the design of the study and collection, analysis, and interpretation of data and in the writing of the manuscript.

This study was approved by the following ethics boards:

- Ottawa Health Science Network Research Ethics Board (#20160914-01H)
- Bruyère Continuing Care Research Ethics Board (#M16-16-055)
- University of Ottawa Research Ethics Board (#A05-17-04)
- L'Hôpital Montfort Research Ethics Board (#SD-DP-27-02-17)

CONFLICTS OF INTEREST

None declared.

ABBREVIATIONS

ARC: Access to Resources in the Community
CHC: Community Health Centre
CR: community resource
EMR: electronic medical record
PHC: primary health care
PCP: primary care provider
RCE: rapid cycle evaluation
RCT: randomized controlled trial
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
TIDieR: Template for Intervention Description and Replication

MULTIMEDIA APPENDIX

Multimedia Appendix 1 - Appendix A - Intervention (Based on TIDieR checklist)
Multimedia Appendix 2 – Appendix B - The ARC Navigation Model
Multimedia Appendix 3 – ARC Promotional Poster
Multimedia Appendix 4 – ARC Promotional Video
Multimedia Appendix 5 – ARC Referral Form
Multimedia Appendix 6 – ARC Instructional Video
Multimedia Appendix 7 – Funding Agreement
Multimedia Appendix 8 – Response to Reviewers
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