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Implementation and impact of an online tool used in primary care to improve the income security of patients: A study protocol

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Implementation and impact of an online tool used in primary care to improve the income security of patients: A study protocol

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Abstract

Objectives

Addressing the social determinants of health of patients has been identified as crucial to reducing health inequities. However, few evidence-based interventions exist. This study emerges from an ongoing collaboration between family physicians, researchers and a charitable financial literacy organization in Canada. Our objective is to answer the following questions: Is an online tool that addresses income security feasible and acceptable to clinicians? Can such a tool be integrated into regular clinic workflow? What are patient perspectives on the tool and what is the short-term impact on income?

Methods

An advisory group made up of patients living on low incomes and representatives from community agencies supports this study. We will recruit three primary care sites in Toronto, Ontario and three in Winnipeg, Manitoba that serve low-income communities. We will introduce clinicians to screening for poverty and how tax filing and applying for government benefits can increase income. Following an orientation session, health providers will be encouraged to use the tool with any patient seen. The health provider and patient will complete the online tool together, generating a tailored list of benefits, along with community resources to assist with obtaining these benefits. A brief survey on this experience will be administered to patients after they complete the tool, as well as a request to contact them in one month. Those who agree to be contacted will be interviewed on whether the intervention impacted their knowledge and ability

to access benefits. We will administer an online survey to all providers and conduct provider focus groups at each site at the end of study.

Discussion

An online tool could help health providers in improving the income security of their patients. Our findings will provide insight into the potential of electronic tools that assist providers to address the social determinants of health.

Strengths and Limitations

- Multi-site study involving clinics in two provinces.
- Pragmatic implementation of a novel tool in the real world of busy primary care clinics.
- Mixed-methods evaluation, using several data sources to triangulate findings.
- Convenience sampling method for patients.
- A short follow-up period (4 weeks after intervention) may underestimate the impact of the novel tool.

Trial registration:

Clinicaltrials.gov: [NCT02959866](https://clinicaltrials.gov/ct2/show/study/NCT02959866). Registered Nov 7, 2016. Retrospectively registered.

Keywords: social determinants of health, income, poverty, primary care, health promotion

BACKGROUND

The social determinants of health (SDOH) have a profound impact on the health of individuals and populations. The World Health Organization defines the SDOH as “the conditions in which people are born, grow, live, work and age. These circumstances are shaped by the distribution of money, power and resources at global, national and local levels”[1]. The health sector has a vital role to play in addressing the root causes of preventable morbidity and mortality by developing and implementing interventions on SDOH. Primary care settings in particular are uniquely opportune spaces to take action[2]. Primary care providers follow patients longitudinally, are community-based and often have knowledge of the broader familial and social contexts that shape health and disease [3]. One of the most important SDOH is income security: a person’s actual, perceived and expected income [4, 5]. Income influences the presence and severity of most health conditions. People living in poverty may have difficulty paying rent [6], affording nutritious food [7], affording transportation and engaging with others socially [6–9]. Many studies have shown that economically marginalized people tend to live shorter lives, experience a greater burden of disease and disability and rate their health status as worse than the wealthy [11–16].

There are currently few, rigorously evaluated SDOH interventions that seek to improve the income security of individuals and families [17, 18]. Welfare benefits advice services within general practices in the United Kingdom have been found to increase the income of recipients, although improvements in health were not assessed in most studies[19]. More recently, several studies in the United States have demonstrated the effectiveness of clinic-based interventions at

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connecting patients to community resources to address SDOH. In Boston, the Well-child Care Visit, Evaluation, Community Resources, Advocacy, Referral, Education (WE CARE) study took place in pediatric clinics [20]. A waiting room survey screened for social needs and members of the health care team provided information on community resources, adding less than two minutes to the visit. At one month, 20% of the intervention group parents reported contacting a referred community resource versus 2.2% of parents in the control group [21]. The online tool, HelpSteps [22, 23], screens for a much larger number of social needs, taking on average 25 minutes to complete, with 90% of users identifying at least one social need and 96% reporting they would recommend its use to a friend or peer [24]. The California iScreen study[25], also tested in pediatric clinics, used the Health Leads [26] model and found that social needs can be identified and providing patient supports led to improvements in parent-reported child health [27]. In Canada, a paper-based clinical tool has helped train physicians and other health providers to consider poverty as a health issue [28]. This tool has been adapted by the College of Family Physicians of Canada for use in all provinces and territories. No studies to date have evaluated the impact of this tool on providers or patients.

Our study focuses on developing, implementing and evaluating an online tool in primary care settings that focuses on income security. This study emerges from an ongoing collaboration between family physicians, researchers and a charitable financial literacy organization, Prosper Canada [29]. This paper describes the protocol for this mixed-methods study that will evaluate the implementation and impact of this online income security tool. Our study will assess: 1) whether health providers find using a tool to address income security in a clinical setting feasible and acceptable; 2) lessons learned and opportunities identified to integrate the tool within the

regular workflow of primary health care organizations; 3) feedback from patients using the online tool and the short-term impacts on awareness and access to benefits.

METHODS/ DESIGN

This study will use qualitative and quantitative methods to evaluate the feasibility and acceptability of using an online tool in primary care to address income security. The online income tool will be implemented at six primary care clinics, three in Toronto, Ontario and three in Winnipeg, Manitoba. All sites serve large numbers of patients with complex health needs and low socioeconomic status (Table 1).

Table 1. Clinic characteristics for 6 primary care sites in Ontario and Manitoba

Site	Location	Clinic type	Patient population	Provider(s) who predominantly administers the online tool	Enrollment in study
80 Bond Clinic, St. Michael's Hospital Academic Family Health	Toronto, Ontario	Family Health Team	Over 30% of patients live in neighbourhoods that have average incomes in the lowest quintile.	Family physicians and nurse practitioner	Reception staff provide patients an information sheet or health care providers

Team					initiate enrollment
South Riverdale Communit ity Health Centre	Toronto, Ontario	Community Health Centre	Priority populations include newcomers and patients with substance use or mental health needs	Family physician, nurse practitioners and social workers	Health care provider initiated
South East Toronto Family Health Team	Toronto, Ontario	Family Health Team	Serves wide range of patients with a focus on the unattached, medically and/or socially complex, high need patients	Family physicians and patient navigator	Health care provider initiated
Mount Carmel Clinic	Winnipeg, Manitoba	Community Health Centre	Serves one of the most impoverished areas in the city. The neighborhood has an unemployment rate of 17% with 34% of the families living in poverty. There are 83% female lone- parent families	Family physicians, nurse practitioners, nurses, social workers, support workers	Health care provider initiated

			and 16.9% of the community are members of a visible minority group with another 29% of Indigenous ancestry.		
Klinik	Winnipeg, Manitoba	Community Health Centre	Serves a diverse inner city community providing a very wide range of services to individuals, families, teens, adults and geriatrics within our geographic community. Special focus for priority populations of marginalized groups such as immigrants and refugees, transgendered	Family physicians, nurse practitioners, nurses, social workers, support workers, counsellors	Health care provider initiated

			individuals and those living with STIs.		
Aikins	Winnipeg, Manitoba	Community Health Centre	Serves a generally low-income north Winnipeg neighborhood. Focus on patients within the catchment area with particular interest in chronic disease care.	Family physicians, nurse practitioner, nurses	Health care provider initiated

The intervention is centred on an online tool that guides users through 12 demographic and income-related questions and subsequently generates a customized list of relevant provincial and federal government benefits and tax credits. The initial screening question “Do you ever have difficulty making ends meet at the end of the month?” has been validated in similar settings to identify patients who live below the Canadian poverty line with 98% sensitivity and 64% specificity [30]. Further questions were determined based on the eligibility criteria for various federal and provincial benefits and tax credit programs. The tool was first used at a community health centre and with a family health team in Toronto for one month to identify technical problems. Following feedback sessions with providers, modifications were made to the tool to improve its overall design for use in this study.

An orientation session will be held at each site to introduce primary care providers to the tool and enroll them in the study as participants. Following this session the tool will be implemented for a 3-month period. The tool can be used by any member of the health care team, including physicians, nurses, nurse practitioners, patient navigators and social workers. Each site will have some flexibility in how the tool will be implemented into the routine workflow of patient care, based on input from providers at the site. Health providers will be encouraged to use the tool with every patient seen. The tool can also be used in an opportunistic way, when patients share a health concern that is linked to low income. Patients who consent to participate in the study can then use the tool with their health provider. At this time, study sites do not have a formal, systematic way to identify low-income patients. To minimize bias by providers or reception staff, all patients who present for care in these clinics will be approached. This intervention was not randomized because excluding low-income patients from receiving information on eligible benefits and accessing additional income supports would be unethical. Moreover, the topic may come up in any given appointment depending on the nature of the visit. Given the limited time during appointments at some sites family physicians will screen patients for low income and refer them to a care coordinator (e.g. social worker) to complete the tool (Figure 1).

Figure 1. Implementation and evaluation of an online income tool

Participants

The 6 clinics testing the tool will introduce the pilot study to health care providers and interested providers will be consented to participate. We will aim to have a diverse group of health care

professionals use the tool with patients. Health providers and clinic staff will inform patients of the study through information sheets provided at the front desk of clinics or during an appointment. After reviewing the information sheet, the patient will note that they consent to proceed. To preserve anonymity, signed consent from patients will not be sought.

All patients seen at the primary care site are eligible to complete the online tool with their provider. The inclusion criteria for the one month follow-up with patients is as follows: used the tool approximately one month ago with their health care provider, able to provide consent, 18 years old or above, able to converse in English and able to be reached via telephone or email.

The primary aim of this pilot study is to assess the acceptability and feasibility of the intervention in a clinic setting. There is no pre-defined sample for patients completing the tool with their provider. This pilot study will help determine study sample calculations for future clinical trials and the usage and length of time to complete the tool will be monitored [31]. Of those patients who complete the tool and survey, a subset will be contacted for follow-up. The target sample size for one-month follow-up is 200 patients in each province for a total of 400 patients. We anticipate that this sample size will be robust enough to determine the acceptability of using the tool, as well as provide data on impact that will allow for sample size calculation for future studies of the impact of such tools on income itself.

Measures

We will collect a set of data points on each use of the tool. We will not be able to distinguish repeat users. The tool will record answers to the following demographic questions: age,

immigration status, employment status, whether someone in the household has a disability, household income and how many people live in the household and any existing benefits or tax credits received by the patient. The tool will also track clinic site, start time and end time of use, benefits recommended (output of tool) and proportion of users who complete the tool.

Patient surveys

At the end of the tool patients will be asked to complete a brief survey on their experience of using the tool and to provide contact information if interested in being contacted in the future. To examine the impact of the tool and whether patients learned about new benefits and/or their financial situation improved a research coordinator will conduct telephone surveys in a subset of patients that use the tool. Patients will be asked whether the tool is helpful, whether the tool would be recommended to a friend, whether the information provided was understood and their level of confidence in taking next steps based on information provided. Since there are no standardized instruments for evaluating this type of intervention the research team developed surveys. At the end of the tool we will ask patients' permission to contact them via telephone or email after one month for structured follow-up interviews.

Provider focus groups and survey

Three months after participating in the online income tool pilots, providers will be asked to complete an online, anonymous survey about their experience of using the tool. The purpose of this survey is to understand the providers' perspective on whether they would use the tool in the future and whether they would recommend it to a colleague. Providers at each site will also participate in a focus group discussion that will explore the use of the tool over the last three

months and the barriers and facilitators to implementation. A set of questions will be used to guide the focus groups and the discussions will be audio-recorded and transcribed verbatim.

Provider observations and feedback

During the three month-period of pilot testing the online income tool at three sites in Winnipeg and Toronto, respectively, the use of the tool and its accompanying feedback from study team members and participating staff is being collected on an ongoing basis. Analytics regarding the number of times the tool is being used at each site are recorded and shared with study team members on a weekly basis and any feedback shared about the tool in informal conversations during site visits, through email, or interim reports is noted in a feedback matrix that will be used when developing the tool in preparation for its next phase of use.

Advisory group

We will organize an advisory committee made of up patients, community agencies and staff to provide ongoing feedback on the project. Our aim is to engage 4-6 patients to provide input on how to improve the online tool and its use in clinical settings. The advisory committee will meet once a month beginning in July 2016 until the end of data collection period in December 2016 to help interpret findings, make recommendations to the online tool and suggestions for integrating its use within the care team. Ongoing engagement with patients and stakeholders will help to determine modifications to the tool, contextualize our findings and promote greater uptake in the future [32].

ANALYSIS PLAN

Quantitative Analysis

The primary outcome of this study is the change in knowledge of benefits (assessed through the end of tool patient survey and telephone interview at 4 weeks). The secondary outcome is change in income (assessed at telephone interview at 4 weeks). Descriptive statistics will be calculated (counts, percentages, means) to summarize variables including patient characteristics, usage of the tool and patient outcomes for all six sites. Outcome measures will be dichotomous and a bivariate analysis (using Student t-tests and chi-square tests, as appropriate) will be performed to determine associations between patient characteristics recorded from the tool and outcome measures (e.g., whether program was helpful, whether the patient is confident in taking next steps and whether their financial situation improved). Independent variables associated with positive patient outcomes and negative patient outcomes will be analyzed separately. Logistic regression analysis will be performed to identify variables independently associated with primary and secondary outcome measures.

Qualitative Analysis

The field notes and transcripts of the focus groups with providers will be analyzed thematically [33]. An initial coding framework will be developed using the focus group guide. Two team members will independently read and code transcripts using NVivo 11 (QSR International). Themes will be refined in an iterative process by comparing codes with the research team and reaching consensus on a final coding framework. The thematic analysis will focus on identifying key facilitators and barriers to implementation and provider perspectives on the impact of the tool and ways to improve similar tools. Field notes collected throughout the study will help contextualize findings for each site and identify similarities and differences across sites. Open-

ended questions from patient and provider surveys will also be thematically coded and categorized. We will identify common experiences associated with using the tool that may provide insight into how the tool works and ways to improve similar tools in the future.

Ethical considerations

This study has been approved by St. Michael’s Hospital Research Ethics Board, the Health Research Ethics Board at the University of Manitoba, and the Michael Garron Hospital Research Ethics Board. Informed consent will be obtained for all study participants. Data collected by the online tool will be anonymous, with no link between answers to questions in the tool and personal identifying data. It is possible that some patients may feel discomfort when asked the screening question and they may feel shame or fear stigma if they are experiencing income insecurity. We will attempt to lessen this possibility by encouraging health providers to normalize the experience for patients, e.g., “I’m asking all of my patients this question over the next 3 months”. All patient and provider surveys will be anonymized. Finally, participants in focus groups will not be identified by name and all transcripts will be anonymized during transcription.

DISCUSSION

This study uses an upstream approach to address a root cause of poor health outcomes: poverty. By exploring the feasibility and acceptability of using an online tool we can establish a standardized process to screen patients for low income in routine primary care settings. We will also examine and report on local factors that influence implementation at the different clinic sites. Moreover, the implementation of the tool will be pragmatic, with the ultimate aim to bring

such tools into broader practice through integration into primary healthcare settings. The findings from this study will provide insight into individual-level interventions to address the social determinants of health in primary care. Such tools may be useful to a diversity of primary care providers and could be applicable to other health care settings, such as in discharge planning at health care institutions. Important strengths of the intervention include opportunities for providers to offer feedback on the content, design and overall usability of the tool and the follow-up with patients about changes in their financial situation. Patients and community agencies represented in the advisory group will help ensure that this study remains focused on patient-centred outcomes and experiences and will contribute particular perspectives to the interpretation of our findings.

We will evaluate the implementation and short-term effects of this online income security tool within six health clinics. We will attempt to engage a broad representation of health providers at each site and will invite all staff to participate in our study. The information provided in the output of the tool may not be suitably tailored to the needs of all individuals. The time frame of this study does not permit us to examine health effects, which we would anticipate would take longer than one month to develop, and which would require a more intense intervention. Future research could examine whether using this tool, in coordination with other services, with patients identified as being at risk of developing complex health and social needs could impact on health and health service use [34, 35]. The hypothesis tested would be that that addressing income security may reduce the risk of poor health and high service use for some patients.

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There are two notable limitations to the current version of the tool. First, it focuses only on income security. A more comprehensive tool could be developed in the future to address multiple SDOH, such as employment, housing and food security and identify different community resources depending on patient needs. Second, while we anticipate that the tool will be able to identify benefits that a patient could be eligible for, the complex process of applying for benefits may be a barrier to improving income security.

This study is timely as awareness and a commitment to act on the SDOH is growing within the health sector in Canada [17, 36–38] and globally [39–41]. Continuing medical education events on poverty and health have been established and new medical school curricula is being created[42]. These efforts may begin to change medical practice. Yet, there are few studies that have evaluated the implementation and impact of such initiatives. The findings of this study will contribute to the design of SDOH interventions in health care, particularly when consider the role of technology and the practical challenges of incorporating interventions into busy health organizations.

List of abbreviations

SDOH social determinants of health

WE CARE Well-child Care Visit, Evaluation, Community Resources, Advocacy, Referral,
Education

Declarations

Ethics approval and consent to participate

This study was approved by the St. Michael's Hospital Research Ethics Board (15-353), the Health Research Ethics Board at the University of Manitoba (HS19275:H2016:019) and the Michael Garron Hospital Research Ethics Board (691-1608-Mis-298).

Consent for publication

Not applicable.

Availability of data and material

The datasets generated and analyzed during the current study are not publicly available due to the requirements of the various Research Ethics Boards, but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

ADP conceived the study. AS, GH, GB, RG, DR, REG, AK and ADP provided key inputs into the design of the study and refinements of the protocol. AA, AR and ADP assisted in the writing of the first draft of the manuscript. ADP, AS, GH, GB, RG, REG and AK assisted with obtaining funding for the study. AA, AR, AS, GH, GB, RG, DR, REG, JB, AK and ADP contributed to critical revisions and editing the manuscript for important intellectual content and approved the final manuscript. ADP had full access to all the information present and takes responsibility for the accuracy of this paper.

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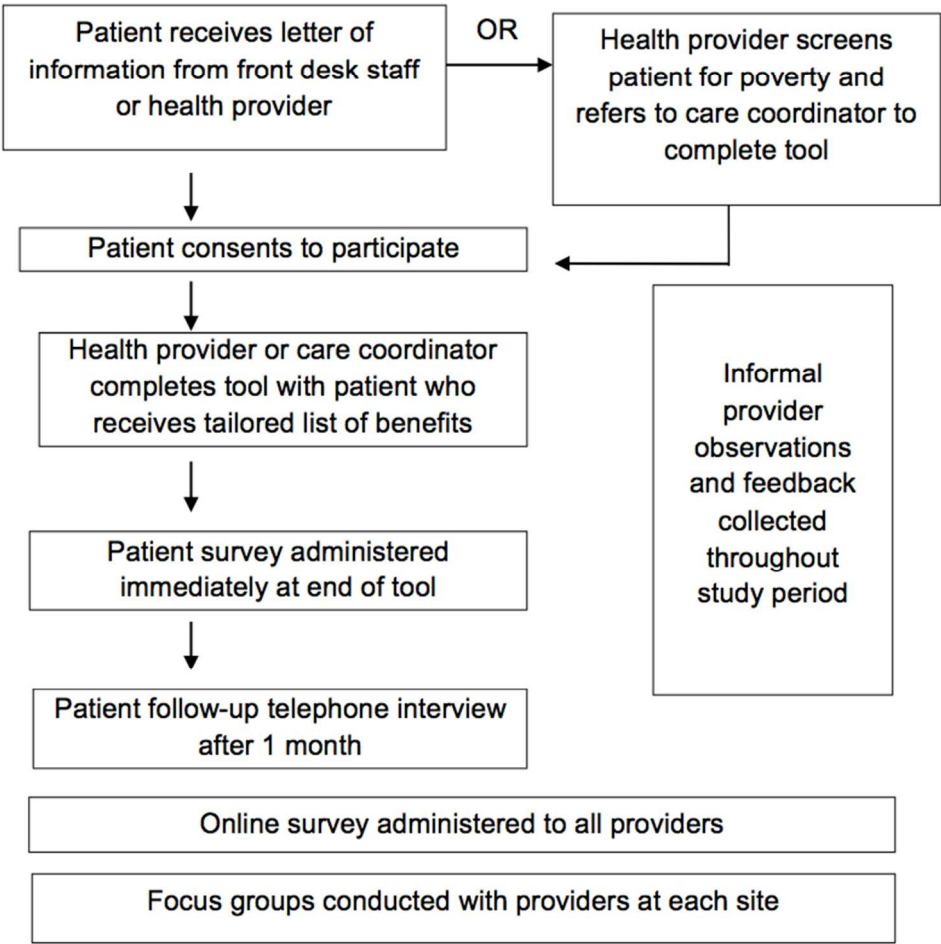
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For peer review only



Implementation and evaluation of an online income tool within primary care settings.

140x138mm (150 x 150 DPI)

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Evaluating the implementation and impact of an online tool used within primary care to improve the income security of patients with complex health and social needs in Ontario and Manitoba

1. Overview

Social conditions that impact the health of individuals have been labeled the social determinants of health (SDOH) and include a person's income security, food security, housing status and educational attainment.^{1,2} This project occurs in the context of a growing number of calls for evidence to inform interventions that address SDOH.³⁻⁵ Our objective is to conduct an implementation evaluation of an online tool that addresses income security at several primary care sites and to assess the short-term impact on patients. This tool works by prompting the health provider to screen for poverty, and if identified, to recommend benefits or other financial resources, as well as local community resources to assist with obtaining these benefits. Using continuing medical education materials that have been created by study team members, we will introduce the concept of screening for poverty and intervening to six clinic sites. We will collect input from these sessions to inform the development of the tool. We will form patient advisory groups in Toronto and Winnipeg to provide input on the tool as well. We will then pilot the tool in the six primary care clinics and collect immediate feedback from patients when they finish using the tool. After the tool has been in use for three months we will send online surveys to all providers at the six clinics and invite them to participate in focus groups. Finally, we will follow-up with patients at one month after they complete using the tool, using a telephone survey, to collect further input and get a sense of how its use had an impact on their knowledge of benefits and ability to access them. Data collected at each point will inform the ongoing refinement and development of the tool.

Relevance to cross-jurisdictional priority research areas: SDOH are relevant to caring for patients with complex health and social needs. For example, Ontarians who are in the top 1% and top 5% of health service use (labeled "high-cost health care users")⁶ are significantly more likely to be low-income, a relationship that persists despite controlling for other key factors including age.⁷ More recent work by the Health Analytics Branch of the Ontario Ministry of Health and Long-Term Care has found that living in an area with high material and social deprivation is a significant predictor of becoming a high-cost health care user.⁸ However, interventions to address SDOH are lacking. This project aims to address this gap, as well as develop new knowledge of how to address SDOH in clinical settings for all patients.

How this project is both novel and innovative: Building on work to date, we will evaluate the implementation of an online tool that assists primary care providers in addressing income security as a high-impact intervention on a key social determinant of health (SDOH). This online tool is currently at the very early stages of development, in partnership with Prosper Canada, a national charitable organization that has a mandate to improve financial literacy and has experience in designing and implementing similar online tools. This new online tool will be modified for use in Ontario and Manitoba in close consultation with patients and providers. It will help providers to screen patients for income insecurity, recommend benefits or other financial resources and then connect the patient to local benefit programs and resources, such as community agencies, financial literacy coaching, tax clinics and free services.

2. Study questions

- a) Do health providers find using a tool to address income security in a clinical setting both feasible and acceptable?
- b) What are the lessons learned and the opportunities identified when implementing an online tool to address income security within the regular workflow of primary health care organizations? What are the jurisdictional or context specific concerns encountered?
- c) What is the perspective of patients on using an online tool to address income security in a primary care setting and what is the short-term impact on awareness of benefits and community resources?

3. Background and significance

The social conditions that impact the health of individuals have been labeled the social determinants of health (SDOH). These are “the conditions in which people are born, grow, live, work and age. These circumstances are shaped by the distribution of money, power and resources at global, national and local levels”.¹ Perhaps the most important SDOH is income security, a person’s actual, perceived and expected income.⁹ Numerous studies confirm that income is a key determinant of health. In every society studied, the poor tend to live shorter lives, experience a greater burden of disease and disability, and rate their health status as worse than the wealthy.¹⁰⁻¹⁶ Income influences the presence and severity of most health conditions. Across population groups, and across time, the income-health link is robust. Material deprivation appears to be a key factor. Living in poverty means being unable to buy basic necessities such as healthy foods¹⁷⁻¹⁹ or pay the rent.²⁰ Some of the poorest citizens – those reliant on social assistance – have been shown to have worse health and be at greater risk of food insecurity than those with other income sources.²¹

Both the Ontario Medical Association⁵ and the Canadian Medical Association (CMA)⁴ have called for the development of new evidence around interventions to address poverty as a health issue. In 2013, in partnership with several media organizations, the CMA conducted a series of town halls across Canada on the topic of “Health care in Canada: What makes us sick?” One of the twelve recommendations that developed from this initiative was, “*That local databases of community services and programs (health and social) be developed and provided to health care professionals, and where possible, targeted guides be developed for the health care sector.*”²²

Research from Ontario on patients with complex health and social needs (i.e. the top 1% and 5% of health care users) has demonstrated that having low income is a strong predictor of becoming a “high-cost user” (HCU). Even after adjusting for age, sex and comorbidities, income security – and related factors such as food security and housing – was a key predictor of health care use.⁷ As the authors noted, “knowledge of the upstream determinants of HCU, particularly those that are non-clinical in nature, such as SES and health behaviors, is desperately lacking”.^{7, p.6}

Interventions to address SDOH are rarely found within our health care system. This is a gap within community-based primary health care, which has a mandate to provide preventative medicine, deliver health promotion and serve the needs of vulnerable communities.²³ While the public health sector has encouraged the implementation of interventions that target low-income

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individuals, these are mainly focused at the community-level.²⁴ We are not aware of any Canadian examples of systematic individual-level interventions that have been implemented to improve income security. Manitoba has made significant progress in developing the tools to address poverty within the health care setting building on the tools developed in Ontario but the tools have not yet been implemented. Anecdotal evidence suggests the positive impact of increased income on patients' health but, as yet, there is no rigorous research evidence in Canada to confirm these claims. However, evidence does exist from other jurisdictions. Welfare benefits advice services have been active for two decades in the United Kingdom. Many of these operate within, or in collaboration with, primary care health care practices.²⁵⁻²⁷ Research has shown that recipients of these services tended to be older, more likely to have a disability or long-term illness, and to rely on welfare benefits as their main source of income,²⁸ hence situating the provision of this advice in primary health care appears to be acceptable and feasible.^{29,30} A systematic review of the literature, mostly from the United Kingdom, concerning welfare advice found that it increased the income of recipients, although improvements in health were not captured in most studies.³¹

Financial advice programs in Toronto are well established in some non-primary care settings, such as the Financial Advocacy and Problem Solving service run by St. Christopher House.³² This program offers expert financial "problem solvers" who work with clients to maximize their income supports, financial literacy, and financial independence. The program also actively promotes the development of similar programs through other agencies and engages in policy advocacy and community development initiatives to address income inequality. According to their internal 2010 evaluation, in that year they served 2,334 clients and their clients accessed more than \$4.5 million in additional funds through the use of their services.

An additional example from Toronto is the work of Street Health in assisting the homeless with applying to the Ontario Disability Support Program (ODSP). In 2005, in collaboration with lawyers, physicians and allied health professionals and a number of organizations, Street Health staff worked with 85 homeless individuals to submit applications for ODSP. This built on previous examples of such assistance programs. The majority had multiple physical and mental health conditions. Of these, 70% needed significant help in overcoming barriers to applying for this additional income, such as the 90-day time limit to apply, accessing a physician to complete an assessment, completing forms and keeping in touch throughout the process. Over 90% of individuals were eventually successful in their application, with the supports provided.³³

It is challenging to estimate the need for such income security interventions. However, many low-income individuals do not file taxes, so miss out on substantial income available through tax benefits. Estimates from the Ontario Ministry of Community and Social Services indicate that social assistance recipients can increase their annual income by 10-50% through tax filing alone.³⁴ Many do not access other eligible government income benefits. Screening to identify patients living in poverty, and to assist those who would benefit to tax file and access other benefits is, therefore, an effective and rapid means of boosting incomes.

Existing tools and approaches to improve income security within health care settings
Distributing a paper-based tool focused on poverty and health

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Dr. Gary Bloch (Co-Applicant on this project), in collaboration with other health professionals, developed a simple tool for practitioners to screen patients for poverty, adjust their health risk assessment accordingly and intervene to increase income.³⁵ Specific interventions that are recommended include identifying if the patient has filed his or her taxes and obtained tax credits, identifying other government income benefit programs patients may be eligible for but not accessing, and referring patients to community and online supports and resources to help them access benefits. This tool has been adapted for, and is being piloted in, Manitoba, British Columbia and Nova Scotia. In Manitoba, there have been a range of ideas developed for distributing this information, which will soon be hosted on the Manitoba Health, Healthy Living and Seniors (Government of Manitoba) website. In addition, an active group of policy, research and practice experts (including Co-Applicants on this project) have been planning to upscale the initiative through electronic medical record (EMR) links, the medical training curriculum and a comprehensive approach for evaluating impact.

Providing a resource book to address social needs

A study conducted in Baltimore at a large urban hospital-based pediatric clinic examined the impact of using a brief screening tool to identify social needs within ten domains, and then provide patients with a tear-out that contained information about a relevant community-based resource. Led by Dr. Arvin Garg, the Well-child Care Visit, Evaluation, Community Resources, Advocacy, Referral, Education (WE CARE) Study found that this intervention increased the odds that a parent would contact a community resource, and most involved reported it added less than 2 minutes to the visit.³⁶

Developing a volunteer advocate program to address social needs

Several programs exist whereby patients are screened for social needs and volunteers assist in connecting these patients with community resources. For example, the Health Leads Program, which began in Boston and now exists in many locations throughout the USA. At the core of this intervention is the action of doctors, nurses and social workers to “prescribe” basic resources such as income, food and heat. A team of advocates “fill” these prescriptions by connecting patients with community resources and support programs. These advocates are volunteers who are trained to access such resources and are based in health care settings. While outcome studies have not been performed on this program, the uptake has been remarkable with 7,000 volunteers having served 23,000 patients since 2010.³⁷ A prospective study of Health Leads by Dr. Arvin Garg in a pediatric clinic in Baltimore found that over 2.5 years, 1059 families made use of the program and within 6 months over 50% had enrolled in at least one community-based resource. Similar programs include Health Begins (<http://www.healthbegins.org/>) in California and Basics for Health, which is beginning at REACH Community Health Centre in Vancouver, British Columbia.³⁸

Using an online tool to address broad social needs

A team of health professionals at Boston Children’s Hospital, led by Dr. Eric Fleegler, identified that a number of children and adolescents presenting in the clinic had significant social needs.³⁹
⁴⁰ In response, they developed an online tool called *HelpSteps* that assists patients and providers screen for social needs and then direct them to local resources. The tool collects information about gender, age, income, housing status, food security, asthma symptoms, environmental risks and health service need. The tool allows the user to select specific agencies and then print out a

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list, including directions and a brief description.⁴¹ A study with 50 users of the tool found that it took on average 25 minutes to use the tool, 90% identified at least one social need and 96% would recommend its use to a friend or peer. The main strengths were that it was private, easy to use, relevant and recommend referrals that were close by. The negative aspects were the length of time it took to use, some challenges with navigating the tool and the lack of capacity at agencies recommended.⁴²

Hiring a staff person to focus on income security health promotion

A full-time income security health promoter works with patients at the St. Michael's Hospital Academic Family Health Team to improve the income security of patients.⁴³ To that end, her activities includes: providing one-to-one case management support and ongoing follow-up to diverse low-income patients and families regarding their income security; conducting outreach to low income patients of the Family Health Teams (FHT), in collaboration with team health providers; developing and implementing targeted information self-help sessions, such as; banking basics, income tax submissions, and social service forms, for the target population; developing and maintaining up-to-date detailed knowledge of financial issues and financial services affecting low-income people, and applying this knowledge in his/her work; assisting individual low-income patients with income security-focused interventions, including access to tax benefits, applications for income security programs such as social assistance and seniors and child benefits, and navigation of disability support programs; and liaising with external organizations, including community social support agencies, legal aid clinics, homeless support agencies, advocacy groups and agencies focused on vulnerable sub-populations to develop referral pathways and supports for patients, with a focus on empowering patients to become change agents. A detailed evaluation of this novel service is underway, led by Dr. Andrew Pinto (Nominated Principle Applicant on this study).

4. Methods

In Part 1, we will conduct an implementation evaluation of the tool at six primary care sites, half in Ontario and half in Manitoba, that serve large numbers of patients with complex health and social needs. We will collect feedback from health providers through an online survey of all users and through focus groups at each site. In Part 2, we will conduct a telephone survey of patients on an ongoing basis at one month after use of the tool. This survey will capture patient perceptions of using the tool as well as their perception of changes in their knowledge of benefits and local resources.

Part 1: Implementation evaluation of an online tool used within primary care to improve the income security

We propose to pilot the implementation of a new online tool to screen for poverty and recommend interventions within primary care organizations. This tool will be developed in close partnership with Prosper Canada. Our project team has been meeting with Prosper Canada staff over the past year. As detailed in our Budget document, we have been successful in jointly securing grants to support this work. This project builds on the software architecture for another tool created by Prosper Canada, "Money Management Tools for Newcomers"

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(<http://www.newcomerscanprosper.org/>). Of note, the online nature of the tool allows for its ongoing refinement and development throughout the early phases detailed below.

First, we will develop a prototype online tool (Appendix E) with input from the study team and colleagues, including the Income Security Health Promoter at St. Michael’s Hospital. Second, we will conduct two patient engagement sessions, one in Toronto and one in Winnipeg, where we will collect input on the concept, design and content from patients identified through the study team and who attend the clinics where the tool will likely be piloted. This early feedback will be invaluable to guide the design of this tool. Patients will be compensated for their time with a modest honorarium. We will conduct a final set of patient engagement sessions toward the end of the project, to present our findings and obtain feedback on the tool at that point.

Third, the concept of the tool will be introduced at six clinic sites that serve large numbers of patients with complex health needs. In Ontario, these will be identified in collaboration with Health Links. In Manitoba, the tool will be implemented in clinics with a high prevalence of people living in poverty. To introduce the tool, a Continuing Medical Education (CME) session will be conducted at each site by study team members, based on materials developed in partnership with the Ontario College of Family Physicians (OCFP) Committee on Poverty and Health (Co-Applicants on this committee include Dr. Gary Bloch (chair), Dr. Ritika Goel and Dr. Danyaal Raza). These sessions will introduce the evidence behind addressing poverty as a health concern and demonstrate the tool to providers. Informal feedback from providers at this stage will be collected and the tool will be modified. Fourth, the tool will then be piloted at these clinics. The proposed sites provide a variety of settings in which to test the tool.

Ontario

Clinics in Ontario will be approached to participate in this study. Investigators involved with this project (Pinto, Goel, Bloch, Raza) are leaders in this field and have had initial discussions with colleagues and administrators about this intervention:

- **St. Michael’s Hospital Academic Family Health Team** serves more than 35,000 patients at six clinics in downtown Toronto. It is one of the largest academic Family Health Teams in the province. While a broad cross-section of the community is served, there is a particular focus on serving marginalized populations. In 2010, over 30% of patients at three of five current clinic sites (St. Jamestown, 410 Sherbourne and 80 Bond) were found to be in the lowest income quintile, and over 50% in the lowest two income quintiles.¹⁴

Two additional clinic sites in Ontario will be identified. Preliminary discussions have been had with colleagues in Kingston and in Sudbury. Appropriate research ethics approval will be sought at each site as required.

Manitoba

A number of clinics in the Winnipeg region will be approached to participate in this study, several of which have connections to investigators involved with this project (Katz, Singer):

- **ACCESS Clinics** offer health and social services that vary from community to community in order to address the unique needs of the communities they serve. Services include front line health care from physicians or nurse practitioners to assistance with mental health, home care, employment and income assistance programs. **ACCESS**

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Downtown is located in the core downtown area of Winnipeg. It is a new new 42,000 sq. ft. foot centre offering many different services including a primary care clinic, and dental clinic, as well as resources for public health, home care, community mental health, employment and income assistance, and Winnipeg Child and Family Services. **Access River East** offers a primary care services as well as individual counselling, hosting health education, workshops and support groups for a wide range of individuals including those who are caregivers, or have specific chronic conditions. **Access Transcona** offers a primary care services as well as individual counselling, hosting health education, book clubs, workshops and support groups for a wide range of individuals including those who are caregivers, widowers, or have specific chronic conditions.

- **Aikins Street Community Health Centre** is a primary care clinic with a health care team that includes physicians, a physician assistant, nurses, a counselor, and a dietitian. The services are available to residents within a defined area of Winnipeg more generally associated with lower socioeconomic status.
- **Northern Connections Medical Centre** is a primary care clinic that offers comprehensive primary care to individuals temporarily in Winnipeg from specific northern communities and military families posted in Winnipeg. The clinic is also a teaching site of the Family Medicine residency program with an interdisciplinary care team that includes primary care physicians, family medicine residents (students), nurses, a registered dietitian, a pharmacist and a social worker.

Each site will have some flexibility in how the tool will be implemented into the routine workflow of patient care, based on input from providers at the site. Health providers will use the tool with every patient seen, at each Annual Physical or Periodic Health Visit, or with specific patient groups (e.g. prenatal patients and well-baby visits). Some sites will also use the tool in an opportunistic way, when patients present with a concern that is linked to social determinants of health. Where possible, there will be a direct link to the tool in the EMR at each site. The tool will be used by any member of the health care team, including physicians, nurses, nurse practitioners, physician assistants, health promoters, dietitians, social workers and others, depending on the clinic site. We will track the professional designation of users of the tool.

Outcome measures

a) *Online data collected through use of the tool*

We will collect a set of data points on each use of the tool once it is in beta-testing mode. We will not be able to distinguish repeat users. The following will be entered in by the health professional working with the patient to go through the tool:

Socio-demographics	Year of birth, gender identity, race/ethnicity, language preference, whether born in Canada or not (and year of arrival), household income and the number of people supported. The format of these questions will match those recommended by the Toronto Centre LHIN. ⁴⁴
Geographic location	Established using Internet Cache Protocol (ICP)
Time	Start time and end time of use
Benefits recommended	Output of tool
Resources recommended	Output of tool

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Completion rate	Proportion of users who complete the tool
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b) Brief survey of participants at conclusion of tool

At the end of the tool, we will pose a number of questions to users ([Appendix A](#)), including asking permission to contact them in the future as part of the evaluation.

c) Online survey to providers

After 3 months, online, anonymous surveys ([Appendix B](#)) will be circulated to all health professionals on their experience of using the tool. We will record contact information for health providers during the introductory sessions held at each site ([Appendix G](#)). We do not intend to collect identifying information on providers other than their professional designation.

d) Focus groups with providers

We will invite all health professionals at each site via email to participate in a focus group discussion that will explore perspectives, experiences and challenges regarding use of the online tool over the last 3 months. A semi-structured interview guide ([Appendix C](#)) will be employed for the focus group and discussions will be audio-recorded and transcribed. To identify obstacles to using the tool we will specifically explore cases where a provider felt the tool would have been appropriate, but the tool was not used. Informed consent will be obtained ([Appendix F](#)).

At St. Michael’s Hospital Academic Family Health Team we will conduct 2 focus groups with health care providers. Focus groups will be conducted at 1 month and 3 months following implementation of the online tool. The 1 month follow-up focus group will provide preliminary feedback on use of the tool. We will explore perspectives, experiences and challenges regarding use of the online tool over the last month and how they plan to use the tool over the next 2 months using a semi-structured interview guide ([Appendix L](#))

Part 2: Impact evaluation of an online tool used within primary care to improve the income security

To examine patient experience of the tool and whether their financial situation improved, a brief (10 minute) telephone survey will be conducted in a subset of patients that use the tool. To recruit patients, at the end of the tool we will ask their permission to contact them via telephone or email to follow-up at 1 month. Ideally, this follow-up will be completed via phone. However, if a patient does not have a phone, email may be used to set up an in-person interview, to be conducted at the patient’s home clinic site.

The inclusion criteria are as follows:

- a) A patient who completed using the tool approximately 1 month ago, either on their own or as part of the screening process with their health care provider
- b) Able to provide consent
- c) Age is greater than or equal to 18
- d) Able to converse in English
- e) Able to be reached via telephone or email

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Patients will be randomly selected into the telephone sample to a target sample size of 200 patients in each province for a total of 400 patients. Study feasibility is the primary driver for limiting the telephone sample to a subset of patients. Further, we feel that 400 patients will be sufficient to determine the impact of using the tool. Three phone calls will be attempted before a patient will be removed from the telephone survey sample. Consent will be obtained and documented at the beginning of the phone call and calls will not be recorded (**Appendix D**). Patients will be excluded if they do not provide consent, are unable to converse in English.

Data Collection and Measures

It is estimated that the interview will take 10 minutes. Several questions will be asked; these focus on learning whether the patient found the online tool helpful, what benefits were suggested and whether resources were accessed in order to obtain these benefits. We will also explore whether there was any change in a patient's financial situation (e.g., increased in income or reduction in expenses). The interviewer will enter data into the Telephone Survey Data Form (**Appendix H**) in real-time. Most data will be coded upon entry and free-text will be coded for qualitative analysis.

Analysis Plan

Descriptive statistics will be calculated (counts, percentages, means) and a bivariate analysis (using t-tests and chi-square tests, as appropriate) will be performed to determine associations between patient characteristics and program outcomes (e.g., whether program was helpful, whether financial situation is improved). A regression analysis is also planned to determine patient predictors of program success. The answers to open-ended questions will be coded and categorized to determine whether certain themes characterize the experience of using the tool and the recommended resources.

5. Collaboration

This project occurs in the context of ongoing collaboration between team members based in Ontario and Manitoba, who have a shared interest in a) screening for SDOH in clinical spaces at the individual level, b) addressing SDOH through innovative interventions in primary health care and c) the use of electronic medical records (EMR) to improve health equity. Team members are also part of a network that includes colleagues in British Columbia, Saskatchewan, Quebec and Nova Scotia, who are working to address SDOH.

This study will support cross-jurisdictional scans of work that is occurring to address social determinants in Canada, with a focus on Manitoba and Ontario. We will establish a standard process for screening patients for income security, a key determinant of health. We will design and implement a standard process for identifying community resources to address upstream factors and SDOH. We will examine and report on local factors that influence implementation of this sort of tool. Finally, we will examine the ability to integrate this tool into the EMR (e.g. through having a link present on dashboards or actually bringing content into the EMR).

This study is clearly focused on an "upstream approach to prevention" of health problems through intervening on a key SDOH, income security. If successful, this innovative approach will add a new element to Community-Based Primary Health Care.

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Key strengths of this project include the strong alliance between academics, front-line clinicians, policy makers and a charitable organization. This project is focused on the development and evaluation the delivery of integrated services within and across the health sector, and engages other sectors in meeting the needs of patients. We will make use of multiple types of data (quantitative and qualitative) drawn from multiple settings. This project engages patients and providers in the development and evaluation of a unique intervention. Finally, the implementation of the tool will be pragmatic, with the ultimate aim to bring such tools into practice.

6. Ethical concerns

a) Informed consent process

For the data collected at the end of the online tool, consent will be implied by answers provided to the questions. Similarly, when providers complete the online survey, a notice will indicate that consent is implied by completing the survey. Focus group participants will complete an informed consent process at the beginning of the group discussion. Finally, an informed consent checklist will be completed with patients who participate in the telephone survey.

b) Potential risks

Because some time will be used for the tool at the beginning of patient interactions, there is the theoretical risk of taking that time away from a time-limited patient appointment. We will emphasize to participants that participation in the study should neither displace discussion of any medical problems during the appointment, nor should it replace any other income-related interventions that the participant would otherwise make. The screening question may lead to an exposition of a patient problem that the practitioner does not have the resources or expertise to manage. In that case, we will recommend that the patient be referred to the in-house social worker or other relevant professional. All study participants will face a slight inconvenience from participating in the study, due to the time dedicated to the questionnaires and the focus-group session. It is possible that some patients may feel discomfort when asked the screening question, and they may feel shame or fear stigma if they are experiencing income insecurity. We will attempt to lessen this possibility by encouraging participants to normalize the experience for patients, e.g., “I’m asking all of my patients this question over the next month”. Study participants may themselves feel discomfort when asking the question to patients. During the initial training session, we will suggest ways to ease into approaching this topic.

c) Potential benefits

There are many potential benefits to this study. It may sensitize health professionals to the importance of income and health and help physicians discover income as a hidden factor complicating some of their patients’ conditions. This study may help health professionals become familiar with easy ways of screening for poverty and assisting their patients with resources. Importantly, this study may provide patients with valuable resources for improving their income. Finally, this study can support the development of a widely-used tool for improving health through income in other jurisdictions.

d) Privacy and confidentiality: All health care providers who are study participants will be recruited via internal email contact. Participants will be assigned a study number, which will then

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be used throughout the study. A master linking log, linking the participant name with study number, will be kept on a password-protected on a secure server. Signed consent forms used in the focus groups will be kept in a locked filing cabinet and will not be linked to the participant's study number. The web-based tool will not track participant names or patient information. All surveys will be anonymized via study number. Responses during the focus-group sessions will be anonymized during or after transcription. The audio recording will be kept in a locked cabinet and destroyed 10 years after completion of the study.

7. Limitations

This study will only examine the implementation and short-term (one month) effects of the income security tool within the defined health clinics at this point. Hence, we will be focusing on early adopters. We will attempt to engage a broad representation of health providers at each site. The information provided may not be suitably tailored to the needs of individuals, which may be a consideration for future research. The time frame of this study restricts the findings to use of the poverty tool and potential use of social resources and services, but does not enable us to examine health effects. Future work will look at the impact of using this tool with patients identified as at risk of developing complex health and social needs, with the hypothesis that addressing income security may reduce the risk for some patients.

8. Study team

Andrew D. Pinto (Nominated Principal Applicant) is a Public Health and Preventive Medicine specialist and family physician at St. Michael's Hospital Academic Family Health Team. He is a Scientist in the Li Ka Shing Knowledge Institute at St. Michael's Hospital. He is an Assistant Professor in the Department of Family and Community Medicine, Faculty of Medicine and the Dalla Lana School of Public Health at the University of Toronto. He has experience in evaluating novel interventions that address SDOH.

Kristin Anderson (Knowledge User) is the Director, Primary Care at Manitoba Health, Healthy Living and Seniors. She has been involved with the poverty tool initiative in Manitoba and a key decision maker for its development and progress.

Adam Fair (Knowledge User) is Director of Programs at Prosper Canada, a national charity dedicated to expanding economic opportunities for Canadians living in poverty through program and policy innovation. He has extensive experience with developing and implementing unique programs to improve financial literacy.

Katelin McDermott (Knowledge User) is a Program Analyst at Manitoba eHealth and works with EMR data quality and optimization for the Primary Care Information Systems office (PCIS). This role supports adoption and effective implementation of clinical information systems, in collaboration with Manitoba Health, Healthy Living and Seniors.

Alan Katz (Principal Applicant) is Professor and Clinician Researcher at the University of Manitoba, Departments of Community Health Sciences and Family Medicine. He is also the Director of the Manitoba Centre for Health Policy; the Research Lead for the Manitoba SPOR PIHCI Network (MSN) and Manitoba Chair in Primary Prevention Research. He has extensive

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research expertise and has been a key collaborator with strategic development of the poverty tool initiative in Manitoba.

Gary Bloch (Co-Applicant) is a family physician within the Department of Family and Community Medicine, St. Michael’s Hospital, and an Assistant Professor within the Department of Family and Community Medicine, University of Toronto. He is Chair of the Social Determinants of Health Committee within the Department of Family and Community Medicine, St. Michael’s Hospital, and the Chair of the Poverty Committee, Ontario College of Family Physicians. He has extensive experience in developing tools to assist primary care providers to address poverty amongst their patients.

Ritika Goel (Co-Applicant) is a family physician at Inner City Family Health Team and Sistering, a women's drop-in centre. She also volunteers and serves as a board member for the Scarborough Community Volunteer Clinic for the Uninsured. She is involved in medical education relating to poverty and health as part of the Ontario College of Family Physicians' Poverty and Health Committee. She will assist with the pilot implementation at Inner City Family Health Team.

Gayle Halas (Co-Applicant) is a Researcher with the University of Manitoba Department of Family Medicine. She has an interest in patient education and interaction and brings a qualitative research perspective to the project and will facilitate the work being done within Manitoba.

John Ihnat (Co-Applicant) is a family medicine resident within the Department of Family and Community Medicine, Faculty of Medicine, University of Toronto. His Residency Academic Project supports this study directly and he will be leading the pilot implementation at Flemingdon Health Centre.

Danyaal Raza (Co-Applicant) is a family physician within the Department of Family and Community Medicine, St. Michael’s Hospital, and a Lecturer within the Department of Family and Community Medicine, University of Toronto. He is a member of the the Social Determinants of Health Committee within the Department of Family and Community Medicine, St. Michael’s Hospital, and is also a member of the Poverty Committee, Ontario College of Family Physicians. He will assist with the pilot implementation at St. Michael’s Hospital.

Alex Singer (Co-Applicant) is a family physician, Assistant Professor in the Department of Family Medicine, University of Manitoba as well as the Director of the Manitoba Primary Care Research Network. Singer was the co-chair of the department of Family Medicine’s EMR implementation committee and is a current member of the Winnipeg Regional Health Authority’s EMR Clinical Advisory Group. He is a consulting member on the Manitoba Health Primary Care Working Group, with a role in facilitating the linkage between the Poverty tool and EMR within WRHA funded clinics and potentially with other EMR users in Manitoba.

Ross E.G. Upshur (Co-Applicant) is currently the Medical Director, Clinical Research, Bridgepoint Health. He is a Canada Research Chair in Primary Care Research. At the University of Toronto he is a Professor at the Department of Family and Community Medicine and Dalla

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Online tool to improve income security

Lana School of Public Health, Adjunct Scientist at the Institute of Clinical Evaluative Sciences, an affiliate of the Institute of the History and Philosophy of Science and Technology and a member of the Centre for Environment. He is an Adjunct Associate Professor in the School of Geography and Earth Sciences and Associate Member of the Institute of Environment and Health at McMaster University. He is the former Director of the University of Toronto Joint Centre for Bioethics (2006-2011) and was a staff physician at the Department of Family and Community Medicine, Sunnybrook Health Sciences Centre from 1998-2013. He will

10. Deliverables

Key deliverables include the development of a new online tool in partnership with Prosper Canada with patient and provider input; the findings from implementation evaluation (based on brief patient surveys at the end of the tool, provider online surveys and provider focus groups); and the findings from the short-term impact evaluation (based on telephone surveys with patients). Further, through this process we will develop training materials for health providers, including a brief presentation and manual, on how to use the tool in clinical practice.

11. Knowledge translation and impact

Our findings from both part 1 and part 2 will inform the refinement of the tool. This study will contribute to our understanding of how to assess and intervene on income insecurity, a significant SDOH within clinical settings. Additional deliverables include the refined income security online tool that can be adapted for other jurisdictions in Canada and training materials for health providers on how to use the tool

This project will be an important step toward the goal of being able to address social determinants of health (SDOH) at an individual and family level. If successful, this tool and others will expand the scope of primary health care and provide a concrete way to address issues that health providers have long felt were important. This will clearly be useful to many providers in Ontario, Manitoba and beyond.

Our team envisions this tool as being dynamic, with the potential to be quickly modified to fit different jurisdictions. We will develop and disseminate a plan to assess community resources that can address SDOH, and this process will be helpful to Ontario's organized primary care sector (e.g. Family Health Teams, Community Health Centres), Local Health Integration Networks and local public health units. In Manitoba a significant coalition of healthcare providers, system planners and community organizations has been working to customize the tool to present local Winnipeg resources.

As an online tool, it is easy to develop new modules to address other key SDOH. This could include child literacy, housing or employment. We see this as of particular of value to areas in Ontario with high levels of health inequities where there are multiple, overlapping health and social services, but no clear system for navigation. This project will contribute to future tools to address these issues.

Online tool to improve income security

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Evaluating the implementation and impact of an online tool used in primary care to improve the income security of patients: A study protocol

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	<u>p.1</u>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	<u>p.3</u>
	2b	All items from the World Health Organization Trial Registration Data Set	<u> </u>
Protocol version	3	Date and version identifier	<u>Appendix</u>
Funding	4	Sources and types of financial, material, and other support	<u>p.18</u>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	<u>p1 & 19</u>
	5b	Name and contact information for the trial sponsor	<u>p.1</u>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	<u>p.19</u>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	<u>p.13</u>

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Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	<u>p.4-6</u>
	6b	Explanation for choice of comparators	<u>n/a</u>
Objectives	7	Specific objectives or hypotheses	<u>p.5-6</u>
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	<u>p.6</u>

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	<u>p.6-9</u>
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	<u>p.11</u>
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	<u>p.9-10</u>
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	<u>n/a</u>
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	<u>n/a</u>
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	<u>n/a</u>
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	<u>p.14-15</u>
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	<u>p.10-11, Fig 1</u>

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	<u>n/a</u>
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<u>n/a</u>

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	<u>n/a</u>
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	<u>n/a</u>
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	<u>n/a</u>
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	<u>n/a</u>
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	<u>n/a</u>

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	<u>p. 11-12</u>
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	<u>p. 10-11</u>

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3	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	<u>p. 11-12</u>
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7	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	<u>p. 13-15</u>
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10		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	<u>n/a</u>
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12		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	<u>n/a</u>
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16	Methods: Monitoring			
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18	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	<u>n/a</u>
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23		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	<u>n/a</u>
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26	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	<u>n/a</u>
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29	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	<u>n/a</u>
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33	Ethics and dissemination			
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35	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	<u>p.15</u>
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38	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	<u>n/a</u>
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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	<u>p.15</u>
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	<u>n/a</u>
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	<u>p.15</u>
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	<u>p.18-19</u>
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	<u>n/a</u>
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	<u>n/a</u>
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	<u>p.17</u>
	31b	Authorship eligibility guidelines and any intended use of professional writers	<u>n/a</u>
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	<u>n/a</u>
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	<u>n/a</u>
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	<u>n/a</u>

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

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Implementation and impact of an online tool used in primary care to improve access to financial benefits for patients: A study protocol



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Implementation and impact of an online tool used in primary care to improve access to financial benefits for patients: A study protocol

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Abstract

Objectives

Addressing the social determinants of health of patients has been identified as crucial to reducing health inequities. However, few evidence-based interventions exist. This study emerges from an ongoing collaboration between physicians, researchers and a financial literacy organization. Our objective is to answer the following questions: Is an online tool that improves access to financial benefits feasible and acceptable to primary care clinicians? Can such a tool be integrated into clinic workflow? What are patient perspectives on the tool and what is the short-term impact on access to benefits?

Methods

An advisory group made up of patients living on low incomes and representatives from community agencies supports this study. We will recruit three primary care sites in Toronto, Ontario and three in Winnipeg, Manitoba that serve low-income communities. We will introduce clinicians to screening for poverty and how tax filing and applying for government benefits can increase income. Following this orientation session, health providers will be encouraged to use the tool with any patient seen. The health provider and patient will complete the online tool together, generating a tailored list of benefits, along with community resources to assist with obtaining these benefits. A brief survey on this experience will be administered to patients after they complete the tool, as well as a request to contact them in one month. Those who agree to be contacted will be interviewed on whether the intervention impacted their access to financial

benefits. We will also administer an online survey to providers and conduct focus groups at each site.

Discussion

An online tool could support health providers who want to help their patients access financial benefits, a key component of income security. Our findings will provide insight into the potential of electronic tools that assist providers to address the social determinants of health.

Strengths and Limitations

- Multi-site study involving clinics in two provinces.
- Pragmatic implementation of a novel tool in the real world of busy primary care clinics.
- Mixed-methods evaluation, using several data sources to triangulate findings.
- Convenience sampling method for patients.
- A short follow-up period (4 weeks after intervention) may underestimate the impact of the novel tool.

Trial registration:

Clinicaltrials.gov: [NCT02959866](https://clinicaltrials.gov/ct2/show/study/NCT02959866). Registered Nov 7, 2016. Retrospectively registered.

Keywords: social determinants of health, income, poverty, primary care, health promotion

BACKGROUND

The World Health Organization defines the social determinants of health (SDOH) as “the conditions in which people are born, grow, live, work and age”, and include the material resources a person has available that are necessary to live a healthy life [1]. SDOH have been identified as a key reason for health inequities between different individuals and groups within a population, and help explain differences in access to health services [2]. The World Health Organization Commission on Social Determinants of Health, the British Medical Association and the Canadian Medical Association have all called on the health sector to play a greater role in addressing the SDOH through implementing and evaluating new interventions and serving as a link between disadvantaged communities and social and community services [3–6]. Primary care settings in particular are uniquely opportune spaces to take action [7]. Primary care providers follow patients longitudinally, are community-based and often have knowledge of the broader familial and social contexts that shape health and disease [8].

One of the most important SDOH is income security: a person’s actual, perceived and expected income [9, 10]. Income influences the presence and severity of most health conditions. People living in poverty may have difficulty paying rent [11], affording nutritious food [12], affording transportation and engaging with others socially [6–9]. Many studies have shown that economically marginalized people tend to live shorter lives, experience a greater burden of disease and disability and rate their health status as worse than the wealthy [16–21]. One aspect of income security is access to financial benefits.

There are currently few, rigorously evaluated SDOH interventions deployed in clinical settings that have been found to improve material conditions and subsequently the health of individuals and families [22, 23]. Welfare benefits advice services within general practices in the United Kingdom have been found to increase the income of recipients, although improvements in health were not assessed in most studies[24]. More recently, several studies in the United States have demonstrated the effectiveness of clinic-based interventions at connecting patients to community resources to address SDOH. In Boston, the Well-child Care Visit, Evaluation, Community Resources, Advocacy, Referral, Education (WE CARE) study took place in pediatric clinics [25]. A waiting room survey screened for social needs and members of the health care team provided information on community resources, adding less than two minutes to the visit. At one month, 20% of the intervention group parents reported contacting a referred community resource versus 2.2% of parents in the control group [26]. The online tool, HelpSteps [27, 28], screens for a much larger number of social needs, taking on average 25 minutes to complete, with 90% of users identifying at least one social need and 96% reporting they would recommend its use to a friend or peer [29]. The California iScreen study[30], also tested in pediatric clinics, used the Health Leads [31] model and found that social needs can be identified and providing patient supports led to improvements in parent-reported child health [32]. In Canada, a paper-based clinical tool has helped train physicians and other health providers to consider poverty as a health issue [33]. This tool has been adapted by the College of Family Physicians of Canada for use in all provinces and territories. No studies to date have evaluated the impact of this tool on providers or patients.

Our study focuses on developing, implementing and evaluating an online tool in primary care settings that focuses on access to financial benefits. This study emerges from an ongoing collaboration between family physicians, researchers and a charitable financial literacy organization, Prosper Canada [34]. This paper describes the protocol for this mixed-methods study that will evaluate the implementation and impact of this online tool. Our study will assess: 1) whether health providers find using a tool to address access to financial benefits in a clinical setting feasible and acceptable; 2) lessons learned and opportunities identified to integrate the tool within the regular workflow of primary health care organizations; 3) feedback from patients using the online tool and the short-term impacts on awareness and access to benefits.

METHODS/ DESIGN

This study will use qualitative and quantitative methods to evaluate the feasibility and acceptability of using an online tool in primary care to address access to financial benefits. The online income tool will be implemented at six primary care clinics, three in Toronto, Ontario and three in Winnipeg, Manitoba. All sites serve large numbers of patients with complex health needs and low socioeconomic status (Table 1).

Table 1. Clinic characteristics for 6 primary care sites in Ontario and Manitoba

Clinic type	Location	Patient population	Provider(s) who will predominantly administer the tool	Method of recruiting patients

Family Health Team	Toronto, Ontario	Over 30% of patients live in neighbourhoods that have average incomes in the lowest quintile.	Family physicians and nurse practitioner	Reception staff provide patients an information sheet or health care providers initiate enrollment
Community Health Centre	Toronto, Ontario	Priority populations include newcomers and patients with substance use or mental health needs	Family physician, nurse practitioners and social workers	Health care provider initiated
Family Health Team	Toronto, Ontario	Serves wide range of patients with a focus on the unattached, medically and/or socially complex, high need patients	Family physicians and patient navigator	Health care provider initiated
Community Health Centre	Winnipeg, Manitoba	Serves one of the most impoverished areas in the city. The neighborhood has an	Family physicians, nurse practitioners, nurses, social workers, support	Health care provider initiated

		unemployment rate of 17% with 34% of the families living in poverty. There are 83% female lone-parent families and 16.9% of the community are members of a visible minority group with another 29% of Indigenous ancestry.	workers	
Community Health Centre	Winnipeg, Manitoba	Serves a diverse inner city community providing a very wide range of services to individuals, families, teens, adults and geriatrics within our geographic community. Special focus for priority populations of marginalized groups	Family physicians, nurse practitioners, nurses, social workers, support workers, counselors	Health care provider initiated

		such as immigrants and refugees, transgendered individuals and those living with STIs.		
Community Health Centre	Winnipeg, Manitoba	Serves a generally low-income north Winnipeg neighborhood. Focus on patients within the catchment area with particular interest in chronic disease care.	Family physicians, nurse practitioner, nurses	Health care provider initiated

Intervention

The intervention is centered on an online tool that guides users through 12 demographic and income-related questions and subsequently generates a customized list of relevant provincial and federal government benefits and tax credits. The initial screening question “Do you ever have difficulty making ends meet at the end of the month?” has been validated in similar settings to identify patients who live below the Canadian poverty line with 98% sensitivity and 64% specificity [35]. Further questions were determined based on the eligibility criteria for various federal and provincial benefits and tax credit programs. The tool was first used at a community health centre and with a family health team in Toronto for one month to identify technical problems. Following feedback sessions with providers, modifications were made to the tool to improve its overall design for use in this study.

Study Procedures

An orientation session will be held at each site to introduce primary care providers to the tool and enroll them in the study as participants. Following this session the tool will be implemented for a 3-month period. The tool can be used by any member of the health care team, including physicians, nurses, nurse practitioners, patient navigators and social workers. Each site will have some flexibility in how the tool will be implemented into the routine workflow of patient care, based on input from providers at the site. Health providers will be encouraged to use the tool with every patient seen. The tool can also be used in an opportunistic way, when patients share a health concern that is linked to low income. Patients who consent to participate in the study can then use the tool with their health provider. At this time, study sites do not have a formal, systematic way to identify low-income patients. To minimize bias by providers or reception staff, all patients who present for care in these clinics will be approached. This intervention was not randomized because excluding low-income patients from receiving information on eligible benefits and accessing additional income supports would be unethical. Moreover, the topic may come up in any given appointment depending on the nature of the visit. Given the limited time during appointments at some sites family physicians will screen patients for low income and refer them to a care coordinator (e.g. social worker) to complete the tool (Figure 1).

Figure 1. Implementation and evaluation of an online income tool

Participants

Providers

The 6 clinics testing the tool will introduce the pilot study to health care providers and interested providers will be consented to participate. We will aim to have a diverse group of health care professionals use the tool with patients including family physicians, nurse practitioners, social workers and patient navigators.

Patients

All patients seen at the primary care site are eligible to complete the online tool with their provider. Health providers and clinic staff will inform patients of the study through information sheets provided at the front desk of clinics or during an appointment. After reviewing the information sheet, the patient will note that they consent to proceed. To preserve anonymity, signed consent from patients will not be sought. The inclusion criteria for the one month follow-up with patients is as follows: used the tool approximately one month ago with their health care provider, able to provide consent, 18 years old or above, able to converse in English and able to be reached via telephone or email.

Sample Size

The primary aim of this pilot study is to assess the acceptability and feasibility of the intervention in a clinic setting and assess the short-term impact of the tool on patients. There is no pre-defined sample for patients completing the tool with their provider. This pilot study will help determine study sample calculations for future clinical trials and the usage and length of time to complete the tool will be monitored [36]. Of those patients who complete the tool and survey, a subset will be contacted for follow-up. The target sample size for one-month follow-up is 200 patients in each province for a total of 400 patients. We anticipate that this sample size

will be robust enough to determine the acceptability of using the tool, as well as provide data on impact that will allow for sample size calculation for future studies of the impact of such tools on income itself.

Quantitative Data Collection

Online Tool Output

We will collect a set of data points on each use of the tool. We will not be able to distinguish repeat users. The tool will record answers to the following demographic questions: age, immigration status, employment status, whether someone in the household has a disability, household income and how many people live in the household and any existing benefits or tax credits received by the patient. The tool will also track clinic site, start time and end time of use, benefits recommended (output of tool) and proportion of users who complete the tool.

Patient surveys

At the end of the tool patients will be asked to complete a brief survey on their experience of using the tool and to provide contact information if interested in being contacted in the future. To examine the impact of the tool and whether patients learned about new benefits and/or their financial situation improved a research coordinator will conduct telephone surveys in a subset of patients that use the tool. Patients will be asked whether the tool is helpful, whether the tool would be recommended to a friend, whether the information provided was understood and their level of confidence in taking next steps based on information provided. Since there are no standardized instruments for evaluating this type of intervention the research team developed

surveys. At the end of the tool we will ask patients' permission to contact them via telephone or email after one month for structured follow-up interviews.

Qualitative Data Collection

Provider focus groups and survey

Three months after participating in the online income tool pilots, providers will be asked to complete an online, anonymous survey about their experience of using the tool. The purpose of this survey is to understand the providers' perspective on whether they would use the tool in the future and whether they would recommend it to a colleague. Providers at each site will also participate in a focus group discussion that will explore the use of the tool over the last three months and the barriers and facilitators to implementation. A set of questions will be used to guide the focus groups and the discussions will be audio-recorded and transcribed verbatim.

Provider observations and feedback

During the three month-period of pilot testing the online income tool at three sites in Winnipeg and Toronto, respectively, the use of the tool and its accompanying feedback from study team members and participating staff is being collected on an ongoing basis. Analytics regarding the number of times the tool is being used at each site are recorded and shared with study team members on a weekly basis and any feedback shared about the tool in informal conversations during site visits, through email, or interim reports is noted in a feedback matrix that will be used when developing the tool in preparation for its next phase of use.

ANALYSIS PLAN

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Quantitative Analysis

The primary outcome of this study is the change in knowledge of benefits (assessed through the end of tool patient survey and telephone interview at 4 weeks). An additional patient outcome that will be measured is change in income (assessed at telephone interview at 4 weeks) (Table 2). Descriptive statistics will be calculated (counts, percentages, means) to summarize variables including patient characteristics, usage of the tool and patient outcomes for all six sites. Outcome measures will be dichotomous and a bivariate analysis (using Student t-tests and chi-square tests, as appropriate) will be performed to determine associations between patient characteristics recorded from the tool and outcome measures (e.g., whether program was helpful, whether the patient is confident in taking next steps and whether their financial situation improved). Independent variables associated with positive patient outcomes and negative patient outcomes will be analyzed separately. Logistic regression analysis will be performed to identify variables independently associated with patient outcome measures.

Qualitative Analysis

A secondary outcome that will be assessed in this study is providers’ perspectives on the feasibility and acceptability of the tool using qualitative analysis. The field notes and transcripts of the focus groups with providers will be analyzed thematically [37]. An initial coding framework will be developed using the focus group guide. Two team members will independently read and code transcripts using Dedoose 7.0.23 (SocioCultural Research Consultants, Los Angeles, CA). Themes will be refined in an iterative process by comparing codes with the research team and reaching consensus on a final coding framework. The thematic analysis will focus on identifying key facilitators and barriers to implementation and provider

perspectives on the impact of the tool and ways to improve similar tools. Field notes collected throughout the study will help contextualize findings for each site and identify similarities and differences across sites. Open-ended questions from patient and provider surveys will also be thematically coded and categorized. We will identify common experiences associated with using the tool that may provide insight into how the tool works and ways to improve similar tools in the future.

Table 2 – Main outcome measures for implementation and impact of tool

Measure	Source	Method of data collection	Domain	Time point
Change in knowledge of benefits	Patient	Patient follow-up survey	Effectiveness	1 month
Change in access to financial benefits	Patient	Patient follow-up survey	Effectiveness	1 month
Acceptability of tool	Provider	Provider focus group and survey	Acceptability	After 3 month study period
Feasibility of tool	Provider	Provider focus group and survey	Feasibility	After 3 month study period

Advisory group

We will organize an advisory committee made of up patients, community agencies and staff to provide ongoing feedback on the project. Our aim is to engage 4-6 patients to provide input on how to improve the online tool and its use in clinical settings. For this study the advisory committee will play an important role in understanding how to improve the tool interface and what information will be most useful for patients to improve the tool output. The advisory committee will meet approximately once a month beginning in July 2016 until the end of data collection to help interpret findings, make recommendations to the online tool and suggestions for integrating its use within the care team. Ongoing engagement with patients and stakeholders will help to determine modifications to the tool, contextualize our findings and promote greater uptake in the future [38].

Ethical considerations

This study has been approved by St. Michael’s Hospital Research Ethics Board, the Health Research Ethics Board at the University of Manitoba, and the Michael Garron Hospital Research Ethics Board. Informed consent will be obtained for all study participants. Data collected by the online tool will be anonymous, with no link between answers to questions in the tool and personal identifying data. It is possible that some patients may feel discomfort when asked the screening question and they may feel shame or fear stigma if they are experiencing income insecurity. We will attempt to lessen this possibility by encouraging health providers to normalize the experience for patients, e.g., “I’m asking all of my patients this question over the next 3 months”. All patient and provider surveys will be anonymized. Finally, participants in

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10 **DISCUSSION**

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12 This study uses an upstream approach to address a root cause of poor health outcomes: poverty.
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14 By exploring the feasibility and acceptability of using an online tool we can establish a
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16 standardized process to screen patients for low income in routine primary care settings. We will
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18 also examine and report on local factors that influence implementation at the different clinic
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20 sites. Moreover, the implementation of the tool will be pragmatic, with the ultimate aim to bring
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22 such tools into broader practice through integration into primary healthcare settings. The findings
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24 from this study will provide insight into individual-level interventions to address the social
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26 determinants of health in primary care. Such tools may be useful to a diversity of primary care
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28 providers and could be applicable to other health care settings, such as in discharge planning at
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30 health care institutions. Important strengths of the intervention include opportunities for
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32 providers to offer feedback on the content, design and overall usability of the tool and the
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34 follow-up with patients about changes in their financial situation. Patients and community
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36 agencies represented in the advisory group will help ensure that this study remains focused on
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38 patient-centred outcomes and experiences and will contribute particular perspectives to the
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40 interpretation of our findings.
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50 We will evaluate the implementation and short-term effects of this online income security tool
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52 within six health clinics. We will attempt to engage a broad representation of health providers at
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54 each site and will invite all staff to participate in our study. The information provided in the
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output of the tool may not be suitably tailored to the needs of all individuals. The time frame of this study does not permit us to examine health effects, which we would anticipate would take longer than one month to develop, and which would require a more intense intervention. Future research could examine whether using this tool, in coordination with other services, with patients identified as being at risk of developing complex health and social needs could impact on health and health service use [2, 39]. The hypothesis tested would be that that addressing income security may reduce the risk of poor health and high service use for some patients.

There are several limitations to the proposed the study. First, the study uses a convenience sampling method so participates who declined to use tool or could not be reached at follow up were not captured. Second, the sites chosen to pilot the tool were already interested in addressing income security at there clinics and all site materials were in English so findings may not be generalizable for other clinic settings. Lastly, while we anticipate that the tool will be able to identify benefits that a patient could be eligible for, the complex process of applying for benefits may be a barrier to improving income security and a 1 month follow-up may be a short time frame to assess impact. However, this is one of the few studies on SDOH interventions that follows up with patients and a major strength is implementing the tool across multiple sites in two provinces.

This study is timely as awareness and a commitment to act on the SDOH is growing within the health sector in Canada [6, 22, 40, 41] and globally [42–44]. Continuing medical education events on poverty and health have been established and new medical school curricula is being created[45]. These efforts may begin to change medical practice. Yet, there are few studies that

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3 have evaluated the implementation and impact of such initiatives. The findings of this study will
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5 contribute to the design of SDOH interventions in health care, particularly when consider the
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7 role of technology and the practical challenges of incorporating interventions into busy health
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For peer review only

List of abbreviations

SDOH social determinants of health

WE CARE Well-child Care Visit, Evaluation, Community Resources, Advocacy, Referral,
Education

Declarations

Ethics approval and consent to participate

This study was approved by the St. Michael’s Hospital Research Ethics Board (15-353), the Health Research Ethics Board at the University of Manitoba (HS19275:H2016:019) and the Michael Garron Hospital Research Ethics Board (691-1608-Mis-298).

Consent for publication

Not applicable.

Availability of data and material

The datasets generated and analyzed during the current study are not publicly available due to the requirements of the various Research Ethics Boards, but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

ADP conceived the study. AS, GH, GB, RG, DR, REG, AK and ADP provided key inputs into the design of the study and refinements of the protocol. AA, AR and ADP assisted in the writing of the first draft of the manuscript. ADP, AS, GH, GB, RG, REG and AK assisted with obtaining funding for the study. AA, AR, AS, GH, GB, RG, DR, REG, JB, AK and ADP contributed to critical revisions and editing the manuscript for important intellectual content and approved the final manuscript. ADP had full access to all the information present and takes responsibility for the accuracy of this paper.

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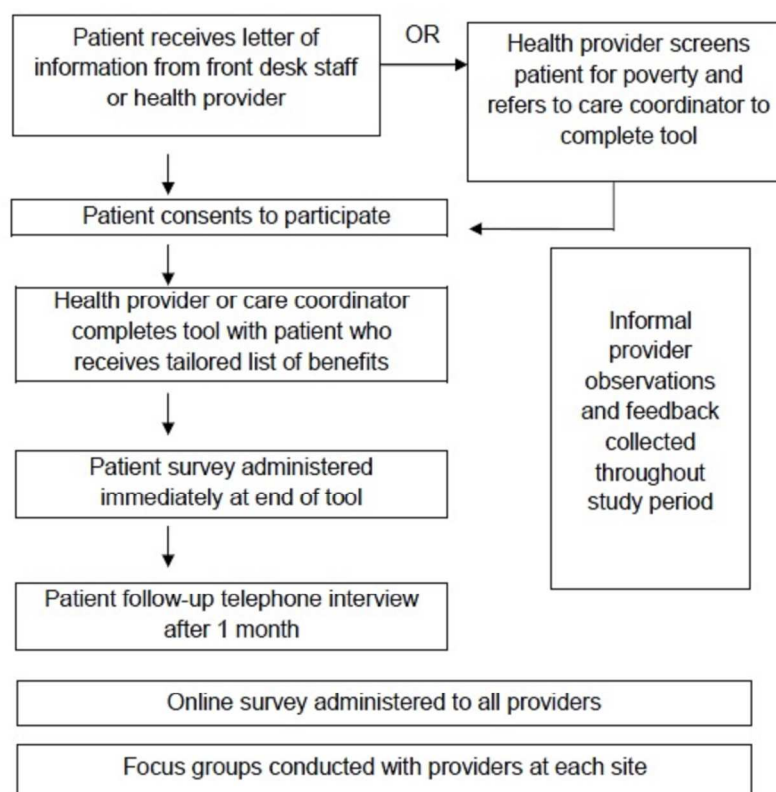
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Figure 1. Implementation and evaluation of an online income tool



231x252mm (300 x 300 DPI)



Evaluating the implementation and impact of an online tool used in primary care to improve the income security of patients: A study protocol

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p.3
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	Appendix
Funding	4	Sources and types of financial, material, and other support	p.18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p1 & 19
	5b	Name and contact information for the trial sponsor	p.1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	p.19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	p.13

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	<u>p.4-6</u>
	6b	Explanation for choice of comparators	<u>n/a</u>
Objectives	7	Specific objectives or hypotheses	<u>p.5-6</u>
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	<u>p.6</u>

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	<u>p.6-9</u>
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	<u>p.11</u>
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	<u>p.9-10</u>
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	<u>n/a</u>
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	<u>n/a</u>
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	<u>n/a</u>
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	<u>p.14-15</u>
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	<u>p.10-11, Fig 1</u>

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2				
3	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	<u>n/a</u>
4				
5				
6	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<u>n/a</u>
7				
8	Methods: Assignment of interventions (for controlled trials)			
9				
10	Allocation:			
11				
12	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	<u>n/a</u>
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18	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	<u>n/a</u>
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21				
22	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	<u>n/a</u>
23				
24				
25	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	<u>n/a</u>
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27				
28		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	<u>n/a</u>
29				
30				
31				
32	Methods: Data collection, management, and analysis			
33				
34	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	<u>p. 11-12</u>
35				
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39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	<u>p. 10-11</u>
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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	<u>p. 11-12</u>
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	<u>p. 13-15</u>
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	<u>n/a</u>
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	<u>n/a</u>
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	<u>n/a</u>
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	<u>n/a</u>
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	<u>n/a</u>
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	<u>n/a</u>
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	<u>p.15</u>
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	<u>n/a</u>

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3	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and	<u>p.15</u>
4			how (see Item 32)	
5				
6		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary	<u>n/a</u>
7			studies, if applicable	
8				
9	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained	<u>p.15</u>
10			in order to protect confidentiality before, during, and after the trial	
11				
12	Declaration of	28	Financial and other competing interests for principal investigators for the overall trial and each study site	<u>p.18-19</u>
13	interests			
14				
15	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that	<u>n/a</u>
16			limit such access for investigators	
17				
18	Ancillary and post-	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial	<u>n/a</u>
19	trial care		participation	
20				
21	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals,	<u>p.17</u>
22			the public, and other relevant groups (eg, via publication, reporting in results databases, or other data	
23			sharing arrangements), including any publication restrictions	
24				
25				
26		31b	Authorship eligibility guidelines and any intended use of professional writers	<u>n/a</u>
27				
28		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	<u>n/a</u>
29				
30	Appendices			
31				
32	Informed consent	32	Model consent form and other related documentation given to participants and authorised surrogates	<u>n/a</u>
33	materials			
34				
35	Biological	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular	<u>n/a</u>
36	specimens		analysis in the current trial and for future use in ancillary studies, if applicable	
37				

38 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
39 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
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Implementation and impact of an online tool used in primary care to improve access to financial benefits for patients: A study protocol

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Manuscripts

Implementation and impact of an online tool used in primary care to improve access to financial benefits for patients: A study protocol

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Abstract

Objectives

Addressing the social determinants of health has been identified as crucial to reducing health inequities. However, few evidence-based interventions exist. This study emerges from an ongoing collaboration between physicians, researchers and a financial literacy organization. Our study will answer the following: Is an online tool that improves access to financial benefits feasible and acceptable? Can such a tool be integrated into clinic workflow? What are patient perspectives on the tool and what is the short-term impact on access to benefits?

Methods

An advisory group made up of patients living on low incomes and representatives from community agencies supports this study. We will recruit three primary care sites in Toronto, Ontario and three in Winnipeg, Manitoba that serve low-income communities. We will introduce clinicians to screening for poverty and how benefits can increase income. Health providers will be encouraged to use the tool with any patient seen. The health provider and patient will complete the online tool together, generating a tailored list of benefits and resources to assist with obtaining these benefits. A brief survey on this experience will be administered to patients after they complete the tool, as well as a request to contact them in one month. Those who agree to be contacted will be interviewed on whether the intervention improved access to financial benefits. We will also administer an online survey to providers and conduct focus groups at each site.

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Ethics and dissemination

Key ethical concerns include that patients may feel discomfort when being asked about their financial situation, may feel obliged to complete the tool and may have their expectations falsely raised about receiving benefits. Providers will be trained to address each of these concerns. We will share our findings with providers and policymakers interested in addressing the social determinants of health within health care settings.

Trial registration:

Clinicaltrials.gov: [NCT02959866](https://clinicaltrials.gov/ct2/show/study/NCT02959866). Registered Nov 7, 2016. Retrospectively registered.

Strengths and Limitations

- Multi-site study involving clinics in two provinces.
- Pragmatic implementation of a novel tool in the real world of busy primary care clinics.
- Mixed-methods evaluation, using several data sources to triangulate findings.
- Convenience sampling method for patients.
- A short follow-up period (4 weeks after intervention) may underestimate the impact of the novel tool.

Keywords: social determinants of health, income, poverty, primary care, health promotion

BACKGROUND

The World Health Organization defines the social determinants of health (SDOH) as “the conditions in which people are born, grow, live, work and age”, and include the material resources a person has available that are necessary to live a healthy life [1]. SDOH have been identified as a key reason for health inequities between different individuals and groups within a population, and help explain differences in access to health services [2]. The World Health Organization Commission on Social Determinants of Health, the British Medical Association and the Canadian Medical Association have all called on the health sector to play a greater role in addressing the SDOH through implementing and evaluating new interventions and serving as a link between disadvantaged communities and social and community services [3–6]. Primary care settings in particular are uniquely opportune spaces to take action [7]. Primary care providers follow patients longitudinally, are community-based and often have knowledge of the broader familial and social contexts that shape health and disease [8].

One of the most important SDOH is income security: a person’s actual, perceived and expected income [9, 10]. Income influences the presence and severity of most health conditions. People living in poverty may have difficulty paying rent [11], affording nutritious food [12–15], affording transportation and engaging with others socially [6–9]. Many studies have shown that economically marginalized people tend to live shorter lives, experience a greater burden of disease and disability and rate their health status as worse than the wealthy [16–21]. One aspect of income security is access to financial benefits.

There are currently few, rigorously evaluated SDOH interventions deployed in clinical settings that have been found to improve material conditions and subsequently the health of individuals and families [22, 23]. Welfare benefits advice services within general practices in the United Kingdom have been found to increase the income of recipients, although improvements in health were not assessed in most studies [24]. Similarly, a health promotion service in Toronto, Canada has been developed to assist patients with income security within primary care settings, but the impact has not yet been reported[25]. Several studies in the United States have demonstrated the effectiveness of clinic-based interventions at connecting patients to community resources to address SDOH. In Boston, the Well-child Care Visit, Evaluation, Community Resources, Advocacy, Referral, Education (WE CARE) study took place in pediatric clinics [26]. A waiting room survey screened for social needs and members of the health care team provided information on community resources, adding less than two minutes to the visit. At one month, 20% of the intervention group parents reported contacting a referred community resource versus 2.2% of parents in the control group [27]. The online tool, HelpSteps [28, 29], screens for a much larger number of social needs, taking on average 25 minutes to complete, with 90% of users identifying at least one social need and 96% reporting they would recommend its use to a friend or peer [30]. The California iScreen study[31], also tested in pediatric clinics, used the Health Leads [32] model and found that social needs can be identified and providing patient supports led to improvements in parent-reported child health [33]. In Canada, a paper-based clinical tool has helped train physicians and other health providers to consider poverty as a health issue [34]. This tool has been adapted by the College of Family Physicians of Canada for use in all provinces and territories. No studies to date have evaluated the impact of this tool on providers or patients.

Our study focuses on developing, implementing and evaluating an online tool in primary care settings that focuses on access to financial benefits. This study emerges from an ongoing collaboration between family physicians, researchers and a charitable financial literacy organization, Prosper Canada [35]. This paper describes the protocol for this mixed-methods study that will evaluate the implementation and impact of this online tool. Our study will assess: 1) whether health providers find using a tool to address access to financial benefits in a clinical setting feasible and acceptable; 2) lessons learned and opportunities identified to integrate the tool within the regular workflow of primary health care organizations; 3) feedback from patients using the online tool and the short-term impacts on awareness and access to benefits.

METHODS/ DESIGN

This study will use qualitative and quantitative methods to evaluate the feasibility and acceptability of using an online tool in primary care to address access to financial benefits. The online income tool will be implemented at six primary care clinics, three in Toronto, Ontario and three in Winnipeg, Manitoba. All sites serve large numbers of patients with complex health needs and low socioeconomic status (Table 1).

Table 1. Clinic characteristics for 6 primary care sites in Ontario and Manitoba

Clinic type	Location	Patient population	Provider(s) who will predominantly	Method of recruiting patients

			administer the tool	
Family Health Team	Toronto, Ontario	Over 30% of patients live in neighbourhoods that have average incomes in the lowest quintile.	Family physicians and nurse practitioner	Reception staff provide patients an information sheet or health care providers initiate enrollment
Community Health Centre	Toronto, Ontario	Priority populations include newcomers and patients with substance use or mental health needs	Family physician, nurse practitioners and social workers	Health care provider initiated
Family Health Team	Toronto, Ontario	Serves wide range of patients with a focus on the unattached, medically and/or socially complex, high need patients	Family physicians and patient navigator	Health care provider initiated
Community Health	Winnipeg, Manitoba	Serves one of the most impoverished areas in	Family physicians, nurse practitioners,	Health care provider

Centre		the city. The neighborhood has an unemployment rate of 17% with 34% of the families living in poverty. There are 83% female lone-parent families and 16.9% of the community are members of a visible minority group with another 29% of Indigenous ancestry.	nurses, social workers, support workers	initiated
Community Health Centre	Winnipeg, Manitoba	Serves a diverse inner city community providing a very wide range of services to individuals, families, teens, adults and geriatrics within our geographic community. Special focus for	Family physicians, nurse practitioners, nurses, social workers, support workers, counselors	Health care provider initiated

		priority populations of marginalized groups such as immigrants and refugees, transgendered individuals and those living with STIs.		
Communit y Health Centre	Winnipeg, Manitoba	Serves a generally low- income north Winnipeg neighborhood. Focus on patients within the catchment area with particular interest in chronic disease care.	Family physicians, nurse practitioner, nurses	Health care provider initiated

Intervention

The intervention is centered on an online tool that guides users through 12 demographic and income-related questions and subsequently generates a customized list of relevant provincial and federal government benefits and tax credits. The initial screening question “Do you ever have difficulty making ends meet at the end of the month?” has been validated in similar settings to identify patients who live below the Canadian poverty line with 98% sensitivity and 64% specificity [36]. Further questions were determined based on the eligibility criteria for various federal and provincial benefits and tax credit programs. The tool was first used at a community health centre and with a family health team in Toronto for one month to identify technical

problems. Following feedback sessions with providers, modifications were made to the tool to improve its overall design for use in this study.

Study Procedures

An orientation session will be held at each site to introduce primary care providers to the tool and enroll them in the study as participants. Following this session, the tool will be implemented for a 3-month period. The tool can be used by any member of the health care team, including physicians, nurses, nurse practitioners, patient navigators and social workers. Each site will have some flexibility in how the tool will be implemented into the routine workflow of patient care, based on input from providers at the site. Health providers will be encouraged to use the tool with every patient seen. The tool can also be used in an opportunistic way, when patients share a health concern that is linked to low income. Patients who consent to participate in the study can then use the tool with their health provider. At this time, study sites do not have a formal, systematic way to identify low-income patients. To minimize bias by providers or reception staff, all patients who present for care in these clinics will be approached. This intervention was not randomized because excluding low-income patients from receiving information on eligible benefits and accessing additional income supports would be unethical. Moreover, the topic may come up in any given appointment depending on the nature of the visit. Given the limited time during appointments at some sites family physicians will screen patients for low income and refer them to a care coordinator (e.g. social worker) to complete the tool (Figure 1).

Figure 1. Implementation and evaluation of an online income tool

Participants

Providers

The 6 clinics testing the tool will introduce the pilot study to health care providers and interested providers will be consented to participate. We will aim to have a diverse group of health care professionals use the tool with patients including family physicians, nurse practitioners, social workers and patient navigators.

Patients

All patients seen at the primary care site are eligible to complete the online tool with their provider. Health providers and clinic staff will inform patients of the study through information sheets provided at the front desk of clinics or during an appointment. After reviewing the information sheet, the patient will note that they consent to proceed. To preserve anonymity, signed consent from patients will not be sought. The inclusion criteria for the one month follow-up with patients is as follows: used the tool approximately one month ago with their health care provider, able to provide consent, 18 years old or above, able to converse in English and able to be reached via telephone or email.

Sample Size

The primary aim of this pilot study is to assess the acceptability and feasibility of the intervention in a clinic setting and assess the short-term impact of the tool on patients. There is no pre-defined sample for patients completing the tool with their provider. This pilot study will help determine study sample calculations for future clinical trials and the usage and length of time to complete the tool will be monitored [37]. Of those patients who complete the tool and survey, a subset will be contacted for follow-up. The target sample size for one-month follow-up

is 200 patients in each province for a total of 400 patients. We anticipate that this sample size will be robust enough to determine the acceptability of using the tool, as well as provide data on impact that will allow for sample size calculation for future studies of the impact of such tools on income itself.

Quantitative Data Collection

Online Tool Output

We will collect a set of data points on each use of the tool. We will not be able to distinguish repeat users. The tool will record answers to the following demographic questions: age, immigration status, employment status, whether someone in the household has a disability, household income and how many people live in the household and any existing benefits or tax credits received by the patient. The tool will also track clinic site, start time and end time of use, benefits recommended (output of tool) and proportion of users who complete the tool.

Patient surveys

At the end of the tool patients will be asked to complete a brief survey on their experience of using the tool and to provide contact information if interested in being contacted in the future. This survey will capture whether patients found the tool helpful, whether they would recommend the tool to a friend or family member and whether they understood the information provided to them. Lastly, the survey will use a Likert scale for patients to mark their confidence in taking next steps based on the information provided to them following their initial use of the tool with providers. Since there are no standardized instruments for evaluating this type of intervention the research team developed surveys to learn about patient perceptions of the tool after immediate

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3 use. At the end of the tool, we will ask patients' permission to have a research coordinator follow
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5 up with them via telephone or email in order to conduct a structured interview one month after
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7 their use of the tool in the clinic. This subset will be a convenience sample of all patients who
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9 provide their contact information and consent to an interview.
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15 ***Qualitative Data Collection***
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18 ***Provider focus groups and survey***
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20 Three months after participating in the online income tool pilots, providers will be asked to
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22 complete an online, anonymous survey about their experience of using the tool. The purpose of
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24 this survey is to understand the providers' perspective on whether they would use the tool in the
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26 future and whether they would recommend it to a colleague. Surveys will also capture how many
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28 times providers used the tool, whether providers felt they had enough time to do the tool with
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30 their patients, as well as the biggest benefit and drawback of using the tool, respectively.
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33 Providers at each site will also participate in a focus group discussion that explores the use of the
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35 tool over the last three months and the barriers and facilitators to implementation. Focus groups
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37 will provide a setting for in-depth discussion around the tool's integration into regular clinic
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39 workflow, suggestions for its improvement, provider attitudes about addressing poverty in
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41 primary care, as well as factors that inhibited use of the tool during piloting at each site. A set of
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43 questions will be used to guide the focus groups and the discussions will be audio-recorded and
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45 transcribed verbatim.
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53 ***Provider observations and feedback***
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During the three month-period of pilot testing the online income tool at three sites in Winnipeg and Toronto, respectively, the use of the tool and its accompanying feedback from study team members and participating staff is being collected on an ongoing basis. Analytics regarding the number of times the tool is being used at each site are recorded and shared with study team members on a weekly basis and any feedback shared about the tool in informal conversations during site visits, through email, or interim reports is noted in a feedback matrix that will be used when developing the tool in preparation for its next phase of use.

ANALYSIS PLAN

Quantitative Analysis

The primary outcome of this study is patient and provider perceptions around the integration of a tool addressing income in primary care settings (assessed through patient surveys, telephone interviews with patients at 4 weeks, provider focus groups, and provider surveys). Additional outcomes that will be measured include patient access to financial benefits 4 weeks after their use of the tool (assessed through telephone interview at 4 weeks) (Table 2). Descriptive statistics will be calculated (counts, percentages, means) to summarize variables including patient characteristics, usage of the tool and patient outcomes for all six sites. Outcome measures will be dichotomous and a bivariate analysis (using Student t-tests and chi-square tests, as appropriate) will be performed to determine associations between patient characteristics recorded from the tool and outcome measures (e.g., whether program was helpful, whether the patient is confident in taking next steps and whether their financial situation improved). Independent variables associated with positive patient outcomes and negative patient outcomes will be analyzed

separately. Logistic regression analysis will be performed to identify variables independently associated with patient outcome measures.

Qualitative Analysis

A secondary outcome that will be assessed in this study is providers’ perspectives on the feasibility and acceptability of the tool using qualitative analysis. The field notes and transcripts of the focus groups with providers will be analyzed thematically [38]. An initial coding framework will be developed using the focus group guide. Two team members will independently read and code transcripts using Dedoose 7.0.23 (SocioCultural Research Consultants, Los Angeles, CA). Themes will be refined in an iterative process by comparing codes with the research team and reaching consensus on a final coding framework. The thematic analysis will focus on identifying key facilitators and barriers to implementation and provider perspectives on the impact of the tool and ways to improve similar tools. Field notes collected throughout the study will help contextualize findings for each site and identify similarities and differences across sites. Open-ended questions from patient and provider surveys will also be thematically coded and categorized. We will identify common experiences associated with using the tool that may provide insight into how the tool works and ways to improve similar tools in the future.

Table 2 – Main outcome measures for implementation and impact of tool

Measure	Source	Method of data collection	Domain	Time point

Acceptability of tool	Provider	Provider focus group and survey, patient survey and telephone interview	Acceptability	After 3 month study period
Feasibility of tool	Provider	Provider focus group and survey, patient survey and telephone interview	Feasibility	After 3 month study period
Change in income	Patient	Patient follow up interview	Effectiveness	1 month
Change in knowledge of benefits	Patient	Patient follow-up interview	Effectiveness	1 month

Advisory group

We will organize an advisory committee made of up patients, community agencies and staff to provide ongoing feedback on the project. Our aim is to engage 4-6 patients to provide input on how to improve the online tool and its use in clinical settings. For this study the advisory committee will play an important role in understanding how to improve the tool interface and what information will be most useful for patients to improve the tool output. The advisory committee will meet approximately once a month beginning in July 2016 until the end of data collection to help interpret findings, make recommendations to the online tool and suggestions for integrating its use within the care team. Ongoing engagement with patients and stakeholders will help to determine modifications to the tool, contextualize our findings and promote greater uptake in the future [39].

ETHICS AND DISSEMINATION

This study has been approved by St. Michael’s Hospital Research Ethics Board, the Health Research Ethics Board at the University of Manitoba, and the Michael Garron Hospital Research Ethics Board. Informed consent will be obtained for all study participants. Data collected by the online tool will be anonymous, with no link between answers to questions in the tool and personal identifying data. Some patients may feel discomfort when asked the screening question and they may feel shame or fear stigma if they are experiencing income insecurity. We will attempt to lessen this possibility by encouraging health providers to normalize the experience for patients, e.g., “I’m asking many of my patients this question over the next 3 months”. Patients may feel obligated to complete the tool with their healthcare providers. During training sessions, all providers will be asked to emphasize that this intervention is optional and not part of routine

care. Patients will also be informed that they can stop using the tool at any time. Healthcare providers will also be trained to manage patient expectations by stating that this tool may or may not identify benefits which could provide increased income. All patient and provider surveys will be anonymized. Finally, participants in focus groups will not be identified by name and all transcripts will be anonymized during transcription.

This study uses an “upstream” approach to address a root cause of poor health outcomes: poverty. By exploring the feasibility and acceptability of using an online tool we can establish a standardized process to screen patients for low income in routine primary care settings. We will also examine and report on local factors that influence implementation at the different clinic sites. Moreover, the implementation of the tool will be pragmatic, with the ultimate aim to bring such tools into broader practice through integration into primary healthcare settings. The findings from this study will provide insight into individual-level interventions to address the social determinants of health in primary care. Such tools may be useful to a diversity of primary care providers and could be applicable to other health care settings, such as in discharge planning at health care institutions. Important strengths of the intervention include opportunities for providers to offer feedback on the content, design and overall usability of the tool and the follow-up with patients about changes in their financial situation. Patients and community agencies represented in the advisory group will help ensure that this study remains focused on patient-centred outcomes and experiences and will contribute particular perspectives to the interpretation of our findings.

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We will evaluate the implementation and short-term effects of this online income security tool within six health clinics. We will attempt to engage a broad representation of health providers at each site and will invite all staff to participate in our study. The information provided in the output of the tool may not be suitably tailored to the needs of all individuals. The time frame of this study does not permit us to examine health effects, which we would anticipate would take longer than one month to develop, and which would require a more intense intervention. Future research could examine whether using this tool, in coordination with other services, with patients identified as being at risk of developing complex health and social needs could impact on health and health service use [2, 40]. The hypothesis tested would be that that addressing income security may reduce the risk of poor health and high service use for some patients.

There are several limitations to the proposed the study. First, the study uses a convenience sampling method so participants who declined to use tool or could not be reached at follow up were not captured. Second, the sites chosen to pilot the tool were already interested in addressing income security at their clinics. Furthermore, all site materials were in English so findings may not be generalizable to other clinic settings. Lastly, while we anticipate that the tool will be able to identify benefits that a patient could be eligible for, the complex process of applying for benefits may be a barrier to improving income security and a 1 month follow-up may be too short of a time frame within which to assess impact. However, this is one of the few studies on SDOH interventions that follows up with patients and a major strength is implementing the tool across multiple sites in two provinces.

This study is timely as awareness and a commitment to act on the SDOH is growing within the health sector in Canada [6, 22, 41, 42] and globally [43–45]. Continuing medical education events on poverty and health have been established and new medical school curricula is being created[46]. These efforts may begin to change medical practice. Yet, there are few studies that have evaluated the implementation and impact of such initiatives. The findings of this study will contribute to the design of SDOH interventions in health care, particularly when consider the role of technology and the practical challenges of incorporating interventions into busy health organizations.

List of abbreviations

SDOH social determinants of health

WE CARE Well-child Care Visit, Evaluation, Community Resources, Advocacy, Referral,
Education

Declarations

Ethics approval and consent to participate

This study was approved by the St. Michael’s Hospital Research Ethics Board (15-353), the Health Research Ethics Board at the University of Manitoba (HS19275:H2016:019) and the Michael Garron Hospital Research Ethics Board (691-1608-Mis-298).

Consent for publication

Not applicable.

Availability of data and material

The datasets generated and analyzed during the current study are not publicly available due to the requirements of the various Research Ethics Boards, but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors' contributions

ADP conceived the study. AS, GH, GB, RG, DR, REG, AK and ADP provided key inputs into the design of the study and refinements of the protocol. AA, AR and ADP assisted in the writing of the first draft of the manuscript. ADP, AS, GH, GB, RG, REG and AK assisted with obtaining funding for the study. AA, AR, AS, GH, GB, RG, DR, REG, JB, AK and ADP contributed to critical revisions and editing the manuscript for important intellectual content and approved the final manuscript. ADP had full access to all the information present and takes responsibility for the accuracy of this paper.

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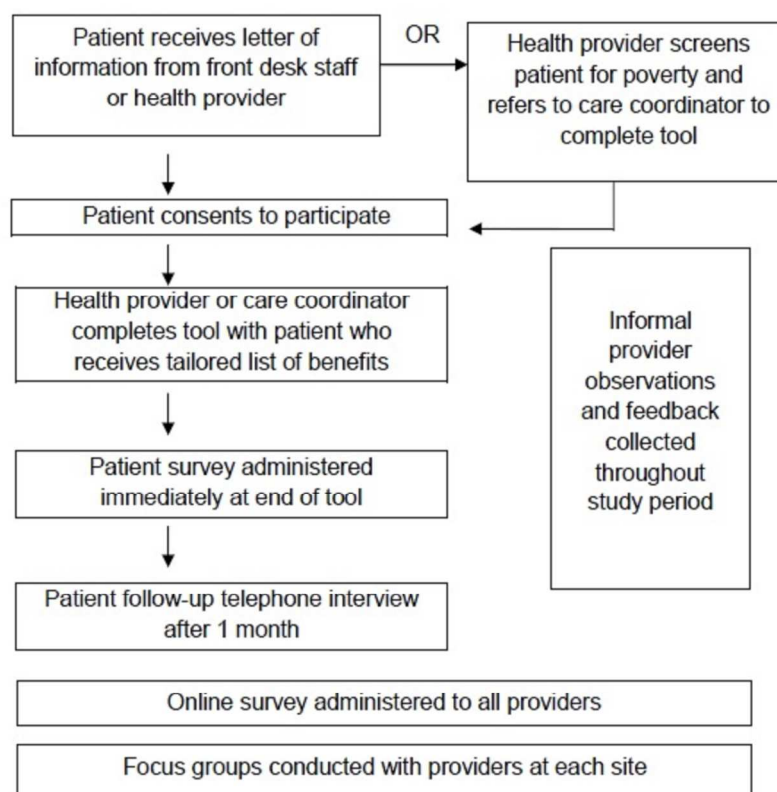
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Figure 1. Implementation and evaluation of an online income tool



231x252mm (300 x 300 DPI)



Evaluating the implementation and impact of an online tool used in primary care to improve the income security of patients: A study protocol

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p.3
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	Appendix
Funding	4	Sources and types of financial, material, and other support	p.18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p1 & 19
	5b	Name and contact information for the trial sponsor	p.1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	p.19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	p.13

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	<u>p.4-6</u>
	6b	Explanation for choice of comparators	<u>n/a</u>
Objectives	7	Specific objectives or hypotheses	<u>p.5-6</u>
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	<u>p.6</u>

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	<u>p.6-9</u>
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	<u>p.11</u>
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	<u>p.9-10</u>
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	<u>n/a</u>
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	<u>n/a</u>
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	<u>n/a</u>
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	<u>p.14-15</u>
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	<u>p.10-11, Fig 1</u>

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3	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	<u>n/a</u>
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6	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<u>n/a</u>
7				
8	Methods: Assignment of interventions (for controlled trials)			
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10	Allocation:			
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12	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	<u>n/a</u>
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18	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	<u>n/a</u>
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22	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	<u>n/a</u>
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25	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	<u>n/a</u>
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28		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	<u>n/a</u>
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32	Methods: Data collection, management, and analysis			
33				
34	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	<u>p. 11-12</u>
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39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	<u>p. 10-11</u>
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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	<u>p. 11-12</u>
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	<u>p. 13-15</u>
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	<u>n/a</u>
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	<u>n/a</u>
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	<u>n/a</u>
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	<u>n/a</u>
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	<u>n/a</u>
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	<u>n/a</u>
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	<u>p.15</u>
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	<u>n/a</u>

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3	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and	<u>p.15</u>
4			how (see Item 32)	
5				
6		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary	<u>n/a</u>
7			studies, if applicable	
8				
9	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained	<u>p.15</u>
10			in order to protect confidentiality before, during, and after the trial	
11				
12	Declaration of	28	Financial and other competing interests for principal investigators for the overall trial and each study site	<u>p.18-19</u>
13	interests			
14				
15	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that	<u>n/a</u>
16			limit such access for investigators	
17				
18	Ancillary and post-	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial	<u>n/a</u>
19	trial care		participation	
20				
21	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals,	<u>p.17</u>
22			the public, and other relevant groups (eg, via publication, reporting in results databases, or other data	
23			sharing arrangements), including any publication restrictions	
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26		31b	Authorship eligibility guidelines and any intended use of professional writers	<u>n/a</u>
27				
28		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	<u>n/a</u>
29				
30	Appendices			
31				
32	Informed consent	32	Model consent form and other related documentation given to participants and authorised surrogates	<u>n/a</u>
33	materials			
34				
35	Biological	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular	<u>n/a</u>
36	specimens		analysis in the current trial and for future use in ancillary studies, if applicable	
37				

38 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
39 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
40 “[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)” license.
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