

**A Comparison of the Impact of Two Social Prescribing Patient Navigation Models
on Health Care Utilization**

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Preface

The research conducted for Chapter 2 of this thesis involves the secondary analysis of data obtained from the ARC-211 randomized controlled trial (RCT) led by Dr. Simone Dahrouge, in which permission to collect patient data was obtained. Adiba Mahbub (AM), the primary author of this thesis was given permission to access and use the data collected from the ARC-211 RCT. Ethics approval was obtained for the conduct of this RCT from the Bruyère Continuing Care Research Ethics Board (Appendix 1).

The data from the RCT was linked to ICES health administrative data for patients who had consented to have their study data linked. Permission to link the RCT data, access, and analyze ICES data was obtained from ICES prior to the beginning of this study. AM joined ICES as an ICES student under Dr. Simone Dahrouge (thesis supervisor), a full-status ICES scientist, to access and use their data.

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The School of Epidemiology and Public Health (SEPH) approved the conduct of the research for this thesis in partial fulfilment of the requirements for a Master's degree in Epidemiology.

Author contributions

AM was the primary author of this thesis, with her thesis supervisor Dr. Simone Dahrouge (SD), and thesis committee members Dr. Claire Kendall (CK), Dr. Alain Gauthier (AG), and Dr. Kiran Saluja (KS), as co-authors for the manuscript in this thesis. AM was responsible for planning the methodology, conducting the analyses, interpreting the findings, and drafting the manuscript. SD provided guidance and feedback throughout the planning of the methodology, in each step of conducting the research and revised drafts of the thesis. SD, CK, AG, and KS all provided guidance and feedback in the interpretations of the findings and in the writing and revisions of the manuscript drafts.

Abstract

Objectives: This study compared the effects of two lay patient navigation models (ARC in-person primary care-based navigation vs. Ontario-211 provincially funded remote navigation) within a social prescribing program on health care utilization in Ontario.

Methods: We conducted comparative analyses of patients who participated in the larger-scale ARC-211 RCT, using study data linked to health administrative data housed at ICES. Changes in outpatient care use between pre and post intervention periods and post-intervention acute care use were compared between study arms.

Results: There was a trend towards a greater decrease in number of outpatient visits in the post-intervention period in the ARC arm compared to the 211 arm, and a trend of greater odds of at least one acute care episode in the 211 arm. These results were not statistically significant.

Conclusions: The ARC in-person patient navigation approach may be beneficial in reducing health care utilization and warrants further investigation.

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List of Abbreviations

RCT = Randomized Controlled Trial

SEPH = School of Epidemiology and Public Health

SDoH = Social Determinants of Health

ED = Emergency Department

SP = Social Prescribing

CHW = Community Health Worker

ARC = Access to Resources in the Community

OHIP = Ontario Health Insurance Plan

IKN = ICES Key Number

NACRS = National Ambulatory Care Reporting System

DAD = Discharger Abstract Database

OMHRS = Ontario Mental Health Reporting System

SD = Standard Deviation

CI = Confidence Interval

DiD = Difference-in-difference

OR = Odds Ratio

RR = Relative Risk

CIHI = Canadian Institute for Health Information

FFS = Fee-for-service

MoH = Ministry of Health

RAI-MH = Resident Assessment Instrument – Mental Health

Thesis Structure

This thesis is presented in a thesis by article/manuscript format, guided by parameters outlined by the SEPH. There are three overall chapters: introduction, manuscript, and discussion.

Chapter 1: is the introduction and describes the extant literature on the subject of the manuscript, the rationale, and objectives of this study.

Interface: this provides an introduction to the RCT that this study stems from, to provide the reader an understanding prior to reading the manuscript, as well as details on approvals and contributions specific to the manuscript in Chapter 2.

Chapter 2: the standalone manuscript describing our study on the comparison of two social prescribing lay navigation models on health care utilization, that addresses this thesis' objectives.

Chapter 3: is the general discussion of the overall thesis, outlining in greater detail the summary of the study findings and provides further insight in the interpretation of the findings, the strengths and limitations, as well as implications and recommendations.

Chapter 1: Introduction

1.1 Background

1.1.1 Social Determinants of Health

Medical based care is now estimated to only account for 10-20% of the modifiable influences on population health outcomes [1]. The other 80-90% are contributors that are categorized under the umbrella term of the social determinants of health (SDoH) [1]. The SDoH encompass a range of non-medical factors that influence health outcomes, such as health-related knowledge and behaviours, socioeconomic factors such as level of income and status in social hierarchies, access to health care, and physical environment factors [2]. Associations between these social factors and their impact on health have been widely observed, especially between socioeconomic status and health indicators [3]. The SDoH are substantial contributors to health inequities seen between populations, creating a social gradient in which health deteriorates with lower socioeconomic status [4]. This observed graded relationship between socioeconomic related factors and various health indicators suggest a dose-response relationship, implying that socioeconomic factors may play a causal role in health [3].

Access to health care is an important SDoH as it has been linked to positive health outcomes [2, 5]. However, the same social factors that influence health can also affect individuals' access to health care, as factors such as race and socioeconomic status play a role in the level of access and quality of health care received [6, 7]. This feedback relationship demonstrates the need to address the SDoH to fill the gap in both access and health inequities.

Negative health outcomes including higher rates of disease and lower life expectancy, are significantly greater in populations with increased burden of poor SDoH [2]. Notably,

considerable bodies of evidence have demonstrated the association between health service utilization and the SDoH [8, 9, 10, 11]. As the number of social needs increases for an individual, the risk of hospitalization also increases [8, 9]. A study using cross-sectional data from the 2016-2018 National Health Interview Surveys, found hospitalized respondents to report increased economic instability, food insecurity, social isolation, and lower education, compared to non-hospitalized respondents [8]. Similarly, studies have found a strong relationship between increased social need and use of emergency departments (ED) and primary care [10, 11].

Frameworks, like the biopsychosocial model, originally conceptualised by psychiatrist George Engel, acknowledge that health is the result of multiple levels of organization [12]. Health and health care access disparities can be overcome by recognizing and addressing social, biological, psychological, environmental, and societal factors that are all complex and integrated in one another [12].

1.1.2 Addressing the Social Determinants of Health in Primary Care

Despite our understanding of the impacts of the SDoH, primary care remains predominantly medically based [13]. There is a pressing need for the consideration of the SDoH, as a high prevalence of primary care visits can be attributed to non-medical needs [14, 15]. Similarly, social conditions play a pivotal role in the medical conditions presented by patients in primary care [16]. Patients may find it difficult to differentiate between medical and non-medical needs due to the interconnected nature between the SDoH and health outcomes, leading to dissatisfaction with the health care system [14]. However, there remains several barriers to addressing the SDoH within primary care. A survey conducted by The Physicians Foundation reported that factors like limited time and resources, lack of information, and

burnout interfered with physicians' abilities to address the SDoH effectively [17]. Participating physicians also reported increased burden to mental and physical well-being when attempting to address their patients' social needs [17]. Furthermore, current medical treatment and guidelines are based on the biomedical model, which direct prevention and treatment interventions towards proximal causes rather than considering the upstream social contributors [16]. Overall, there is a lack of confidence, training, and resources for primary care providers to adequately address social needs, while other providers believe that it is not even a part of their role in primary care [16]. This gap in primary care presents a dire need for alternative avenues of addressing the SDoH. The use of community resources and social prescriptions are increasingly being used to fill this gap [14].

1.1.3 Social Prescribing

1.1.3.1 What is Social Prescribing?

With a considerable proportion of primary care visits being attributed to social needs, an aging population, increased chronic disease, and increased complexity of health and social needs, the use of social prescriptions is on the rise [18]. Social prescribing (SP) is an intersection of the medical and social models of health which provide health care providers with a referral process to direct patients to resources that can address health and social needs [14]. Generally, these resources are available locally, often provided voluntarily or through community and social organizations, known as the 'third sector' (third to public and private sector) [19]. The UK has an extensive foundation of SP initiatives and has conducted many studies, and other high-income countries including Canada, the United States, and Australia are following suit [20]. SP is a complex and person-centered intervention that can be implemented through a variety of schemes. Generally, interventions can include a number of tailored components including

awareness, education, health promotion, goal setting, and navigation. The Alliance for Healthier Communities in Ontario identifies the following elements as essential for any SP pathway: a person with a social or health need, a prescriber who places value on the connection between the SDoH and health, a navigator who the patient is transferred to and collaborates with to be connected to appropriate community resources, the social prescriptions, and a data pathway that ensures data is being collected to evaluate outcomes and quality [21].

1.1.3.2 Community Resources

Community-based resources are non-clinical services available to help community members meet their health and social needs, often complementing or enhancing primary care services. A large variety of resources are available that can address mental, physical, psychosocial, social, and socioeconomic determinants of health. Examples can include sports clubs, self-help groups, housing aid programs, parenting courses, and chronic disease management programs [19]. Reviews have reported that community-based interventions aimed to prevent and manage chronic diseases have found positive outcomes [22-24]. Another review focusing on primary care patients found that community-based interventions effectively encouraged physical activity, prevented falls, and improved self care [25]. Similarly, interventions in urban areas found improvements in health behaviours, health literacy, and a number of health status outcomes [26]. In Ontario, community resources are available and funded for [27], but often go underused [28]. Studies that have explored barriers to accessing community resources have reported that patients did not use services due to lack of awareness and health literacy, stigma, linguistic barriers, accessibility barriers, and financial issues [29-32].

The implementation of navigation services within primary care is one means of addressing some of these barriers and facilitating access.

1.1.3.3 What is the Social Prescribing Process?

Overall, the process involves healthcare professionals connecting patients who have unmet health and social needs to non-clinical community-based resources [34]. As there is no agreed upon definition, there are a number of informal and formal pathways that patients can be connected to community resources. Patients can self-initiate contact with patient navigation services that help to guide patients in accessing community resources [33, 35]. Primary care providers can refer patients directly to resources, but more commonly transfers the patient to a link worker trained in designing a social prescription with the patient and providing navigational services [33, 35]. Link workers, also called a variety of other names including a lay navigator, are commonly non-health professionals often based in primary care settings or within community organizations, who help provide patients with support in accessing health and social resources [34, 35].

1.1.4 Patient Navigation

The concept of patient navigation is rooted in cancer care [36]. The American Cancer Society in 1989 reported that patients of low socioeconomic status faced greater barriers in accessing cancer care and endured greater negative outcomes [36]. Due to these findings, a patient navigation program was created in Harlem, New York to help eliminate barriers that patients faced in accessing timely care [36]. Now, navigation programs help to support cancer patients of all demographics and its use has extended to many areas of the health care system [37].

Complex patients in primary care require a number of supports and services, often resulting in fragmentation in the delivery of care [38-40]. Navigators can help to address fragmentation by communicating with all parties providing and receiving care, facilitating care, and helping patients navigate across the health care system [37]. Patient navigation is a patient-centric model of service delivery that can involve a number of activities including provision of information, emotional support, aid in bridging language and cultural gaps, and logistical support, all in efforts of eliminating barriers and facilitating access to necessary services [36, 41]. Patients face a number of barriers resulting from their intersectionality. Barriers to access can stem from lack of knowledge [42-44], poor communication with health care providers, financial barriers, language/cultural factors, and accessibility issues such as distance and transportation [42, 44, 45]. Navigators can provide tailored services to cater to each patient's unique circumstances and help them overcome barriers.

Currently, much of the literature is focused on patient navigation in the context of chronic disease and cancer [46, 47]. Studies conducted in non-cancer patients included patients with diabetes, HIV/AIDS, cardiovascular disease, chronic kidney disease, dementia, and multimorbidity [46]. Reviews and meta-analyses have reported favorable outcomes including increased uptake of screenings, adherence to follow-up treatments and appointments [46, 48, 49], timely care, increased rates of cancer therapy completion, and financial benefits [49].

A scoping literature review was conducted by Carter et al. that focused on patient navigation in primary care settings with an emphasis on connections with community-based health and social services [37]. Generally, navigation was linked to positive outcomes such as improved knowledge, increased access to care, reduced financial stress, improved general

wellness, patient satisfaction, and improved self-efficacy [37]. The review included studies using a range of navigation models such as the use of lay navigators, community health workers (CHW), nurse-led navigation, teams of health professionals, and teams of health professionals in combination with lay navigators [37].

There isn't a single definition for what a lay navigator is, and their roles can vary greatly between studies [37, 47, 50]. Although there are studies that include health professionals such as nurses and social workers as patient navigators in the context of accessing non-medical community resources [37], a lay navigator is a non-health professional [34, 35]. Health professional-led navigation involves activities and knowledge that go beyond basic navigation services, such as provision of treatment support, and requires additional experience and formal education [37, 50]. Lay navigators are trained to carry out activities specific to navigation and may be trained to address the specific needs of certain populations, such as low-income populations or immigrants [37]. Several studies include CHWs as lay patient navigators [37, 47], who received different levels of training and had a variety of roles as a patient navigator [47]. CHWs that are considered lay navigators have little to no formal education related to this field, but undergo job-specific training over a period of a few days to a few weeks [37, 47].

1.1.5 Effectiveness of Social Prescribing

1.1.5.1 Pilot Studies

As studies have pointed towards positive outcomes of SP for individuals, SP is now an integral part of the National Health Service in the UK [51]. Several pilot trials, especially in the UK, have implemented SP models and have evaluated its impacts on a number of outcomes [52]. The commonly cited, and one of the largest SP schemes, the Rotherham SP pilot explored

the effects of social prescriptions over a two-year period between 2012 and 2014, and was re-contracted in 2015 [51, 53]. 1067 individuals were referred to SP services that were funded, including informational services, physical activity programs, community-based activities, and mentoring services [51]. The study found that 83% of participants experienced an improvement in well-being after three to four months of being referred to services [51]. Inpatient admission, emergency attendances, and outpatient visits all decreased by as much as 20%, which in turn led investigators to estimate a return on health care costs [51].

In Ontario, the Alliance for Healthier Communities commenced a year-long SP pilot project, the “first-of-its-kind”, called *Rx: Community – Social Prescribing*, while partnering with UK mentors [54]. 1100 community members across 11 community health centers participated, and were provided 3300 social prescriptions [54]. Participants reported that they experienced improvements in their mental health, decreased loneliness, and increased social connectedness [54]. Additionally, health providers found that SP helped to decrease repeat visits [54]. Based on the results of this pilot, the Alliance recommends further investment in SP initiatives to build integrated systems and increase community connectedness [54].

1.1.5.2 Systematic Reviews

Systematic reviews report that some studies have found evidence of SP being linked to positive outcomes, but results are mixed [52, 55-58]. Improvements in mental health, well-being, general health or quality of life have been reported [52, 55-58], however some studies have reported no difference in these outcomes [52, 56]. Improvements in these outcomes were often found in uncontrolled studies [52] and were only short-term outcomes [52, 55]. Some studies also reported reductions in loneliness [52, 55, 57], while others found no difference [52,

56]. With regards to patient-reported outcomes, evidence suggests positive impacts on self-rated health, patient rating of high quality of care [56], and overall satisfaction with SP programs [55].

Similarly, studies that have been conducted to investigate the effects of SP on health care utilization, have also found mixed results [52, 55, 56]. For primary care visits, a matched group design study found significant longitudinal reductions in general practitioner consultation rates in the SP intervention arm [59], and two uncontrolled before-and-after studies also reported reduced primary care use [60, 61]. Other studies, including a non-randomized trial that found non-significant reductions in primary care contact [62] and an RCT by Grant et al. found no difference in primary care use between the intervention and control arms [63]. Regarding ED visits, an RCT comparing the use of a CHW to usual care found a decrease in visits in the CHW arm [64]. An uncontrolled before-and-after study also reported a statistically significant reduction in accident and emergency attendances [65]. Concerning hospitalizations, an RCT by Kangovi et al. comparing a CHW to usual care reported a reduction in repeat hospital admissions [66] and a continuation of the study a few years later found a non-significant reduction in admissions [67]. An uncontrolled before-and-after study also reported a reduction in inpatient admissions [65].

1.1.6 Effect of Type or Intensity of Patient Navigation

There is currently very little evidence on the comparison of different types of patient navigator models or the effects of different intensities of navigation. One study conducted in women with an abnormal mammography, compared the effects of three navigation intensities: full navigation, limited navigation, and no contact with a navigator [68]. This study found that

those who had interacted with the navigator had a greater odds of fewer days to diagnostic resolution and timelier follow-up, compared to those with no contact [68]. This study found that even women with minimal navigation contact had better outcomes [68]. Specific to social prescription, a study comparing the use of an on-site navigator to the use of remote services, found that significantly more referrals were made when a navigator was on-site, but no significant difference was found in navigator contact [69]. Although some SP studies did report average number of navigator contacts, the effects of the frequency of contact were scarcely studied [56]. A cluster RCT conducted in socioeconomically deprived areas of Glasgow, Scotland found that there was a positive association between consultation rate with the navigator and uptake of community resources [70]. The same study found that a subgroup of patients that met with the navigator three or more times had improvements in various outcomes including quality of life and mental health [70]. A systematic review by Kiely et al., found that an RCT with a more intense SP intervention involving weekly contacts was the only study included in the review with a significant positive effect on health care utilisation, suggesting that patients with more complex needs may benefit from more intense navigation [56].

1.1.7 Gap in Literature

Despite the momentum and widespread use of social prescription in countries including the UK, there is a lack of evidence of its effectiveness from highly quality controlled studies [52, 55, 56]. Positive effects have been reported from a number of studies, however, are mainly found in uncontrolled studies over short follow-up periods [52, 55-57]. Systematic reviews have reported that studies are limited by design weaknesses including lack of comparator groups [52, 55] and high attrition [55, 57], and found it difficult to conclude on effectiveness due to high

variability between studies [52, 55-57]. Of the few existing controlled studies, effects were small or differences were not statistically significant [52, 55-57].

There is a lack of any type of study that has compared the effects of different types or intensities of SP patient navigation models [52, 55-57]. Specific to the effects of SP lay navigation on health care utilization, several studies have been conducted as uncontrolled before-and-after studies, but there remains a scarcity in controlled studies [56]. There are currently no studies comparing the effects of two different SP navigation models on health care utilization [52, 55-57]. Four RCTs were found comparing the use of a SP lay navigator to usual care [63, 64, 66, 67]. The lay navigators were referred to as a referral facilitator in one study [63] and were CHWs in the other three [64, 66, 67]. These studies focused on specific patient populations including those with psychosocial problems [63], patients residing in high-poverty neighbourhoods with multimorbidity [66, 67], and low-income patients with a history of ambulatory care use in the past year [64]. None of these studies were conducted on general primary care patients.

1.2 Rationale

Studies have demonstrated that SP patient navigation models are associated with a number of positive outcomes including improved mental health, well-being, general health or quality of life [52, 55-58], as well as reduced health care utilization [59-61, 64-66]. Generally, there is a scarcity in the literature regarding controlled studies exploring the impact of SP lay navigation on health care utilization. Of the few that exist, none explored the effects of the intervention on a general primary care patient population. There is also a lack of studies comparing the effects of different lay navigation models or comparing the effects of different

navigation intensities, in the context of SP. There is an evidence base that SP navigation models are effective, and that different models or intensities can have varying effects [56, 68-70], providing indication that further research would be valuable. However, no controlled studies were found to compare the effects of different SP lay navigation models on health care utilization. This thesis aims to fill this gap in the literature.

1.3 Thesis Objectives

1. Compare the pre-post change in outpatient use between patients randomized to one of two lay navigation models within the context of SP (primary care based, longitudinal, patient-centered model vs. provincially funded remote services); and
2. Compare the post-intervention odds of having at least one episode of acute care use between patients randomized to one of two lay navigation models within the context of SP (primary care based, longitudinal, patient-centered model vs. provincially funded remote services).

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Interface

The following chapter is the manuscript for our study that compared the effects of two patient navigation models in the context of SP, on health care utilization. This manuscript addresses both of this thesis' objectives. The two models included the Access to Resources in the Community (ARC) primary care-based navigation model and the Ontario-211 provincially funded online directory and remote navigation service, both used to facilitate patients' access of community resources. In 2019, these two models were compared in the ARC-211 RCT, a multi-site, mixed-methods study led by Dr. Simone Dahrouge. This RCT assessed the effects of these two models on access to community resources, as well as secondary outcomes such as patients' ability to access resources and their experience with the navigation services. Ethics approval (Appendix 1) for the ARC-211 RCT was obtained from Bruyère Continuing Care Research Ethics Board. A flow chart of patients included in the ARC-211 RCT can be found in Appendix 2.a.

For this thesis, a subset of patients in the ARC-211 RCT, who provided their health card number and consented to have their study data linked to health administrative data, were included. AM was given permission to use this subset of the ARC-211 RCT for this thesis and the following manuscript. For this thesis, baseline study data collected at enrolment was linked to health care utilization data housed at ICES for a period of four study years. Descriptions of the data sources at ICES that were used to derive the outcome data for this thesis can be found in Appendix 3, and a visualization of the data linking process can be found in Appendix 4.

Author contributions

AM and SD planned the study methodology. AM conducted the analyses and wrote the manuscript. SD provided guidance at each stage of study conduction, interpretation, and writing of the manuscript. SD, CK, AG, and KS all contributed to the interpretation of the study findings, provided feedback on progress, and revised drafts of the manuscript. This manuscript has not been submitted for publication yet. All co-authors will re-revise the manuscript to ensure journal guidelines are met prior to submission for publication.

Chapter 2: A Comparison of a Primary Care-Based Patient Navigation Model and Provincially Funded Remote Navigation Model on Healthcare Utilization

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Abstract

Background: Undesirable social determinants of health can lead to unmet health and social needs, that often cannot be addressed in primary care. These unmet needs may contribute to enhancing barriers to accessing resources required to address these needs. Social prescribing consists of a referral, usually from primary care providers, to access resources that can help address health and social needs, followed by some level of patient navigation support to access the resource. Social prescribing navigation models have been linked to a number of positive outcomes, including decreased health care utilization. We aim to compare the effects of two social prescribing lay navigation models on health care utilization.

Methods: This was a secondary analysis of data from a randomized controlled trial that compared two navigation models within a social prescribing program: Access to Resources in the Community (ARC) longitudinal, in-person, and primary-care based service model vs the provincially funded Ontario-211 online/telephone information and remote navigation service. Of the 326 patients who were enrolled in this trial, 150 patients who consented to have their data linked to health administrative data housed at ICES (ARC=83, Ontario-211: 67) were included in this study. We compared the pre (Year -1/-2) -post (Year 0 and Year +1) differences in the number of outpatient and primary care visits, between study arms, using multivariate linear regressions. We compared the odds between the study arms, of whether patients had ≥ 1 emergency department and ≥ 1 hospital episode in the post-intervention years (Year 0 and Year +1), using multivariate logistic regressions, while adjusting for pre-intervention use. Regression models were all adjusted with socio-demographic covariates.

Results: Linear regression results favoured the ARC arm, with a greater decrease in number of post-intervention outpatient and primary care visits compared to Ontario-211, although results were not statistically significant ($p>0.05$). Logistic regression results similarly favoured the ARC arm, with lower odds of ≥ 1 post-intervention emergency department and hospital episode in the ARC arm compared to Ontario-211, however, these results were also not statistically significant ($p>0.05$).

Conclusions: The ARC arm was favoured in all four categories of health care utilization, but results were not significant. This study indicates that the ARC in-person patient navigation approach may be beneficial in reducing health care utilization and warrants further investigation with larger sample sizes to confirm such findings.

2.1 Background

The social determinants of health (SDoH) contribute to health inequities between populations [1]. The unmet needs and conditions that manifest from the SDoH account for a high prevalence of primary care visits [2-4]. Furthermore, studies have demonstrated an association between increased social need and emergency department (ED) visits and hospitalizations [5-8]. However, primary care providers face many barriers, including limited appointment times and lack of training, that prevent them from adequately addressing patients' social needs [4].

Social prescribing (SP) is being increasingly used to address the complexity of patients' health and social needs [9]. SP provides a pathway for primary care providers to refer patients with identified health and social needs to link workers who will help them overcome barriers and enable access to the needed resources [10]. Lay navigators, often called link workers, are non-health professionals and are trained specifically for SP [11]. The resources patients are referred to are usually community-based, and often provided through voluntary or social enterprises known as the 'third-sector', third to the public and private sector [12]. Such community resources can include chronic disease management programs, art classes, sports clubs, parenting courses, and much more, and help to enhance social connectedness or provide non-medical alternatives for health and social concerns [12].

Generally, studies that have explored the effectiveness of SP often found improvements on a number of patient outcomes such as well-being, health status, quality of life, and social connectedness [13-18]. However, most studies had a pre-post single arm design, resulting in uncertainty surrounding the evidence [13-18]. The evidence surrounding the impact of SP on

health care utilization, includes evidence of reductions in primary care visits, ED visits, and hospitalizations, but these studies also suffer from high risk of bias related to their study design [13-16]. Three randomized controlled trials (RCTs) have been conducted comparing the use of a lay navigator to usual care and found reductions in ED visits [19] and repeat hospital admissions [20] in the navigator arm, while others found no significant differences [21, 22].

In addition, little is known of the effects of different types or intensities of navigation services, especially in the context of social prescription [23]. One SP cluster RCT study found that when comparing in-person patient navigation to remote navigation, doctors made significantly more referrals to the in-person navigator, but did not find a difference in number of resources accessed [24]. In Glasgow, Scotland, a cluster RCT study found that a subgroup of patients that met with a navigator three or more times had improvements in outcomes including quality of life and mental health [25]. A review by Kiely et al. also found that an RCT with a more intense SP navigation intervention compared to other studies included, was the only one that found positive effects on health care utilization [15]. These studies suggest that navigation intensity may play a role in the effectiveness of SP navigation, but more research is required.

Our study is a secondary analysis of an RCT of SP that compared the Access to Resources in the Community (ARC) in-person lay navigator to the Ontario-211 online and telephone navigation service, both used to facilitate access to community resources. The original RCT was designed in efforts to address the gap in literature of randomized controlled studies comparing the effects of different SP navigation models. Specifically, the following study aims to add to the

literature by assessing the effects of the two navigation models on health care utilization among patients in primary care settings.

2.2 Methods

2.2.1 Study Design

This study includes patients who participated in the larger-scale ARC-211 RCT and had consented to have their study data linked to health administrative data. We used pre-post design for outpatient visits and a post-evaluation, accounting for baseline utilization for acute care use.

2.2.2 Participants and Setting

ARC-211 RCT

We derived patients for this study from the larger-scale RCT that compared the ARC navigation services to the provincial Ontario 211-navigation services within a SP study on community resource utilization. The study methodology for the ARC-211 RCT is described in greater detail in its manuscript that is in-preparation.

We recruited from the Eastern Ottawa and Sudbury regions, two regions in the province of Ontario (Canada) with prevalences of Francophones living in minority situations of $\geq 25\%$ [26, 27]. All primary care practices were eligible to be included in the study, excluding community health centers which have existing navigation support integrated in their services. We invited practices to participate via email followed by phone calls until the required sample size was achieved. Practices were enrolled if at least one family physician or nurse practitioner consented to participate in the study. Patients of participating primary care providers were eligible to be enrolled in the RCT if they had at least one identified health or social need that their provider

believed could benefit from the use of navigation services for community resources. We excluded patients who had a condition that required immediate care.

Participating practices posted promotional posters to encourage patients to discuss their health and social needs with their primary care provider. We provided orientation sessions to all practice members to inform them of the benefits of SP and the breadth and value of health and social resources available to their patients, and explained the referral process. Primary care providers informed these patients about the study, and completed a referral form with the interested patients, which listed the patient's contact information and type of health and social needs for which they were being referred. The study research assistant contacted the patients who were referred, to further describe the study, to confirm their eligibility and obtain their consent, and administered the baseline survey.

We enrolled patients between March 2018 and December 2019 with each city having a 12-month enrollment period. Patients were randomly assigned to the ARC or 211 study arm in a 1:1 allocation after having completed the baseline survey which captured sociodemographic information and data on their health and social needs. A subset of patients had voluntarily consented to have their study data linked to health administrative data, and provided their Ontario Health Insurance Program (OHIP) number (health card number) for this process. Randomization was conducted based on an electronic randomization schedule, and arm allocation was concealed until patient registration was complete. Each study region had a designated independent statistician who prepared this schedule for their region.

The main outcome of the original ARC-211 RCT was resource utilization which was measured by whether patients had accessed at least one community-based resource and the number of resources they had accessed within the three-month intervention period. The study aimed to detect an absolute difference of 20% in access of community resources between the two arms and required 306 patients to achieve 80% power and 5% two-sided significance level. Accounting for common sizes of practices and dropout rate, 12 practices were required.

2.2.3 Interventions

2.2.3.1 ARC

The ARC navigator was a lay, in-person, bilingual (English and French) navigator, situated in the participating practices. The navigator underwent a 12-week training that covered a variety of topics, such as the SDoH and person-centered care, to help prepare the navigator in supporting patients to find and access resources. Each practice had the responsibility of developing their own system of referring patients to the navigator. A room at each practice was designated for the navigator to meet with referred patients for two half days during the week. The first meeting with the navigator was recommended to be face-to-face at the practice, and subsequent meetings took place according to each patient's preference (i.e., in person, telephone, email). Navigators provided services to patients in their preferred official language. Patients outlined their priorities, needs, and barriers to the navigator, and developed a plan together to address these. The aid provided by the navigator included identifying resources to meet the patient's health and social needs, emotional support, and support to overcome barriers, for example finding methods of transportation to reach resources. The navigator also played a role in relaying information between the community resources and the patient's

primary care provider. A report of the navigator's services was provided to patients' primary care providers after completion of navigation support.

2.2.3.2 Ontario-211

The research assistant directed patients in this arm towards Ontario-211 and described their services. The research assistant informed these patients that the service was free, always accessible, available in multiple languages, and was a means to confidentially connect to local resources. Their services are available 24 hours, seven days a week, through an online directory, telephone service, or through online chatting options. Support is often provided solely during the first point of contact, with little follow-up if any.

2.2.4 Data Sources

2.2.4.1 Data Linkage

We used the OHIP number provided at enrolment to link the ARC study data to various databases housed at the ICES. We used the patient's unique ICES Key Number (IKN), assigned to each person residing in Ontario to link the study data to databases containing the measures of health care utilization. ICES is an independent research corporation funded by the Ontario Ministry of Health (MOH) and the Ministry of Long-Term Care (MLTC) [28]. ICES provides an inventory of linkable health administrative datasets that they are authorized to collect from the publicly funded health care in Ontario, for the purpose of creating an evidence base for health policy, planning, and evaluation [28]. Policies and procedures approved by the Information and Privacy Commissioner of Ontario governs the access of this data [28].

Each patient's date of enrolment in the RCT, referred to as the "Index date", was used to establish the date range associated with each study year. We obtained data retrospectively for the year prior to the index date (Year -1) and the year prior to that (Year -2), and prospectively

for the first (Year 0) and second (Year +1) year after the index date, for a total period of four years. A flowchart of this data linking process and study timeline can be found in Appendix 4.

2.2.4.2 RCT Survey Data

Baseline sociodemographic data collected from the RCT survey that was linked to data housed at ICES, included patients' age, sex, region, immigration status, education, financial situation, occupation, whether they were a caregiver, marital status, whether they lived alone, race, and language spoken at home. All sociodemographic variables were dichotomized, except language spoken at home which included three categories. The categorizations and descriptions of these variables can be found in Appendix 5.

2.2.4.3 ICES data: Outcome Measures

Our outcomes were the number of outpatient medical visits (categorized as all outpatient and primary care visits only) and acute care use (ED episodes and hospital episodes) in the four years evaluated. Outpatient visits were treated as continuous variables while acute care measures were dichotomized as patients having at least one episode (yes/no) due to the low prevalence of episodes.

We obtained outpatient visits from the OHIP Claims Database. These included home, office, and virtual visits, and excluded long-term care visits. Primary care visits were those having a primary care fee code that was billed by any general or family physician. We obtained ED episode data from the National Ambulatory Care Reporting System (NACRS). Hospital episodes were derived from a combination of records in the Discharge Abstract Database (DAD) and the Ontario Mental Health Reporting System (OMHRS) database for general and mental health related hospital episodes, respectively.

2.2.5 Statistical Analysis

We conducted all analyses using SAS (version 8.3).

Missing survey data was imputed prior to linkage to avoid case wise deletions. We used 14 imputations, and used standard SAS procedures to conduct analyses on complete sets of data and the mianalyze procedure was used to pool the analyses. The mianalyze procedure derives univariate inferences based on all imputations. All analyses were completed using the original study arm allocation (intent-to-treat), regardless of the degree of each patients' level of compliance with the intervention.

2.2.5.1 Descriptive

We describe sociodemographic patient characteristics at baseline using means (standard deviations [SD]) and percentages. We calculated the mean number of visits and 95% confidence intervals (CI) for outpatient visits in each study year and established the baseline measure as the mean number of visits in Year -2 and Year -1. We established the proportion of patients with at least one ED and one hospital episode for each year, and established the baseline ED and hospital episodes as the proportions (95% CI) of patients with at least one episode in Year -2 or Year -1.

2.2.5.2 Comparative analyses

2.2.5.2a Outpatient visits: Difference-in-difference (DiD)

We used multiple linear regression modeling to compare the pre-post change in all outpatient and primary care visits between study arms (DiD: $\Delta_{211} - \Delta_{ARC}$). The dependent variable was the difference between the number of visits in each post-intervention year (Year 0 and Year +1) and baseline (a negative value representing a decrease in the number of visits), and the main independent variable was the study arm. The ARC study arm was the reference

category, and a positive DiD indicates more visits in the 211 arm. Further explanation and an example of a DiD calculation can be found in Appendix 6.

2.2.5.2b Acute care use: Post-intervention comparison

For acute care use, we used multiple binary logistic regressions in which the dependent variable was the occurrence of at least one episode (ED, hospital) in each post-intervention year (Year 0 and Year +1), and the main independent variable was the study arm. The presence of an episode at baseline was included as a co-variate to account for the baseline risk. The ARC study arm was the reference category, and an odds ratio (OR) greater than one indicates a higher odds of acute care utilization in the 211 arm.

2.2.5.2c Covariates

We adjusted all regressions using the baseline sociodemographic variables obtained through the RCT survey. This included age, sex, region, immigration status, education, financial situation, occupation, whether patient was a caregiver, marital status, whether patient lived alone, race, and language spoken at home.

If we observed co-linearity between the baseline sociodemographic patient characteristics in the models, one variable was removed. The variables removed are specified in the respective regression output tables for each outcome measure.

2.2.6 Reporting Guidelines

The 2010 CONSORT checklist for clinical trials, along with the CONSORT-Outcomes 2022 Extension was used as the reporting guidelines for this article.

2.3 Results

2.3.1 Patient Characteristics

A total of twelve practices working under a capitation-based model, eight of which were in Ottawa and four in Sudbury, were enrolled in the study, and 50 physicians and five nurse practitioners from these practices consented to participate. Figure 1 is a flow chart depicting the patients that were included in this study. 326 patients of these participating primary care providers were enrolled into the ARC-211 RCT who were randomized to either intervention arm. 158 (48.5%) of these patients consented to have their study data linked to health administrative data and provided their OHIP number. We successfully linked 150 patients to the data housed at ICES; 83 patients in the ARC arm and 67 in the 211 arm.

The index date of patients consenting to this analysis ranged from October 2018 to December 2019, and the healthcare utilization measures were obtained from October 2016 to December 2019 for the pre-intervention (baseline) period, and October 2018 to December 2021 for the post-intervention period.

The mean age of patients in both arms were similar (ARC: 51.1 (SD 16.6); 211: 51.7 (SD 16.6)) and the majority of patients in both arms were female (ARC: 74.7%, 211: 67.2%) and were from Ottawa (ARC: 72.3%, 211: 88.1%) (Table 1). There were some potentially important imbalances across the two arms in the sociodemographic profile of the patients (Table 1). Imbalances were seen in education level (no university degree: ARC 65.9%, 211 73.1%), perceived financial situation (poor to tight: ARC 51.9%, 211 61.9%), race (not Caucasian: ARC 19.7%, 211 26.3%), and occupation (not in school/unemployed: ARC 53.7%, 211 70.8%).

Baseline outcome measures were similar between arms for all outpatient visits (ARC: 9.8 (95% CI 8.1, 11.5), 211: 9.3 (95% CI 7.6, 11.0)) and for only primary care visits (ARC: 5.7 (95% CI 4.8, 6.6), 211: 5.2 (95% CI 4.4, 6.0)). The baseline proportion of patients with at least one ED episode was 54.2 (95% CI 42.9, 65.2) in the ARC arm and 56.7 (95% CI 44.0, 68.8) in the 211 arm, while the proportion of at least one hospital episode at baseline in the ARC arm was 21.7 (95% CI 13.4, 32.1) and in the 211 arm was 11.9 (95% CI 5.3, 22.2). Although the prevalence of ≥ 1 ED episode was not low (<40% in each study year), the proportion of patients with multiple occurrences in each year was less than 15%, thus ED episodes could not be treated as a count or linear outcome. Appendix 7 portrays additional information for ED and hospital episodes and includes the mean number (95% CI) of episodes at baseline and in each study year.

2.3.2 Health Care Utilization Outcomes

Figure 2 depicts the mean number of outpatient visits (a: all; b: primary care only) in each study arm across the four study years. Table 2 includes the difference in number of visits between each post-intervention year (Year 0 and Year +1) and baseline, as well as the unadjusted DiD in number of all outpatient and only primary care visits for 211 relative to ARC. The unadjusted DiD for all outpatient visits was 0.2 (95% CI -2.2, 2.7) and 1.6 (95% CI -1.0, 4.1) for Years 0 and +1, respectively. For primary care related visits, this difference was 0.4 (95% CI -0.8, 1.6) and 0.9 (95% CI -0.6, 2.3) in Year 0 and Year +1, respectively. The positive DiDs represent a greater negative pre-post change in the ARC arm, although differences were not significant.

Figure 3 depicts the proportions of patients with acute care episodes in each study arm across the four study years (a: ED; b: hospital). Table 3 displays the unadjusted relative risk (RR)

and OR of each acute care measure in each post-intervention year, comparing 211 to the ARC arm. The unadjusted OR for ≥ 1 ED episode was 0.8 (95% CI 0.4, 1.6) and 1.5 (95% CI 0.7, 3.2) in Year 0 and Year +1, respectively. For ≥ 1 hospital episodes, the unadjusted OR was 0.9 (95% CI 0.3, 2.1) and 1.6 (95% CI 0.4, 6.9).

2.3.3 Multivariate Regressions

2.3.3.1 Outpatient Visits

The adjusted DiD measures can also be found in Table 2. Accounting for baseline sociodemographic characteristics, the DiD in the annual number of all outpatient (Year 0: (1.0 (95% CI -1.6, 3.5; $p=0.45$), Year +1: (2.4 (95% CI -0.3, 5.1; $p=0.082$)) and primary care visits (Year 0: (0.7 (95% CI -0.6, 1.9; $p=0.30$), Year +1: 1.0 (95% CI -0.6, 2.6; $p=0.22$)) was in favour of the ARC arm, but was not statistically significant.

The full outputs of the multivariate analyses we conducted for outpatient visits are shown in Table 4 (all outpatient visits) and 5 (only primary care visits). Some baseline factors were associated with these outcomes including not being married (all outpatient visits), being in a poorer financial situation, not speaking French or English, and being a caregiver (primary care visits only).

2.3.3.2 Acute Care

The adjusted ORs for both acute care outcomes can also be found in Table 3.

2.3.2.2a ED episodes

Accounting for baseline sociodemographic factors and the baseline risk level variable, the ORs (211 vs ARC) for ≥ 1 ED episode in Year 0 was 0.7 (95% CI 0.3, 1.5; $p=0.33$) and in Year +1 was 1.7 (95% CI 0.7, 4.1; $p=0.26$) (Table 3). The ORs were not statistically significant, but were in favour of the ARC arm in Year +1.

The full outputs of the multivariate analyses we conducted for ≥ 1 ED episode is shown in Table 6. Some baseline factors were associated with these outcomes including having had ≥ 1 ED episode in the two years prior to study enrolment, having no university degree, and being a Francophone.

2.3.2.2b Hospital episodes

Accounting for baseline sociodemographic factors and the baseline risk level variable, the ORs for ≥ 1 hospital episode in Year 0 was 1.2 (95% CI 0.4, 3.3; $p=0.73$) and in Year +1 was 1.8 (95% CI 0.5, 6.8; $p=0.37$) (Table 3). These measures were also not statistically significant, but in favour of the ARC arm.

The full outputs of the multivariate analyses we conducted are shown in Table 7. Some baseline factors were associated with these outcomes including having had ≥ 1 hospital episode in the two years prior to study enrolment and being an immigrant.

2.4 Discussion

This study compared the impact of two navigation models within a SP program; a longitudinal, patient-centered, holistic support (ARC), and an episodic, primarily informational and referral service (211) on health care utilization in the two years post-study enrolment. Our findings indicated a non-significant trend towards the favoring of the ARC arm for decreased outpatient and primary care visits in the years following the intervention, as well as a reduction in ED and hospital episodes specifically in Year +1. This study adds to the limited body of evidence exploring the impacts of SP on health care utilization. To our knowledge this is the first controlled study to compare two different SP patient navigation models on health care utilization.

Several studies have reported on the impact of SP on health care utilization, but all assess the effects of lay navigation compared to usual primary care [19-22]. One RCT was conducted in patients enrolled in 2018-2019 from a low-income neighbourhood in Detroit, Michigan among patients with increased acute care use in the 12 months prior to enrolment, and found that their results favoured the community health worker (CHW)/lay navigator arm, with this arm having significantly fewer ED visits in the one-year follow-up period, compared to the usual care arm [19]. While this study found fewer ED visits in the intervention arm, we could not support this conclusion as we did not evaluate the difference in number of ED episodes due to the low prevalence of episodes in our study population and instead compared the odds between our study arms. Our findings cannot conclude that either arm involved a reduction in number of ED episodes, rather that there was a favoring of the ARC arm which had a non-significant lower odds of ≥ 1 ED episode, compared to 211. Another study conducted on a Philadelphia, Pennsylvania population of high-poverty primary care patients with multiple chronic diseases who were enrolled in 2013-2014, found a non-statistically significant difference in prevalence of hospitalizations at 6 months and at 1 year, favouring the CHW arm compared to the goal-setting (usual care) arm [20]. This study was conducted again in a similar patient population who were randomized in 2015-2016, and found a statistically significant lower odds of repeat hospitalizations in patients who were hospitalized in the CHW arm compared to the goal-setting arm [21]. Although these studies are comparing measures of association between their study arms as our study does, the difference in study design makes our studies incomparable. These studies are comparing SP navigation to usual care using an RCT design where the effects on acute care use may be more evident due to the stark difference between

the study arms. Our study, although stems from an RCT, cannot be considered randomized and compares two arms that both involve SP navigation, which may contribute to our non-significant ORs from comparing acute care use between study arms that share a similar goal.

In terms of the effects of SP navigation on primary care use, this favoring of lay navigation seen in other studies was not reflected in an older RCT conducted in the UK among general practice patients who had psychosocial problems, randomized between 1997 and 1998, in which no difference in the number of contacts with primary care was found between the study arms [22]. Although our study did assess the change in number of primary care visits like the described study, we could not evaluate this difference in either study arm separately as we would not be able to distinguish any differences from the effects of COVID-19 on these outcomes. We used DiD measures to help discount the effects of the pandemic, thus, we cannot conclude that either arm involved a difference in number of visits, but rather we can say that the ARC arm was favored as the DiD measures indicated a non-significant greater negative pre-post change in this arm compared to 211. These studies found in the literature indicate that SP navigation can reduce health care utilization but are not comparable to our study due to difference in study design as we are comparing the effects of two different navigation models.

The studies discussed, focused on specific patient populations including patients who were socioeconomically disadvantaged who also had multiple chronic diseases [20, 21] or who also had a history of acute care use [19], or patients with psychosocial problems [22]. A couple of these studies found significant reductions in certain health care utilization measures [19, 21]. We conducted this study in general primary care patients, although they were more likely to be socioeconomically disadvantaged. As our results did not show any significant reductions in

health care utilization in either study arm, this may suggest that certain demographics of patients may benefit from using health and social resources in the community, more than others, and experience these benefits over shorter periods of time. This is supported by existing evidence that shows that health inequities resulting from SDoH, chronic clinical conditions, and behavioural health needs are risk factors for potentially avoidable health service use as well as high-cost use [29-31]. Facilitating access to community resources through lay navigation, may help to address upstream health and social factors that may be associated with increased hospitalizations and ED visits. Specific to our patient population, effects of lay navigation may take longer to manifest. Conducting a similar study over an extended period of time will help to explore the long-term effects of lay navigation over a number of time points. Further research is also required to investigate how lay navigation may affect different patient populations.

Regarding studies that have compared different models or intensities of SP patient navigation, one study was found in the literature. A cluster RCT conducted by Messmer et al. involved a patient navigator who split their time providing in-person SP services within health centers, who also provided remote services at other times [24]. This study found that when the navigator was on-site, more referrals were made but no differences in navigator contact or resource uptake was found [24]. This study is similar to ours with regard to the interventions being compared, as ARC was also an in-person service situated within practices being compared to the remote 211 navigation service, however the study by Messmer et al. did not assess the effects of the interventions on health care utilization [24]. Another study conducted as a quasi-experimental cluster RCT in Scotland, investigated the effects of different practice-based SP navigation intensities [25]. This study found that in the subset of patients who had contacted

the navigator, patients with more navigator contact had significantly more community resource uptake, as well as improvements in outcomes such as quality of life and mental health [25]. Similarly, the review conducted by Kiely et al., found that the more intense primary care-based SP intervention in Kangovi et al.'s 2013 RCT was the only study included in this review that found significant reductions in health care use [15]. Although none of these studies are directly comparable to ours, these studies demonstrate the effectiveness of more intense, patient-centered SP navigation models situated within practices. Further controlled research, especially RCTs, are required to compare the effects of different SP models on health care utilization.

Although not significant, our results suggested a favouring of the ARC arm for health care utilization reduction that may largely be attributed to the nature of the intervention. Patient navigation interventions like ARC allow patients' unique and holistic needs to be addressed through adherence to patient-centered care principles and provision of an environment that can nurture patient development [32]. Studies have reported that successful SP characteristics which patients have appraised include personalised services, focus on holistic change, and strong but flexible relationships between patient and navigator [33, 34]. These features of SP lay navigation interventions can help to foster confidence and empowerment [33, 35] which are linked to positive patient behaviours and outcomes [36]. Additionally, ARC was situated in primary care practices which may have also contributed to the favoring of this intervention. Link workers embedded in primary care practices can facilitate more intense support and navigation, and increased meeting with navigators is associated with positive patient outcomes [15].

The characteristics of ARC are also features of patient activation interventions, which can contribute to increased primary care attendance [37, 38]. Patient activation can be enhanced by interventions that nurture skill development, that encourage autonomy, and provide health coaching [37]. Lay navigation is a patient-centered intervention that covers these elements of patient activation [38]. Patients who have higher activation scores are more likely to engage in healthy behaviors, adhere to treatment, and obtain regular care, which may prompt patients to see their primary care provider more regularly [37, 38]. The fostering of patient activation would make an initial increase in the number of primary care visits in Year 0 of our study, a possibility. However, our study did not specifically explore the impacts on patient activation measures and our findings did not reflect an increase in mean number of primary care visits compared to baseline, nor did the ARC arm have a greater mean number of visits compared to 211. Two controlled studies that did include patient activation as a secondary outcome, also did not find significant differences in activation in the SP arm [20, 21]. Further investigation into the impacts of SP navigation of varying intensities may be beneficial, as studies have found greater patient activation to be linked to fewer hospitalizations, re-admissions, and fewer ED visits [37, 39].

Strengths and Limitations

This study is the only controlled study to our knowledge that compares two different models of patient navigation within a SP program, on health care utilization, providing some insight for the methodology for future studies and reason to conduct more research through controlled designs. We used longitudinal health care utilization data from ICES, providing us with reliable outcome data rather than self-reported data. This is a valuable strength of this

study, as other SP evaluations have found acquiring health care utilization data to be difficult [40]. However, there are also several limitations to our study. First, our post-intervention period overlapped with the COVID-19 pandemic, contributing to fluctuations in outcome data that cannot be attributed to navigation. Additionally, it is unknown if the pandemic affected the behaviours and health care utilization of sociodemographic groups included in this study, differently. There was a trend towards a dip in health care utilization in Year +1 compared to previous study years, although these changes were mostly not statistically significant, reflecting the trends reported by the Canadian Institute for Health Information (CIHI) [41, 42, 43]. However, the use of longitudinal data has allowed us to look at health care utilization both retrospectively and prospectively from the enrolment date, allowing us to calculate DiD measures which helps to deduct bias resulting from temporal trends [44]. Second, our study involved a small sample size which may explain the wide confidence intervals and lack of significant findings, making a type 2 error a possibility. Another limitation of this study was that although patients were initially randomized to either intervention arm, only patients who provided a valid health card number were included in this study. Thus allocation of patients in this study could no longer be considered randomized, creating an imbalance in arms at baseline which may have biased the results.

2.5 Conclusion and Future Directions

Although our results were not significant, our findings along with other studies provide a signal that SP lay navigation situated in primary care may be associated with positive outcomes [21] and reduced health care utilization [19-21]. SP lay navigation is a very patient-centered, holistic, and complex intervention, inevitably making it difficult to study using rigorous

methodologies. Evidence shows that complex interventions that produce positive effects in smaller studies that are usually observational or uncontrolled, may not produce the same results in controlled studies [45]. Since we do not know the time period for SP to have an impact, future studies should be conducted over longer study periods to provide enough data points to establish concrete utilization trends as well as the opportunity to investigate longer-term impacts. There is currently a large gap in the existence of controlled studies, especially randomized controlled studies, but there is evidence to support furthering this area of research. Future studies should aim to conduct RCTs with larger samples to minimize selection bias and improve generalizability.

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Manuscript Tables and Figures

Figure 1. Flow chart of patients included in study and analysis

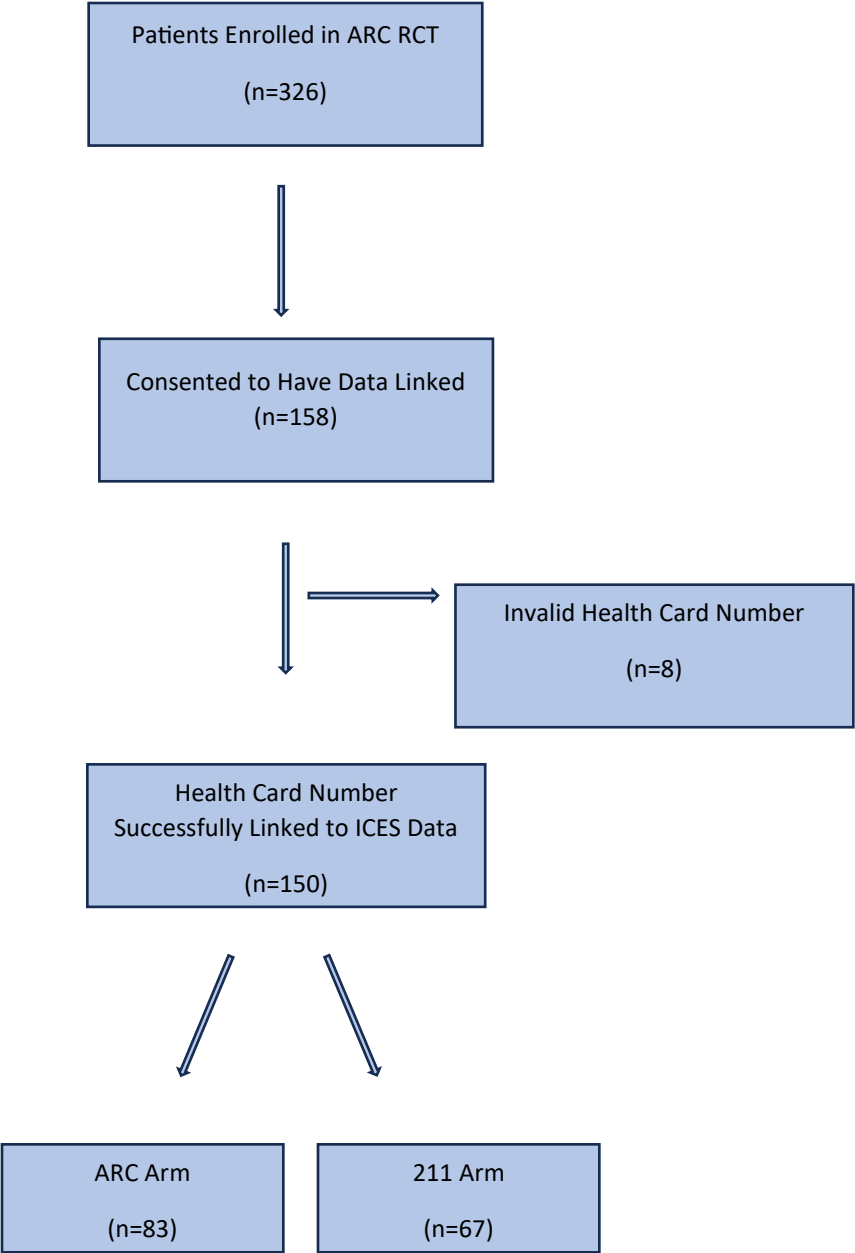


Table 1. Descriptive characteristics of patients in the ARC arm, 211 arm, and overall cohort

Characteristic	ARC (n=83)	211 (n=67)	Overall (n=150)
Baseline Socio-demographic and Health			
Age (years), mean (SD)	51.1 (16.6)	51.7 (16.6)	51.3 (16.6)
Age ≥50 years, n (%)	43 (51.8)	40 (59.7)	83 (55.3)
Ottawa region, n (%)	60 (72.3)	59 (88.1)	119 (79.3)
Female, n (%)	62 (74.7)	45 (67.2)	107 (71.3)
Immigrant, n (%)	16 (19.3)	12 (17.9)	28 (18.7)
No university-level degree, n (%)	54 (65.9)	49 (73.1)	103 (68.7)
Poor to tight financial situation, n (%)	41 (51.9)	39 (61.9)	80 (53.3)
Non-Caucasian, n (%)	15 (19.7)	15 (26.3)	30 (20.0)
Not working or in school, n (%)	44 (53.7)	46 (70.8)	90 (60.0)
Caregiver, n (%)	34 (43.6)	25 (39.67)	59 (39.3)
Not married, n (%)	48 (60.8)	42 (67.7)	90 (60.0)
Lives Alone, n (%)	34 (41.0)	28 (42.4)	62 (41.3)
*Language Spoken at Home, n (%)			
French or Other only	24 (28.9)	20 (29.9)	44 (29.3)
Health Service Utilization			
^a All outpatient visits, mean (95% CI)	9.8 (8.1, 11.5)	9.3 (7.6, 11.0)	9.6 (8.4, 10.8)
^b Primary care visits, mean (95% CI)	5.7 (4.8, 6.6)	5.2 (4.4, 6.0)	5.5 (4.9, 6.1)
^c ≥ 1 ED episode, % (95% CI) [#]	54.2 (42.9, 65.2)	56.7 (44.0, 68.8)	55.3 (47.0, 63.5)
^d ≥ 1 Hospital episode, % (95% CI) [#]	21.7 (13.4, 32.1)	11.9 (5.3, 22.2)	17.3 (11.6, 24.4)

*Reference category for language spoken at home was English only

^a All outpatient episodes = Baseline value of the average number of all outpatient episodes for Year -2 and Year -1

^b Primary care episodes = Baseline value of the average number of only primary care episodes in Year -2 and Year -1

^c ≥1 ED episode = Proportion of patients having had at least one ER episode in Year -2 or Year -1

^d ≥1 Hospital episode = Proportion of patients having had at least one hospital episode in Year -2 or Year -1

[#]Baseline mean number (95% CI) of ED and hospital episodes can be found in Appendix 7

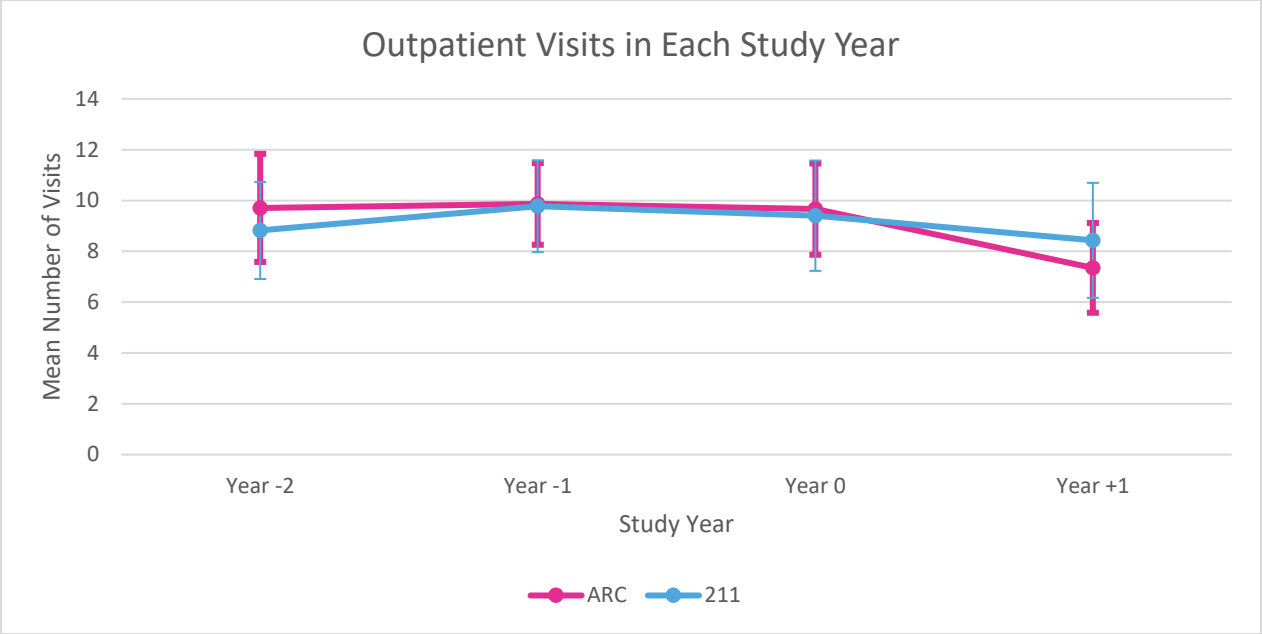


Figure 2a. Mean number (95% CI) of all outpatient visits in each study arm across the four study years

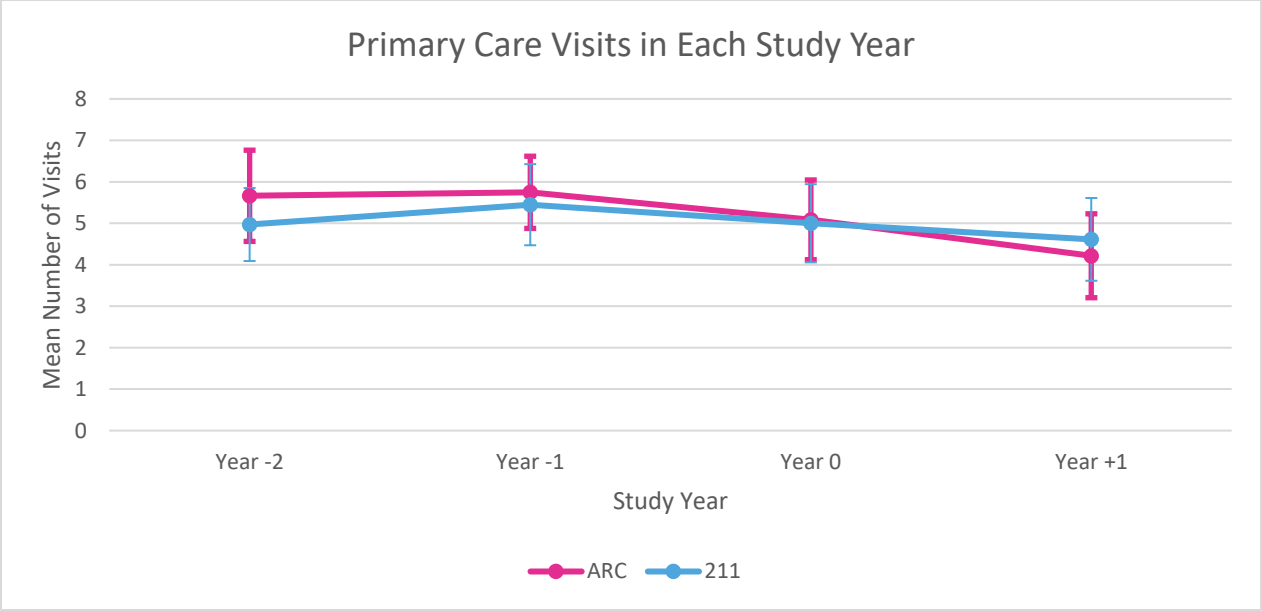


Figure 2b. Mean number (95% CI) of only primary care visits in each study arm across the four study years

Table 2. Difference in number and DiD in number of outpatient visits between study arms

All outpatient visits				
	Difference in the Number of visits from baseline *		DiD across arms**	
	ARC (n=83)	211 (n=67)	Unadjusted	Adjusted
All visits				
Year 0	-0.1 (-1.9, 1.7)	0.1 (-1.5, 1.7)	0.2 (-2.2, 2.7), p = 0.85	1.0 (-1.6, 3.5), p=0.45
Year +1	-2.4 (-4.2, -0.7)	-0.9 (-2.8, 1.1)	1.6 (-1.0, 4.1), p = 0.23	2.4 (-0.3, 5.1), p=0.082
Primary care visits only				
Year 0	-0.6 (-1.4, 0.1)	-0.2 (-1.2, 0.8)	0.4 (-0.8, 1.6), p = 0.51	0.7 (-0.6, 1.9), p=0.30
Year +1	-1.5 (-2.5, -0.5)	-0.6 (-1.7, 0.5)	0.9 (-0.6, 2.3), p = 0.23	1.0 (-0.6, 2.6), p=0.22

*Difference = Year 0 (or Year +1) – Baseline (95% CI)

** $\Delta_{211} - \Delta_{ARC}$ (95% CI), p-value

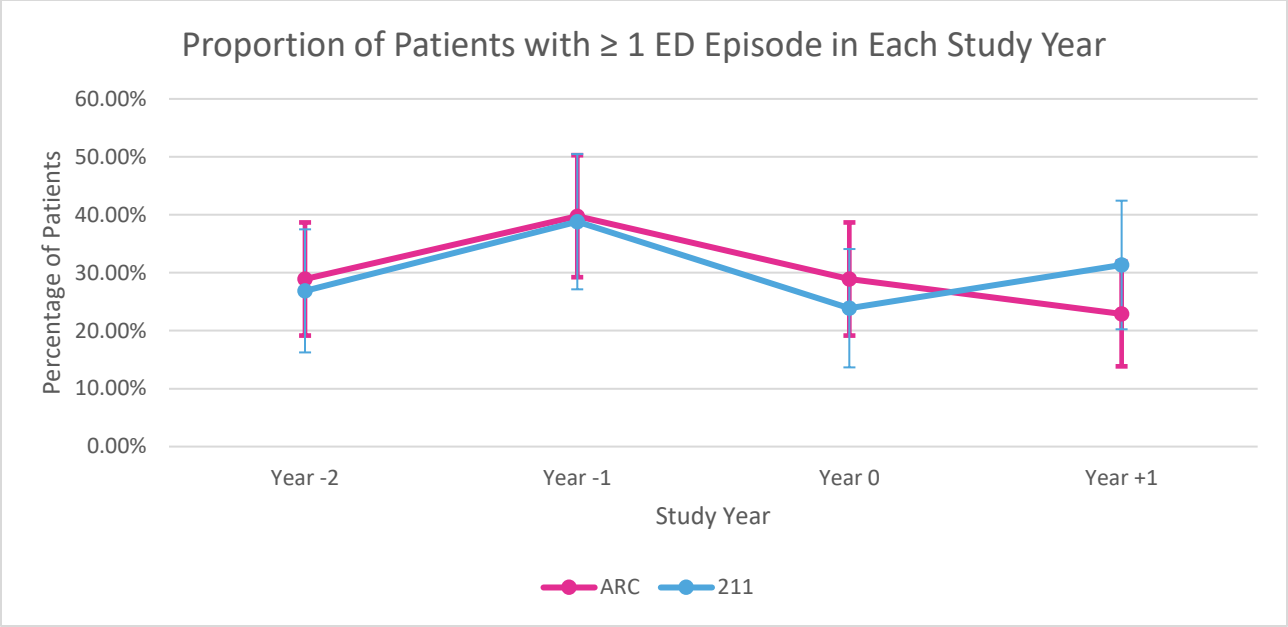


Figure 3a. Percentage proportion (95% CI) of at least one ED episode in each study arm across the four study years

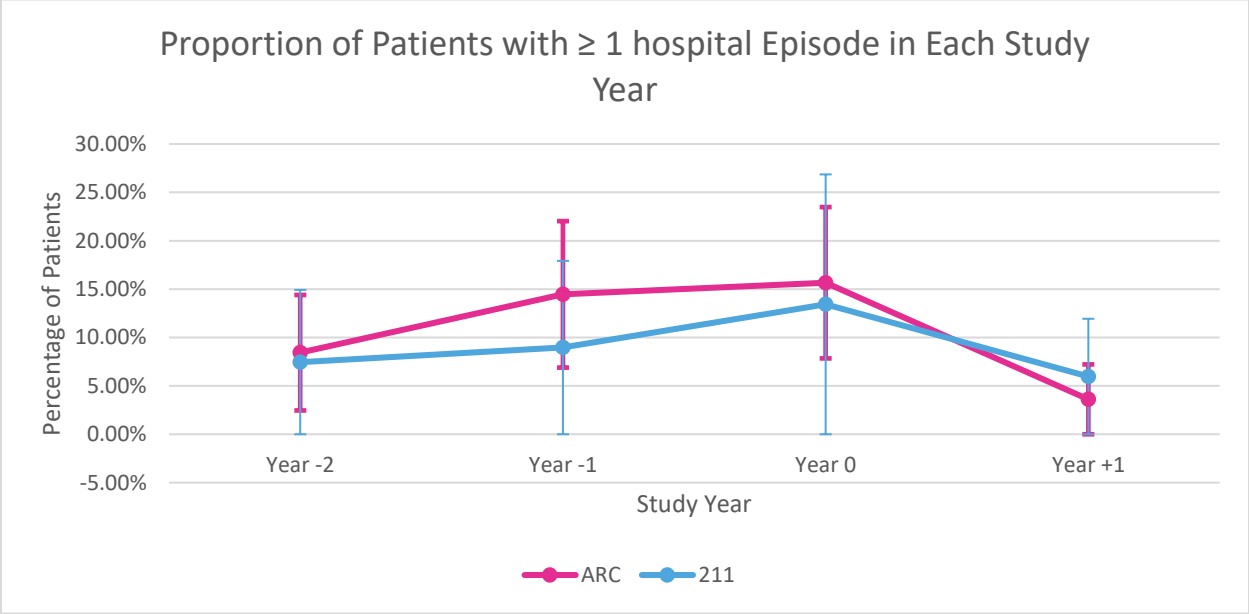


Figure 3b. Percentage proportion (95% CI) of at least one hospital episode in each study arm across the four study years

Table 3. Relative risk, unadjusted and adjusted odds ratio of patients with ≥ 1 ED episode and ≥ 1 hospital episode compared between study arms

≥ 1 ED episode			
	Relative Risk^a	Unadjusted Odds Ratio^b	Adjusted Odds Ratio^c
Year 0	0.8 (0.5, 1.4)	0.8 (0.4, 1.6), p = 0.49	0.7 (0.3, 1.5), p = 0.33
Year +1	1.4 (0.8, 2.3)	1.5 (0.7, 3.2), p = 0.25	1.7 (0.7, 4.1), p = 0.26
≥ 1 hospital episode			
Year 0	0.9 (0.4, 1.9)	0.9 (0.3, 2.1), p = 0.72	1.2 (0.4, 3.3), p = 0.73
Year +1	1.7 (0.4, 7.1)	1.6 (0.4, 6.9), p = 0.51	1.8 (0.5, 6.8), p = 0.37

^a p_{211}/p_{ARC} (95% CI)

^{a b c} OR (95% CI), p-value: ARC is reference category

Table 4. Multiple linear regression results (^aDiD) of study arm and all outpatient visits in Year 0 and Year +1

Parameter	Year 0			Year +1		
	Estimate	95% CI	p-value	Estimate	95% CI	p-value
211 arm	1.0	-1.6, 3.5	0.45	2.4	-0.3, 5.1	0.082
≥50 years	0.1	-2.5, 2.8	0.93	-1.3	-4.2, 1.6	0.38
Sudbury	3.1	0.0, 6.3	0.052	1.6	-1.8, 5.0	0.37
Female	1.8	-1.0, 4.6	0.21	0.3	-2.7, 3.3	0.85
Immigrant	3.6	-0.1, 7.3	0.054	1.1	-2.9, 5.0	0.60
No university degree	0.0	-2.7, 2.8	0.996	-1.7	-4.6, 1.3	0.28
Poor-tight financially	-2.3	-5.3, 0.7	0.13	-2.0	-4.8, 0.8	0.16
Not Caucasian*	--			--		
Not working/in school	-0.2	-2.8, 2.5	0.88	-1.8	-4.6, 1.1	0.22
Caregiver	2.0	-0.9, 4.9	0.17	0.5	-2.4, 3.5	0.73
Not married	3.3	0.1, 6.5	0.042	0.6	-3.0, 4.2	0.74
Lives alone**	--			0.8	-2.4, 4.1	0.63
Francophone	-1.2	-7.5, 5.2	0.72	1.9	-4.9, 8.7	0.58
Does not speak English/French at home	-1.6	-4.5, 1.3	0.27	-1.7	-4.7, 1.4	0.29

^a DiD = $\Delta 211 - \Delta ARC$

*Race covariate removed from Year 0 and Year +1 regressions due to opposite effect on outcome compared to immigrant covariate

**Lives alone covariate removed from Year 0 regression due to opposite effect on outcome compared to marital status covariate

Table 5. Multiple linear regression results (^aDiD) of study arm and only primary care visits in Year 0 and Year +1

Parameter	Year 0			Year +1		
	Estimate	95% CI	p-value	Estimate	95% CI	p-value
211 arm	0.7	-0.6, 1.9	0.30	1.0	-0.6, 2.6	0.22
≥50 years	-0.5	-1.8, 0.8	0.43	-0.6	-2.3, 1.0	0.45
Sudbury	1.1	-0.4, 2.7	0.15	0.3	-1.6, 2.3	0.74
Female	0.2	-1.1, 1.6	0.74	0.1	-1.7, 1.8	0.92
Immigrant	0.5	-1.3, 2.3	0.61	0.1	-2.2, 2.4	0.93
No university degree	1.0	-0.4, 2.3	0.15	-0.2	-2.0, 1.5	0.78
Poor to tight financial situation	-2.0	-3.3, -0.7	0.003	-0.1	-1.8, 1.5	0.90
Not Caucasian*	--			--		
Not working/in school	0.0	-1.3, 1.3	0.98	-0.1	-1.8, 1.6	0.92
Caregiver	1.5	0.2, 2.8	0.028	0.0	-1.7, 1.7	0.99
Not married	1.3	-0.2, 2.7	0.082	-0.4	-2.2, 1.4	0.65
Lives alone**	--			--		
Francophone	-0.3	-3.4, 2.8	0.85	1.7	-2.3, 5.6	0.41
Does not speak English/French at home	-2.2	-3.6, -0.8	0.002	-0.7	-2.5, 1.1	0.47

^a DiD = $\Delta 211 - \Delta ARC$

*Race covariate removed from Year 0 and Year +1 regressions due to opposite effect on outcome compared to immigrant covariate

**Lives alone covariate removed from Year 0 and Year +1 regressions due to opposite effect on outcome compared to marital status covariate

Table 6. Multiple logistic regression results of study arm and ≥ 1 ED episode in Year 0 and Year +1, adjusted ORs

Parameter	Year 0			Year +1		
	Adjusted OR	95% CI	p-value	Adjusted OR	95% CI	p-value
^a 211 arm	0.7	0.3, 1.5	0.33	1.7	0.7, 4.1	0.26
At least 1 ER episode in Y-1/-2	5.5	2.2, 13.7	0.003	2.5	1.0, 5.9	0.047
≥ 50 years	1.8	0.7, 4.5	0.20	2.0	0.7, 5.5	0.18
Sudbury	1.3	0.5, 3.6	0.62	1.3	0.4, 3.8	0.65
Female	0.7	0.3, 1.8	0.49	2.2	0.8, 6.5	0.15
Immigrant	0.9	0.3, 3.1	0.85	2.0	0.5, 8.3	0.33
No university degree	1.2	0.5, 3.2	0.68	4.2	1.3, 13.7	0.019
Poor to tight financial situation	1.4	0.6, 3.4	0.48	1.2	0.5, 3.1	0.72
Not Caucasian	--			1.7	0.5, 6.1	0.45
Not working/in school	1.0	0.4, 2.5	>0.999	1.0	0.4, 2.4	0.91
Caregiver	1.3	0.5, 3.22	0.58	1.9	0.7, 5.0	0.18
Not married	2.2	0.8, 6.27	0.14	0.9	0.3, 2.9	0.90
Lives alone	--			0.9	0.3, 2.4	0.82
Francophone	0.7	0.3, 1.8	0.45	2.6	1.0, 6.7	0.041
Speaks other language at home	0.3	0.02, 3.5	0.32	1.1	0.2, 8.3	0.92

^aARC is reference category

*Race covariate removed from Year 0 regression due to opposite effect on outcome compared to immigrant covariate

Table 7. Multiple logistic regression results of study arm and ≥ 1 hospital episode in Year 0 and Year +1, adjusted ORs

Parameter	Year 0			Year +1		
	Adjusted OR	95% CI	p-value	Adjusted OR	95% CI	p-value
^a 211 arm	1.2	0.4, 3.3	0.73	1.8	0.5, 6.8	0.37
At least 1 hospital episode in Y-1/-2	6.0	1.8, 19.5	0.003	0.3	0.0, 3.7	0.34
≥ 50 years	0.6	0.2, 1.7	0.30	0.6	0.2, 2.6	0.51
Sudbury	2.7	0.8, 9.6	0.12	4.0	0.9, 18.1	0.070
Female	1.4	0.4, 4.7	0.59	5.4	0.7, 45.6	0.12
Immigrant	4.7	1.2, 19.0	0.030	1.7	0.3, 11.1	0.57
No university degree	0.7	0.2, 2.3	0.59	0.6	0.1, 2.4	0.44
Poor to tight financial situation	0.9	0.3, 2.7	0.82	0.4	0.1, 1.6	0.18
Not Caucasian	1.7	0.4, 6.8	0.44	--		
Not working/in school	2.7	0.8, 9.2	0.11	1.3	0.3, 5.5	0.71
Caregiver	0.9	0.3, 2.8	0.89	2.0	0.4, 8.8	0.38
Not married	1.3	0.3, 5.2	0.74	1.1	0.2, 6.2	0.88
Lives alone	1.3	0.4, 4.1	0.70	1.4	0.3, 7.9	0.67
Francophone	0.9	0.3, 4.0	0.80	0.4	0.1, 2.4	0.34
Speaks other language at home	0.5	0.1, 4.2	0.52	0.5	0.0, 14.9	0.67

^aARC is reference category

*Race covariate removed from Year +1 regression due to opposite effect on outcome compared to immigrant covariate

Chapter 3: Discussion

3.1 Summary of Findings

Our study population consisted of 150 patients who consented to have their survey data, collected from the larger-scale ARC vs 211 RCT, linked to health care utilization data housed at ICES. Overall, this sample was derived from general primary care practices, but patients were more likely to be disadvantaged in certain sociodemographic characteristics as they were referred for health and social needs that likely stemmed from poor upstream SDoH. In the overall cohort, the mean (SD) age of patients was 51.3 (16.6) and included higher proportions of patients who had no university degree (68.7%), were not working or in school (60.0%), and were not married (60.0%). However, only 18.7% of patients were immigrants and 29.3% were either Francophones or did not speak either official language of Canada.

Despite our non-significant results, our results suggest that there is a favoring of the ARC arm. When comparing the number of outpatient visits in each post-intervention year to baseline, both arms undergo a decrease in number of visits for all outpatient and only primary care visits, although these changes were mostly not statistically significant. Except, in Year 0 the 211 arm had a non-significant slight increase in number of visits. In Year +1, the ARC arm had a significant decrease in the number of all outpatient and primary care visits, seen in the unadjusted negative pre-post change. The ARC arm had a greater negative pre-post change in Year 0 and Year +1 in both outcomes compared to 211, reflected in the positive but non-significant unadjusted and adjusted DiD measures. Regarding acute care use, the RR and unadjusted and adjusted OR for both ED and hospital episodes in Year 0 were close to one, indicating that both arms had similar odds of having at least one episode, although these results were not significant. However, in Year +1 these measures were greater than one indicating a

greater risk (RR) or odds (OR) of at least one episode in the 211 arm compared to the ARC arm, but again this was not significant.

3.2 Comparison to Literature

This study is novel in that it is the first to our knowledge to compare the effects of two different SP patient navigation models on health care utilization. There is very little literature on the comparison of different types of navigation models or the comparison of different intensities of SP, and none specifically looking at differential impacts on health care utilization. Due to this gap in the literature, there are no studies for our results to be directly compared to. A few RCTs have been conducted that have studied the effects of SP lay navigation on health care utilization, but were compared to a usual care arm and involved follow-up assessments that ranged between one and 12 months [1-4]. Whereas, our study design cannot be considered randomized and involved the comparison of two arms that both provided intervention options, with follow-up assessments at 12 months and 24 months. Three of the SP navigation RCTs were conducted in the U.S. [1-3] and one in the UK [4], but all were conducted in specific subsets of primary care populations. Heisler et al., conducted their study in Michigan, beginning in 2018 in patients from a low-income neighborhood who also had a history of acute care use within the year previous to study enrolment [1]. This study found a significant reduction in post-intervention ED visits in the SP arm [1]. The other two U.S. studies were conducted by Kangovi et al., beginning in 2013, and again conducted a similar study that began in 2015 in high poverty patients that had multiple chronic diseases [2, 3]. The second study found significantly lower odds of repeat hospitalizations in the lay navigator arm, compared to usual care [3]. Our acute care use results compared the odds of ED and hospital episodes

between the two intervention arms, thus cannot be compared to these studies due to the difference in study design. Our study also did not explore the difference in mean number of episodes between the post-intervention and pre-intervention period, preventing us from determining if either arm resulted in a reduction of acute care use like the Heisler et al. study [1]. Two of these studies found significant reductions in health care utilization [1, 3], which may partially be attributable to the patient population. The two studies focused on U.S. patients who were evidently disadvantaged regarding health and socioeconomic status [1, 3]. These are populations that have increased risk of avoidable ED and hospital use [5-7], thus may benefit from SP over shorter periods of time. Although these studies are not comparable to our study in design and study population, they provide evidence that SP lay navigation can reduce health care utilization.

The study conducted in the UK, began in 1997 and studied the effects of SP lay navigation compared to usual care on primary care use, however, did not find any significant differences between the arms [4]. This study is not directly comparable to our study design due it being an RCT with a usual care control arm and a study population in the UK with patients who had psychosocial problems [4]. Our study did find decreases in primary care visits in the post-intervention period, however these pre-post changes were unadjusted and were only significant in Year +1 in the ARC arm. Our study also could not conclude on the comparative effects of the two interventions on outpatient and primary care use, due to non-significant DiD measures.

With regards to existing literature on the comparison of different SP navigation models, one study was found. This study was conducted by Messmer et al. as a cluster RCT in which the navigator split their time providing services on-site at health centers as well as providing remote

services at other times [8]. This study is the closest to ours in terms of the interventions that are being compared. Our study compared a navigator situated in primary care practices and the Ontario-211 remote navigation services. However, the study by Messmer et al. compared two modes of navigation conducted by the same navigator and the study outcomes did not include the effects on health care utilization. The use of the same navigator removed the differential effects that could result from differences in techniques between multiple independent navigators, and simply compared the avenue in which navigation was provided. This study found that when the navigator was on-site, significantly more referrals were made, but did not find any differences in the number of successful contacts with the navigator or in the proportion of patients that had enrolled in resources [8]. Theoretically, if clinicians made more referrals when the navigator was on-site, then more patients became aware of their own needs and were provided a means of addressing them. Other studies have found these elements of patients' involvement in their health care decisions to be linked to positive patient outcomes [9].

The two navigation interventions compared in our study can also be interpreted as two intensities of SP navigation, with the ARC intervention being the more intense one. The ARC navigator prioritized patient-centered care and encouraged in-person navigation and follow-up, but also gave patients the option for services to be provided over the phone, through text, or email. 211 was available as an informational source through their online directory while also providing services over the phone, text, and email, but almost exclusively provided services at initial contact. SP navigation intensities were also compared in a quasi-experimental cluster RCT conducted in Scotland [10]. This study compared SP navigation to usual care and found a significant trend of an increase in community resource uptake with increasing number of

navigator contacts, in the subset of patients that had contacted the navigator [10]. This study also found that patients who had face-to-face contact with the navigator three or more times had significant improvements in quality of life, anxiety, depression, and exercise [10]. This study demonstrates that a more intense experience with SP navigation can contribute to significant improvements in patient outcomes. Although our study did not include the same outcomes, our results also favour the more intense ARC intervention as comparative results suggest that there is a non-significant trend towards reduced health care utilization in this study arm. The systematic review by Kiely et al., also found that out of all studies included, an analysis of the RCT originally conducted in 2013 by Kangovi et al., was one of the more intense interventions (IMPACT intervention) and was the only study that found reduced health care utilization, providing further evidence for the support of intense SP interventions [11]. Further research is required to assess the comparative effects of different types of SP navigation models or different SP intensities through controlled designs, on a variety of outcomes including health care utilization, as there is a scarcity of this study design in SP research.

Our study only considered the study arm and did not consider whether patients accessed community resources. Navigators themselves provide direct support through activities like motivational interviewing, coaching, and help with goal-setting [12]. These elements can positively influence patients' sense of awareness and empowerment, which are linked to outcomes like improved healthy behaviors, treatment adherence, and reduced health care utilization [13]. The favoring of the ARC arm in our results may only reflect the benefits of the navigator alone as we did not take into account whether the patients carried through with accessing community resources. We did not include access of community resources in our

regression analysis as this is a direct downstream outcome of study arm, which can also affect health care utilization. Some SP studies in the literature reported on the number of contacts patients had with the navigator, but did not report on the uptake of resources [11]. Participation in community resources have been associated with positive outcomes including improved health literacy, engagement in healthy lifestyle, and improvements in quality of life and self-care [14, 15]. Studies assessing the impacts of participating in community resources on health care utilization have found mixed results [16, 17]. A cohort study found that more frequent participation was associated with less inpatient and community health care but greater outpatient and dental care [16]. And a cross-sectional study found that those who accessed community resources had fewer primary care visits and outpatient hospital visits, but this was not statistically significant when adjusting for sociodemographic covariates [17]. There is some evidence that community resource engagement can help reduce health care utilization, but there are not enough studies exploring this impact. Future studies should aim to assess impacts of community resource engagement on health care utilization through randomized controlled design.

3.3 Strengths and Limitations

Our study contributes to filling the gap in the literature as the first study to our knowledge that compares the effects of two SP navigation models on health care utilization using an controlled design. The health care utilization data we used was obtained through ICES, which houses administrative health data for all residents in Ontario who are eligible for health care. ICES receives patient-level data directly from the facilities that patients obtained care from, providing us with all of the available data on ED, hospital, outpatient, and primary care

use for our patient population. This ensured that we had full coverage and reliable outcome data, a great strength of this study. The use of ICES data also allowed us to obtain data for a period of four years for each patient, and gave us the opportunity to have a baseline level to compare the post-intervention data to, and calculate DiD measures. The aim of this was to assess whether the two interventions had a differential effect on health care utilization, rather than whether SP navigation can have any effect at all, an objective several studies have already explored.

Our study also had a few limitations. Firstly, the research objective of this thesis was not the main objective of the larger-scale RCT, which led to a design limitation. Originally, Ottawa and Sudbury patients were randomized to either the ARC or 211 arm, and those who consented and provided their OHIP number to have their data linked were included in this study. Patients were not required to provide OHIP numbers, thus allocation could no longer be considered randomized, contributing to imbalances in the arms specific to this study (Table 1). Additionally, the processes in which the Ottawa and Sudbury regions obtained consent and OHIP numbers may have been different and likely played a role in the imbalance of patients from either region in each arm (Table 1). This may have introduced selection bias as there were imbalances in baseline sociodemographic data between the arms. These imbalances involved greater proportions of 211 patients in the disadvantaged categories of certain sociodemographic variables including education, financial situation, race, and occupation. Appendix 2.b includes a table of the baseline sociodemographic variables in the overall RCT, portraying a more balanced allocation. This design limitation may have biased the results, as research suggests that more complex and disadvantaged patients may benefit more from SP navigation [1, 3], especially

more intense forms [11]. Further research can be designed specifically for this objective, and ensure arms are balanced at baseline through strategies like block randomization [18].

Secondly, the nature of SP navigation makes it difficult to be studied using a rigorous controlled design, especially when comparing two models where there is overlap. There are many elements involved in the pathway of SP navigation, and each can contribute to the effects on outcomes such as health care utilization. In our study, both the ARC and 211 arms involved lay navigation, but the ARC arm provided the option of in-person services. However, ARC also offered remote services over the phone, text, and email to make it more accessible, overlapping with the mode of remote services offered by 211. This similarity between the interventions may have contributed to our small and non-significant measures. In existing studies, SP navigation models were compared to usual care, where the effects manifested more evidently [1, 3]. Our study compares two SP models that involve overlap in the types of services provided, both possibly having a positive influence on health care utilization, therefore not much of a differential effect was found. Moreover, the individualised nature of the interventions means each patient may receive different amounts and types of care, inevitably affecting outcomes and increasingly making it difficult to study using rigorous methodology. Detailing the types of services that patients received in either arm, including number and type of follow-up would have helped to clarify how different the two arms were and would have provided the option for subgroup analysis. It may also be beneficial for future studies to be designed so that navigation services in each arm are standardized and not too extensive to prevent overlap, and to better differentiate the effects of each model on outcomes.

Another limitation of this study was that the COVID-19 pandemic likely interfered with our results. The post-intervention period in our study spanned October 2018 to December 2021. This period overlapped with the beginning of COVID-19 which was declared a pandemic by the World Health Organization [19] and declared a state of emergency in Canada, both in March of 2020 [20]. It was expected that due to this overlap, there would be a decrease in health care utilization due to the COVID-19 restrictions, independent from the effects of navigation use. In the first year of the pandemic (March 2020-June 2021), the CIHI reported fewer hospital and ED admissions compared to the pre-pandemic year [21, 22]. However, for physician services there was a drop only in Wave 1, and numbers returned to near pre-pandemic levels around September 2020 [23]. In our study, Year 0 ranged between October 2018 to December 2020, and Year +1 ranged between October 2019 to December 2021. In Year 0, there wasn't a noticeable fluctuation in health care utilization, explained by the fact that only a portion of patients' Year 0 overlapped with the onset of the pandemic. Year +1 overlapped with the first year and a half of the pandemic, where rates of hospital and ED episodes decreased in the first post-enrolment study year [24, 25]. During this time, CIHI reported that ED admission numbers returned to near pre-pandemic numbers [24] while hospital admissions remained low [25]. The results of this study suggest that there was a trend towards a dip in the proportion of patients who had at least one ED or hospital episode, and a trend towards a lower mean number of outpatient and primary care visits in Year +1, although most of these changes in utilization were not significant. We used DiD which relies on the assumption that group-specific means may differ, but are constant over time in the absence of the intervention [26]. By differencing out the group-specific means, DiD measures help to minimize biases resulting from

trends in time such as the effects of COVID-19. Regardless, the overlap of the post-intervention period with COVID-19 was a limitation of this study due to the variability it caused in health service use, independent from patients' participation in the study.

Lastly, our small sample size was also a limitation. The calculated required sample size was 306 patients for the overall RCT and 326 patients were enrolled. However, only 150 patients had their survey data successfully linked to ICES data and could be included in this study. The small sample reduced the generalizability of our results and may have contributed to effects that were not significant due to the possibility of a type 2 error. The increased sampling variability caused by the small sample may have contributed to event rates and trends in health care utilization that may not be representative of the general population and may have contributed to increased fluctuation and outliers in the data. A larger sample could help to reduce variability in our outcomes of interest, seen in our wide confidence intervals, to better be able to identify differences between pre and post periods, as well between arms. A larger sample may have also helped to alleviate some bias created by the sociodemographic imbalances at baseline.

3.4 Recommendations

Our study could not definitively conclude that the ARC intervention can better reduce health care utilization, compared to the Ontario-211 intervention. However, our results showed that the ARC arm was favored (not statistically significant) in all four categories of health care utilization, regarding reduced use compared to 211. Our study in combination with existing literature indicates that SP navigation models embedded in primary care practices can lead to positive outcomes [3, 8, 11]. These models create opportunities for more intense services, can

facilitate coordination across the SP pathway, and can improve outcomes in complex patients [11]. Additionally, the availability of navigators within practices can facilitate increased referral to these interventions [8]. This study is of a controlled design and contributes to filling the gap of studies comparing two models of SP navigation, but there remains a gap in the literature concerning the availability of RCTs [11, 27-29]. Future studies should focus on using randomized controlled designs to explore the effects of various models on health care utilization in different patient populations. Studies have shown that more complex and disadvantaged patients may demonstrate positive outcomes from SP navigation over shorter follow-up periods [1, 3, 11]. The duration of the interventions can also play a role [10, 11]. It's possible that less complex or general primary care patients may need shorter interventions [11] but may manifest positive outcomes over longer periods of time. Future research can be conducted to assess the effects of various lengths of intervention periods in populations of varying complexities. It's also important for studies to consider the complexity of the intervention and ensure methods include detailed documentation of the types of services provided to each patient.

An important concept to consider with SP navigation and its effectiveness, is that SP involves many pathway elements that can influence its success. Primary care providers first need to appropriately help patients identify needs that can be addressed through community resources and then refer them to navigation services. Certain factors can influence how likely and adequately providers will engage in this step. This can include providers' awareness and attitudes on SP, communication between navigators and health providers to serve as a reminder of the intervention and to create trust, the ease of the referral process, and having adequate resources [30]. Additionally, the study by Messmer et al. demonstrates that providers are more

likely to make a referral when navigational services are situated in primary care practices [8]. In the ARC-211 RCT, providers were encouraged to help patients identify needs through informational sessions explaining SP, the benefits of SP for both patients and providers, and suggestions of referral processes. At the patient-level, several factors will affect their decision to contact the navigator. Patients' understanding of their needs and the SP process, their beliefs and attitudes towards SP, their level of motivation [30], their relationship with their health provider, whether they feel safe and comfortable [31], and the accessibility of the navigator [32] can play a role in whether patients use navigation services. The ARC study aimed to encourage patients to contact navigators through phone call reminders, the option of meeting in-person or remotely, and follow-up options. The environment and relationship that the navigator creates with the patient will then play a crucial role in the patients' decisions and actions. Successful SP navigator schemes involve flexible but strong relationships [32, 33] and navigators require characteristics like empathy, cultural sensitivity, and active listening [34]. A successful patient-navigator relationship and experience will foster patient-activation, confidence, and empowerment [33, 35], allowing them to take steps to access community resources. The ARC navigator fostered strong relationships with their patients through shared decision making, provision of emotional support, and offering different avenues of communication. It is imperative that SP navigation models are created in such a way that all of these elements and processes in each stage of the pathway are addressed, to ensure success and accessibility at each step, allowing for SP to be effective.

The ultimate goal of each step of the SP pathway is to get patients to access community resources so that they can address their needs. There are a number of barriers that can make

accessing community resources difficult including linguistic barriers [36], lack of knowledge, lack of transportation, poor mental and physical health, and financial barriers [37-40]. Navigators can help to ease some of these barriers and facilitate access through provision of information and finding community resources that cater to patients' unique circumstances. For example, community resources provided through teleservices can help to address transportation barriers, and free resources can alleviate financial burden. However, there are system-level barriers that navigators cannot address, such as low availability of community resources or lack of a variety of resources within patients' communities [41]. Further investments into SP and community resources are required to help remove both patient and system-level barriers to access. It's crucial that all of the pathway elements leading to access are taken into consideration, as the successful uptake of community resources is what is meant to address patients' poor SDoH.

Although reviews have found mixed results, many studies have found SP navigation to be associated with a number of positive outcomes including improved well-being [27-29] general health [11, 27-29] social connectedness [27, 29] and reduced health care utilization [11, 27-29]. In Ontario, the Alliance for Healthier Communities found that patients referred to SP had improved mental health, well-being, self-efficacy, decreased repeat primary care visits, and increased care integration [42]. They have called for policymakers, health care and social support organizations, and academic institutions to further advance SP initiatives [42]. Investments and policy should be geared towards integrating more SP navigation models within primary practices in Ontario to help address upstream risk factors and the pressing health and social needs that health care providers cannot address in primary care. Research and academic institutions should focus on conducting randomized controlled studies to continue to grow a

reliable evidence base for further support of the large-scale integration of SP navigation models within primary care.

3.5 Final Conclusions

SP can help to address the health and social needs that cannot be addressed in primary care, while providing health providers with a structured referral pathway. Patient navigators within the SP context can play a pivotal role in addressing the fragmentation patients may face when attending to multiple health and social needs, and can also help to overcome a number of barriers. Given the variety of positive outcomes associated with SP patient navigation, we aimed to add to the literature by comparing the effects of two SP lay navigation models on health care utilization. This thesis compared the effects of an in-person, primary care-based navigation service (ARC) to the provincially funded remote navigation service (211), on both outpatient use and acute care use. Although our results were not significant, our findings point towards a trend of the favoring of the ARC intervention in regard to reduced outpatient visits, primary care visits, ED episodes, and hospital episodes. This thesis provides a signal that patient-centered, holistic, and more intense SP navigation models may be beneficial in addressing health and social needs that contribute to avoidable health care use. This thesis is the first controlled study to compare two models of SP navigation and provides a basis for similar studies to be conducted in the future.

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Thesis Appendices

Appendix 1: Ethics Approval Letter for Original ARC-211 RCT

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June 13, 2018

Dr. Simone Dahrouge
Director of Research and Scientist
C.T. Lamont Primary Health Care Research Centre
Bruyère Research Institute

Re: "Access to Resources in the Community/Acces aux Ressources
Communautaires (ARC) - A Randomized Controlled Trial"
(Bruyère REB Protocol #M)

Final Approval

Dear Dr. Dahrouge,

The Bruyère Continuing Care Research Ethics Board (REB) is pleased to give you ethical approval for the above noted study for the period of June 13, 2018 to June 13, 2019.

The following documents have been approved:

- REB IRIS Application;
- Protocol;
- Appendix A – English ARC Community resource referral form;
- Appendix B1 – Bilingual promotional poster;
- Appendix B2 – English ARC RCT poster;
- Appendix B3 – English promotional brochure;
- Appendix C – English ARC Navigator feedback form;
- Appendix D1 – English practice invitation letter;
- Appendix D2 – English practice and provider information sheet and consent form;
- Appendix D3 – English provider information and consent form - interview;
- Appendix D4 – English invitation to participate form;
- Appendix D5 – Practice recruitment – follow-up telephone call;
- Appendix D6 – English information brochure;
- Appendix E1 – English patient participant information and consent form;
- Appendix E2 – English patient participant interview consent form – interview;
- Appendix E3 – English patient instructions;
- Appendix F – Study timeline;
- Appendix G – English practice survey;
- Appendix H – English provider survey;
- Appendix I – English patient survey;

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At Bruyère, we promise you... Kind • Safe • Care*

- Appendix J – English navigator training;
- Appendix K – English rapid cycle evaluation;
- Appendix L – English provider interview guide;
- Appendix M – English patient interview guide;
- Appendix N – English navigator interview guide;
- Appendix O – practice set-up log;
- Appendix P – Navigator log;
- Appendix Q – Consenting pathways;
- Appendix R – Statement of relationship;
- Budget

The Bruyère Continuing Care REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethics Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; the provisions of the Personal Health Information Protection Act 2004; and the Food and Drug Act of Health Canada and its applicable Regulations.

Please be advised that any complaints made by participants must be reported to the REB. All changes to the approved protocol must be approved by the REB.

Please complete an Annual Project Update/Notification of Termination form 6 weeks prior to the approval end date as noted above.

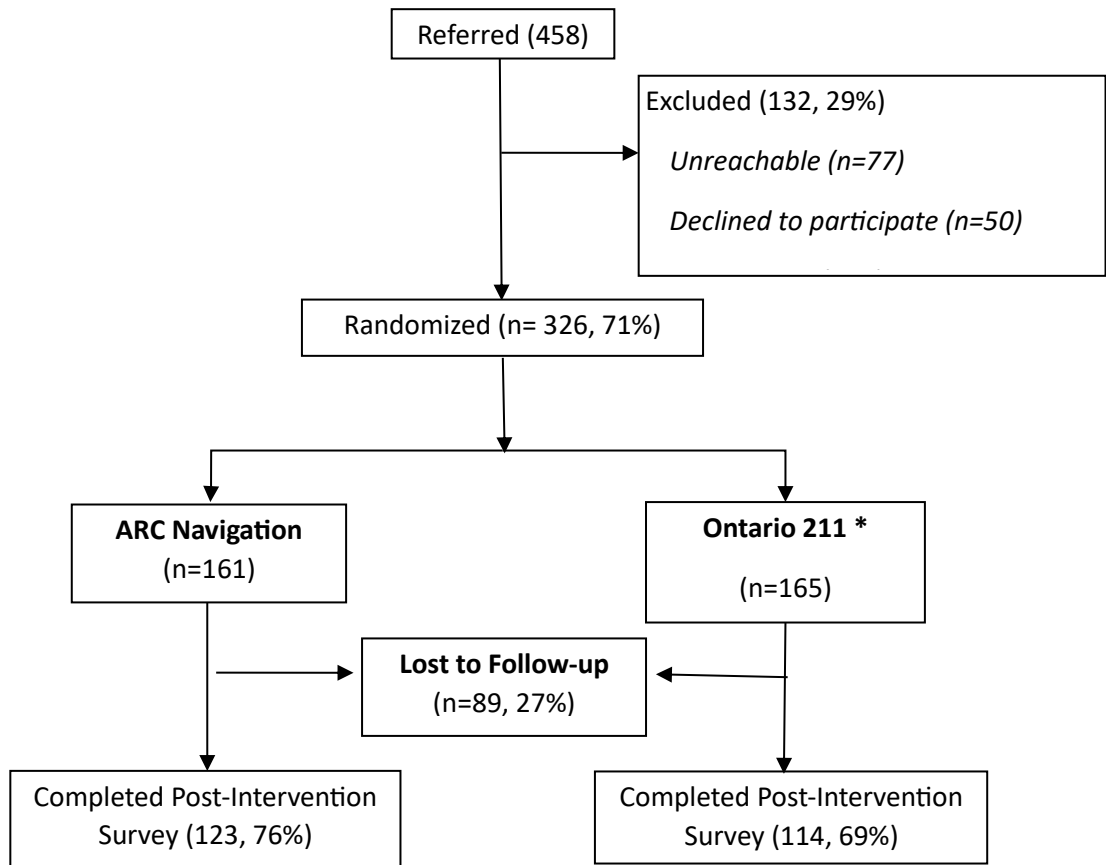
We wish you the best of luck with your research endeavors.

Sincerely,

Gordon DuVal, SJD
Chair, Bruyère Research Ethics Board
Bruyère Continuing Care

Appendix 2: Supplemental Information on ARC-211 RCT

2.a Recruitment and Retention Flow Diagram in Original ARC-211 RCT



*Three individuals of the same household referred together were randomized as a unit and were assigned the 211 arm.

2.b Patient Baseline Characteristics in Original ARC-211 RCT

	ARC	211	Overall
Region (% Ottawa)	122 (76%)	125 (76%)	247 (76%)
Gender (% Female)	106 (66%)	115 (70%)	221 (68%)
Immigrant (%)	26 (16%)	23 (14%)	49 (15%)
Education (% No University Degree)	110 (69%)	123 (75%)	233 (72%)
Financial (% Tight, Poor)	82 (55%)	95 (64%)	177 (59%)
Non, Caucasian (%)	33 (24%)	37 (26%)	70 (25%)
Not working or in school* (%)	95 (59%)	100 (61%)	195 (60%)
Has someone under charge# (%)	53 (34%)	59 (39%)	112 (37%)
Single ^ (%)	102 (67%)	105 (70%)	207 (68%)
Lives alone (%)	64 (40%)	69 (42%)	133 (41%)
Francophone# (%)	52 (32%)	53 (32%)	105 (32%)
Age, years (SD)	50.0 (17.9)	47.3 (17.0)	48.6 (17.5)

* includes unemployed, retired, on leave; ^ includes single, widowed, separated; # Has children or adult under their charge; # includes all patients who responded "French" for any of these questions (overall # patients): Languages usually spoken at home (82), Mother tongue (84), Preferred language for primary care provider (39), Preferred language of health care services (34), If mother tongue is not French or English, preferred official languages (6) (Ontario, 2021). & Numbers of conditions reported by patients amongst 11 common conditions elicited.

Appendix 3: ICES Data Sources

The following descriptions of the datasets used for this thesis were obtained from the ICES data dictionary database.

Outpatient and acute care visits were distinguished using unique admission dates for each patient, to avoid counting a visit more than once.

Outpatient

Ontario Health Insurance Plan (OHIP)

OHIP data includes data from most claims paid for by the OHIP, for services by health care providers who can claim under OHIP. Providers can include physicians, groups, laboratories, and out-of-province providers. Most physicians that provide non-fee-for-service (FFS) services are required to submit shadow-billings (similar to FFS claim, but amount claimed is \$0.00), providing more accurate data on physician service utilization. A fee code is used to identify the service, and each record is associated with one fee code/service. Claims are submitted by the service provider to the Ministry of Health (MOH) office. ICES receives data on a monthly basis directly from the MOH. We included all home, office, and virtual visits, but omitted long-term care. For primary care related visits in this study, data was obtained through all primary care fee codes billed by any general or family physician.

ER episodes

CIHI National Ambulatory Care Reporting System (NACRS)

The NACRS contains data from Ontario hospital and community-based ambulatory care including day surgery, outpatient and community-based clinics, and emergency departments. Data is collected at the time of service during patients' visits, and methods of data collection can vary between facilities. NACRS data is updated quarterly at ICES.

Hospital episodes

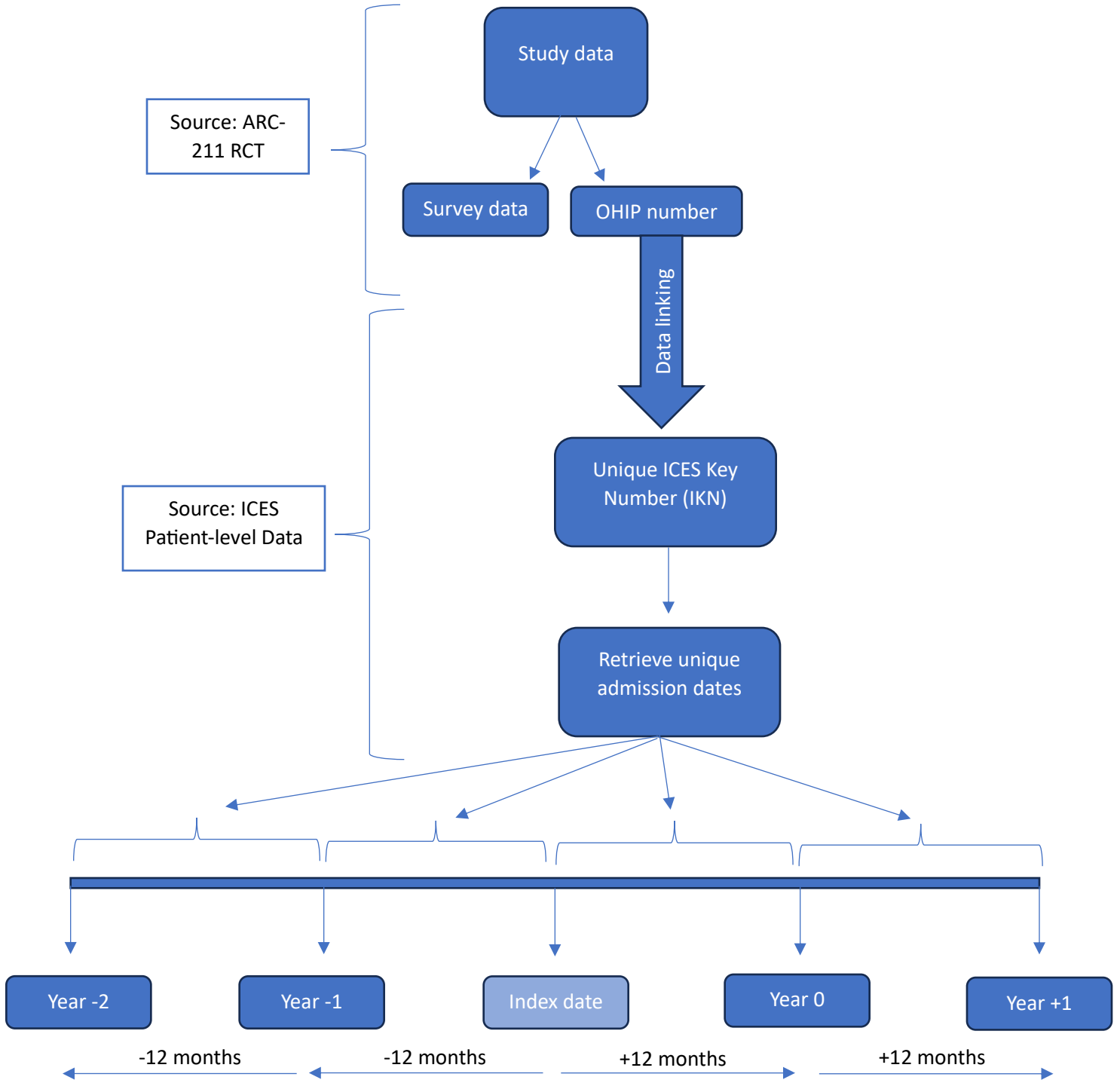
CIHI Discharge Abstract Database (DAD)

The DAD contains patient-level inpatient data from Ontario acute, rehab, chronic, and day surgery institutions since 1988. Records in the DAD represent one case or separation which can include a discharge, sign-out, or death. Once patients are discharged from the hospital, an abstract including both administrative and clinical data from each patient's stay, is created by a medical records coder. Hospitals provide this data directly to CIHI in one-month batches, and updates at ICES quarterly.

CIHI Ontario Mental Health Reporting System (OMHRS)

The OMHRS includes data on patients in adult designated inpatient mental health beds in Ontario general, provincial psychiatric, and specialty psychiatric facilities (child/adolescent mental health records are collected in DAD). OMHRS data is collected using the Resident Assessment Instrument – Mental Health (RAI-MH), a tool used to assess inpatient mental health patients. The RAI-MH is a standardized instrument that collects information on where patients are admitted from and the reason of admission, and where they are discharged to and the reason for it. Each record in the OMHRS includes data from a single assessment, and depending on the length of stay, there may be multiple records for one stay. Data was submitted directly from the hospitals to CIHI, and is updated at ICES quarterly.

Appendix 4: Data Linking and Study Timeline Visualization



Appendix 5: Categorization of Covariates used in Regressions and Description

Covariate	Categorizations
Age	<50 years of age [reference] ≥50 years of age
Sex	Male/other gender [reference] Female
Immigrant status	Not an immigrant (born in Canada) [reference] Canadian born
Education: Highest level of education completed	Completed a university level degree [reference] No university level degree
Financial situation	Modestly comfortable to very comfortable [reference] Poor to tight financial situation
Occupation	Currently working or in school [reference] Not working or in school
Caregiver	Does not have a dependent (adult or child) [reference] Supports at least one dependent
Marital status	Married [reference] Not married (single, widowed, separated)
Lives alone	Does not live alone [reference] Lives alone
Race	Caucasian [reference] Other race
Language spoken at home	Speaks English only [reference] *Speaks French (+/- English or other language) *Speaks other language only (no English or French) <i>*The above two categories were grouped together in Table 1 to suppress small cells</i>

Appendix 6: Difference-in-difference (DiD) Explanation and Example

Refer to table below for values

Difference in number of outpatient visits between Year 0 and baseline (average number of visits in Year - 2 and Year -1), in each arm + DiD between arms:

ARC:

$$\Delta\text{ARC} = [\text{Mean (95\% CI) Year 0}] - [\text{Mean (95\% CI) Baseline}]$$

$$\Delta\text{ARC} = [9.66 (7.87, 11.46)] - [9.79 (8.12, 11.46)]$$

$$\Delta\text{ARC} = -0.13 (-1.91, 1.66)$$

211:

$$\Delta 211 = [\text{Mean (95\% CI) Year 0}] - [\text{Mean (95\% CI) Baseline}]$$

$$\Delta 211 = [9.40 (7.23, 11.57)] - 9.30 (7.56, 11.04)$$

$$\Delta 211 = 0.11 (-1.51, 1.72)$$

DiD = $\Delta 211 - \Delta\text{ARC}$

$$\text{DiD} = [0.11 (-1.51, 1.72)] - [-0.13 (-1.91, 1.66)]$$

$$\text{DiD} = 0.23 (-2.21, 2.67)$$

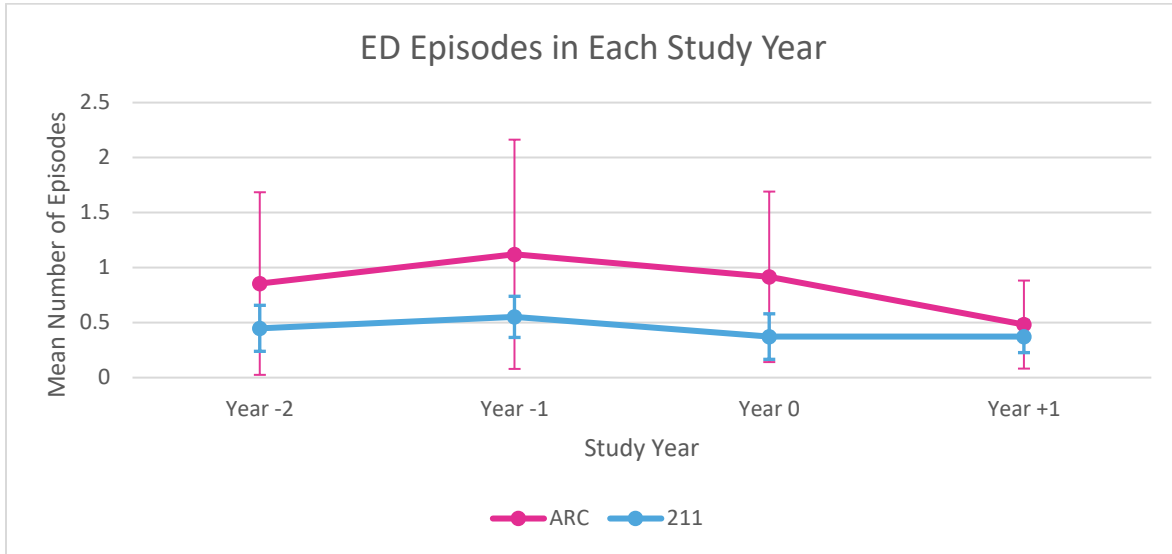
Here the positive DiD indicates (although not statistically significant), that the 211 arm had a lesser negative difference in number of outpatient visits. In this case, the 211 arm had a non-significant increase in number of visits and the ARC arm had a non-significant decrease. In the case of the DiD for Year +1, both arms had a decrease in number of visits, but the ARC arm had a greater negative difference, therefore the DiD is still positive.

Average number of all outpatient visits at baseline, Year 0 and Year +1, mean (95% CI)			
	ARC (n=83)	211 (n=67)	
Average of Year -2 & Year -1	9.79 (8.12, 11.46)	9.30 (7.56, 11.04)	
Year 0	9.66 (7.87, 11.46)	9.40 (7.23, 11.57)	
Year +1	7.35 (5.58, 9.12)	8.43 (6.17, 10.70)	
Difference in number of visits, mean (95% CI)			
	ARC (n=83)	211 (n=67)	Difference-in-difference ($\Delta 211 - \Delta\text{ARC}$)
Year 0 - Baseline	-0.13 (-1.91, 1.66)	0.11 (-1.51, 1.72)	0.23 (-2.21, 2.67)
Year +1 - Baseline	-2.44 (-4.16, -0.72)	-0.87 (-2.78, 1.05)	1.57 (-0.98, 4.13)

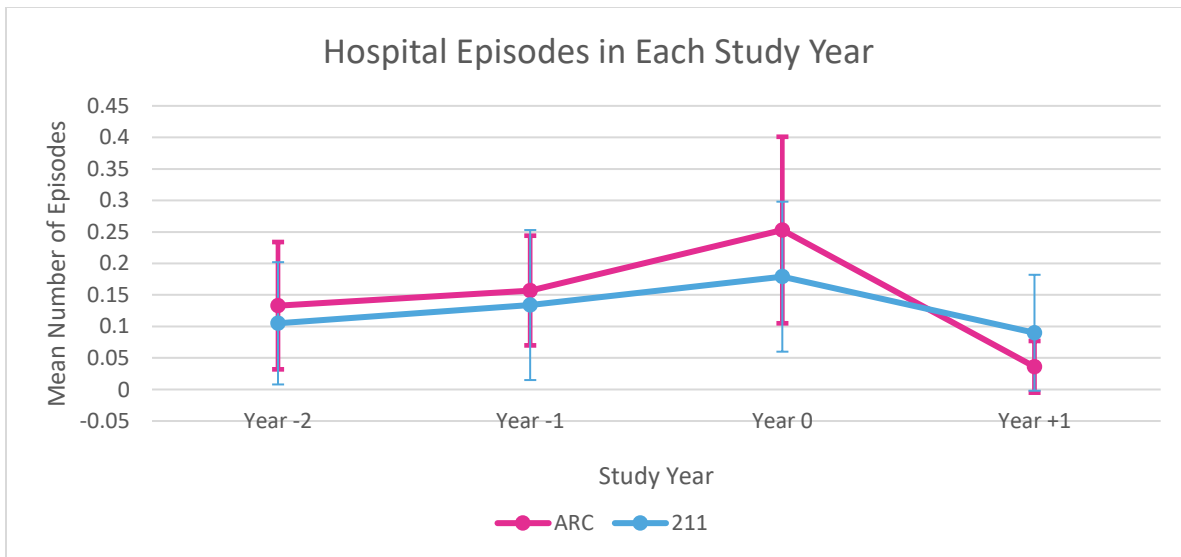
Appendix 7: Mean Number of ED and Hospital Episodes

7.a: Mean number (95% CI) of ED and hospital episodes at baseline (Year -2 and Year -1 combined)

Outcome Measure	ARC (n=83)	211 (n=67)
ED episodes	1.0 (0.06, 1.9)	0.5 (0.3, 0.7)
Hospital episodes	0.2 (0.08, 0.2)	0.1 (0.02, 0.2)



7.b Mean number (95% CI) of ED episodes in each study arm across the four study years



7.c Mean number (95% CI) of hospital episodes in each study arm across the four study years