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Navigator Program for Hospitalized Adults Experiencing Homelessness

Study Protocol for a Pragmatic Randomized Controlled Trial

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Abstract

Introduction: People experiencing homelessness suffer from poor outcomes after hospitalizations due to systemic barriers to care, suboptimal transitions of care, and intersecting health and social burdens. Case management programs have been shown to improve housing stability, but their effects on broad post-hospital outcomes in this population have not been rigorously evaluated. The Navigator Program is a Critical Time Intervention case management program that was developed to help homeless patients with their post-discharge needs and to link them with community-based health and social services. This randomized controlled trial examines the impact of the Navigator Program on post-hospital outcomes among adults experiencing homelessness.

Methods and Analysis: This is a pragmatic randomized controlled trial testing the effectiveness of the Navigator Program at an urban academic teaching hospital and an urban community teaching hospital in Toronto, Canada. Six hundred and forty adults experiencing homelessness who are admitted to the hospital will be randomized to receive support from a Homeless Outreach Counsellor for 90 days after hospital discharge or to usual care. The primary outcome is follow-up with a primary care provider (physician or nurse practitioner) within 14 days of hospital discharge. Secondary outcomes include post-discharge mortality or readmission, number of days in hospital, number of emergency department visits, self-reported care transition quality, and difficulties meeting subsistence needs. Quantitative outcomes are being collected over a 180-day period through linked patient-reported and administrative health data. A parallel mixed-methods process evaluation will be conducted to explore intervention context, implementation, and mechanisms of impact.

Ethics and Dissemination: Ethics approval was obtained from the Unity Health Toronto Research Ethics Board. Results of the main trial and process evaluation will be reported in peer-reviewed journals and shared with hospital leadership, community partners, and policy makers.

Trial Registration: This trial has been registered with ClinicalTrials.gov (NCT04961762)

Strengths and Limitations of the Study

- The Navigator Program is a patient-centered case management intervention informed by a prior prospective cohort study and designed in tandem with community partners, healthcare teams, and people with lived experience of homelessness.
- Linkage of patient-reported data with administrative health data allows for rigorous assessment of a much wider range of post-hospital outcomes relative to previous case management studies for people experiencing homelessness.
- This randomized controlled trial is accompanied by a parallel mixed-methods process evaluation that will investigate intervention implementation, causal mechanisms, study context, participant experiences, and outcomes.
- Blinding of participants, homeless outreach counselors, and healthcare teams are not possible given the active and collaborative nature of the intervention.
- This study takes place at an urban academic teaching hospital and an urban community teaching hospital in Toronto, Canada, and findings may not be generalizable to individuals experiencing homelessness in other contexts and settings.

Introduction

Background and Rationale

More than 235,000 Canadians experience homelessness annually, of which 27% are women, 19% are youth, and a growing number are identifying as racial, ethnic, sexual, and gender minorities.[1,2] This population experiences disproportionate intersecting physical, mental, and social burdens that greatly increase morbidity and mortality relative to the general population.[3–5] For example, rates of acute and chronic physical health problems, trauma, mental illness, and substance use are much higher among homeless adults.[6–8]

Homeless individuals often experience substantial barriers to obtaining health care and frequently suffer from unmet health needs.[9–11] Many have other immediate competing priorities such as securing food and shelter that preclude consistent engagement with healthcare services.[12,13] Homeless individuals are also much less likely to have a primary care provider (PCP) or usual source of care compared to the general population.[14,15] Lack of primary care likely contributes to poor outcomes among the homeless population, given that access to primary care is associated with lower mortality and reductions in unnecessary emergency department (ED) visits and hospital admissions.[16,17] Indeed, there is abundant evidence suggesting that homeless adults rely heavily on acute care services, and rates of ED visits and hospitalizations are much higher among homeless versus non-homeless adults.[18–21] A related problem is the high rate of hospital readmissions among homeless adults.[19,20,22,23] Many of these readmissions are thought to be potentially preventable with more complete treatment and better coordination of health and social services following hospital discharge.[24,25] In the general population, timely access to primary care follow-up after hospitalization has been consistently associated with lower rates of readmissions.[26–28] Qualitative studies have also revealed that homeless individuals face unique challenges following discharge from hospital, such as difficulties storing medication, inability to find shelter, and not being provided appropriate discharge instructions.[29–31] Altogether, systemic barriers to primary care, competing priorities, and poor care transitions all contribute toward poor post-hospital outcomes and reliance on acute care settings among homeless individuals.

Case management is a core component of care for homeless individuals, serving to navigate and coordinate health and social services for this population.[32] Such programs have been adapted and implemented for several subgroups of homeless individuals, including frequent users of acute healthcare services and those with complex needs and mental illness.[33–35] Systematic reviews have found that case management is effective in improving housing stability, reducing substance use, and removing barriers to securing employment in this population.[32,36] However, few studies have rigorously evaluated the effect of case management on broad post-hospital outcomes among the overall homeless population. One randomized controlled trial (RCT) of a combined transitional housing, long-term housing, and case management intervention reported reductions in hospitalizations, number of hospital days, and ED visits among homeless adults with chronic illnesses.[35] However, this study could not evaluate the independent effects of the multiple intervention components and did not assess other post-hospital or patient-reported outcomes. A smaller RCT of a Critical Time Intervention (CTI) case management program focused specifically on homeless patients with severe mental illness was found to improve continuity of care, prevent homelessness, and reduce psychiatric readmissions following hospital discharge.[37–39]

Accordingly, this current RCT seeks to investigate the effectiveness of an adapted CTI case management program – the Navigator Program – in improving post-hospital outcomes among adults experiencing homelessness at an urban academic teaching hospital and an urban community teaching hospital in Toronto, Canada. CTI is a time-limited case management program which delivers focused case management at critical times or situations in the lives of clients, such as transitioning from hospital care to community care.[36] The Navigator Program features Homeless Outreach Counsellors (HOCs) – whose roles are to create strong links between community services and patients through regular contact, supporting patients in following their post-discharge care plans, and helping patients in meeting their health- and social-related competing priorities. This intervention was informed by a recent prospective cohort study conducted at the same hospital, which found that having an active case manager, sending discharge summaries to PCPs, and informal support were associated with reduced readmissions among homeless adults.[22] The first HOC position was created in February 2019 and has since been expanded to two positions and adapted through conversations with community

partners and hospital staff. Ultimately, the goal of the Navigator Program is to help homeless patients who are discharged from the hospital overcome systemic barriers and discontinuities in care that often result in poor health and high acute care utilization.

Objectives

This RCT seeks to evaluate the effectiveness of the Navigator Program in improving post-hospital outcomes among adults experiencing homelessness. It will specifically evaluate outcomes related to PCP follow-up, acute care utilization, difficulties meeting subsistence needs, care transition, and overall health following hospital discharge.

A detailed mixed-methods process evaluation will be conducted alongside the RCT. This evaluation primarily aims to provide a deeper understanding of intervention implementation, mechanisms of change within the intervention, and the way in which the Navigator Program interacts with the internal and external contexts to influence both implementation and RCT outcomes in expected or unexpected ways.[40,41] This evaluation will also aim to understand the in-hospital and post-discharge experiences of participants in the intervention and control arms, exploring differences and similarities qualitatively. It is important to investigate how RCT outcomes are shaped by intervention implementation or by the intervention itself, and to identify which parts of the Navigator Program did or did not work to achieve the intended goals and why.

Methods and Analysis

Design and Setting

This study is a pragmatic RCT that is being conducted at an urban academic teaching hospital (St. Michael's Hospital) and an urban community teaching hospital (St. Joseph's Health Centre) in Toronto, Canada. Recruitment began in October 2021 and is ongoing.

Eligibility Criteria

To be eligible for the study, patients must meet the following criteria: (1) are 18 years of age or older, (2) be admitted to any medical or surgical service (excluding psychiatry and obstetrics), and (3) are identified as experiencing homelessness (as per the Canadian definition of homelessness) at the time of admission or anytime during the hospital admission.[42] Patients will

be excluded from the study if they meet any of the following criteria: (1) are unable to provide informed consent or (2) were connected with a HOC prior to the initiation of the RCT and have received services from the HOC within 90 days preceding their current admission. Each individual patient can be randomized only once during the study period. Patients admitted to psychiatric and obstetric services are excluded from this study because optimal immediate post-discharge follow-up for these patients should be with specialists rather than with PCPs.[43,44] Furthermore, recommended follow-up timeframes for these patients are often longer than 14 days, thus rendering the primary outcome not applicable.

Recruitment and Data Collection

Clinical or research staff will identify potential participants on weekdays. Once identified, a member of the patient's circle of care will ask the patient for permission to introduce the patient to the research team. The research team will then confirm patient eligibility and explain the purpose, process, risks, and benefits of the study to potential participants. Participants may choose to enroll in the study by providing written informed consent.

A baseline interview will be conducted with participants prior to randomization and as a soon as possible after admission to the hospital and confirmation of eligibility. Sociodemographic information will be collected, including age, gender, race, Indigenous identity, education level, housing status, and social service utilization. Participants who complete the baseline interview will receive a $20 CAD gift card to compensate them for their time. Another 30-day interview will take place at least 30 days (but no longer than 50 days) after the discharge date to assess patient-reported post-hospital outcomes. At this time, the research team will contact PCPs to ascertain any follow-up visits. Baseline and 30-day interviews will be conducted in person or remotely. Data from interviews will be collected with tablets using electronic surveys hosted by Snap Professional Software.

The research team will also undertake a chart review of hospital records after discharge to ascertain characteristics of the admission, information about discharge, participant health information, and history of alcohol and substance use.

Plans to Promote Continued Participation

Several strategies will be implemented to minimize attrition. At the baseline interview, study participants will be asked to provide detailed contact information, as well as the names and contact information of family, friends, and other service providers who may be contacted if the research team cannot reach the participant directly. In addition to active outreach from the research team, participants will be instructed to contact the research team after discharge to schedule a 30-day interview. Participants who contact the research team 2-3 weeks following their discharge to confirm their contact information and schedule the 30-day interview will receive an additional $10 CAD honorarium upon completion of the interview. Participants who complete the 30-day interview will also receive a $40 CAD honorarium and reimbursement for any travel-related expenses, when applicable, for the interview.

Randomization

Participants will be randomized by a third-party internet randomization service (randomize.net). The program will assign participants to either the intervention or the usual care arm using permuted-block randomization, with a 1:1 allocation ratio and random permuted blocks. This process will maintain balanced group sizes between the intervention and usual care arms at intermediate points in the recruitment process and minimize the possibility of the research team predicting study allocation.[45]

Intervention

Participants randomized to the intervention arm will be assigned to work with an HOC. The HOC will connect with participants as early as possible during the admission and will provide support for 90 days after hospital discharge. The period of support may occasionally be extended beyond 90 days for certain patients, if the HOC deems this to be necessary and appropriate. The main role of the HOC is to support continuity and comprehensiveness of care by helping participants follow their post-discharge plans and facilitating strong links with community-based health and social services. Day-to-day HOC activities fall into five main categories: 1) making connections and referrals to community-based providers, 2) supporting and advocating for patients during the hospital stay and discharge process, 3) supporting patients with health-related matters during the post-discharge period, 4) supporting patients with social-related matters

during the post-discharge period, and 5) transferring patient-related information to other healthcare and community-based providers **(Table 1)**. The intensity and types of support from HOCs will be tailored to the specific needs of the individual.

Usual Care

Participants in the usual care arm will be discharged without support from the HOCs. However, all participants will still receive support as usual from Care Transition Facilitators (CTFs) and/or social workers. CTFs and social workers help patients during their hospital stay to arrange discharge plans and make follow-up arrangements. However, unlike HOCs, CTFs and social workers do not typically work with patients after hospital discharge.

The typical discharge process involves counseling from the discharging physician and healthcare team, who make recommendations or appointments for follow-up care as needed. Patients will also be provided with a written discharge summary and prescription(s) as needed. If the patient has an identified PCP, a copy of the discharge summary is emailed to the PCP.

Data Linkage

ICES is an independent, non-profit research institute funded by an annual grant from the Ontario Ministry of Health and the Ministry of Long-Term Care. As a prescribed entity under Ontario's privacy legislation, ICES is authorized to collect and use health-related data for the purposes of health system analysis, evaluation, and decision support. Secure access to these data is governed by policies and procedures that are approved by the Information and Privacy Commissioner of Ontario.

Data from participants covered under the publicly-funded single-payer Ontario Health Insurance Plan (OHIP) will be linked to ICES administrative health data from 3 years prior to the admission to 1 year following discharge.[46] PCP visits, outpatient visits, ED visits, inpatient hospitalizations, and mortality will be ascertained from the OHIP physician billing claims database, the National Ambulatory Reporting System, the Discharge Abstract Database, the Ontario Mental Health Reporting System, and the Registered Persons Database.

Table 1: Examples of Main Activities of Homeless Outreach Coordinators

Category	Examples
1. Connection to Community-Based Providers	• Referral to case managers, housing workers, harm reduction services, and shelters
2. Patient Advocacy During Hospital Stay and Discharge Process	• Link to addiction and harm reduction services within hospital and surrounding area • Help patients apply for housing, social benefits, and identification • Connect to social activities and provide other materials for in-hospital entertainment • Participate in creation of discharge plan and support patient/team in the actual discharge process
3. Health-Related Support After Discharge	• Remind patients about their medication regimes • Arrange medication storage at post-discharge setting • Help patients fill prescriptions (direct patients or accompany them to local pharmacies) • Help patients with accessing opioid agonist therapy and safer supply • Help patients procure medical aides and devices • Remind patients about upcoming medical appointments • Attend medical appointments with patients • Help patients find and connect with primary care providers • Help patients arrange for home care, wound care, eye care, and dental care • Connect patients to disease-specific programs • Purchase medical-related items to help follow through with post-discharge plans
4. Social-Related Support After Discharge	• Help patients apply for housing, social benefits, and identification • Arrange transportation to post-discharge setting • Help patients find alternative shelter based on unique needs
5. Information Transfer	• Follow-up with shelters and case managers to ensure that they have the patient discharge plan and are supporting it • Ensure that outpatient services are also aware of patient discharge plan and following through with it • Ensure that this hospital and other hospitals are aware of the hospitalization and discharge plan

Outcomes

The primary outcome is follow-up with a PCP (physician or nurse practitioner) within 14 days of hospital discharge. This outcome was chosen given the unique and substantial barriers to primary care access faced by the homeless population and the fact that timely access to primary care after hospitalization is linked to better outcomes.[15,47] In-person visits, virtual encounters, and phone calls will all be considered as follow-up with a PCP. The primary outcome will be ascertained through participant self-report at the 30-day interview, phone calls to PCP offices, and ICES data linkage. In the event of discrepancies between these sources of information, we will use pre-specified rules to adjudicate the primary outcome **(Appendix Table 1)**.

Several other outcomes will be assessed given the multiple potential effects that are expected from this complex intervention.[41] Secondary outcomes include a composite measure of all-cause mortality or readmission, total number of days spent in hospital post-discharge, and number of ED visits within 30-, 90-, and 180-days post-discharge. Acute care utilization (readmissions and days in hospital) outcomes will not include labor and delivery visits and planned readmissions. If a patient is transferred between services within the hospital, the entire hospital stay will be treated as a single admission. Other secondary outcomes include self-reported quality of care transition (three-item Care Transitions Measure) after hospital discharge and self-reported change in difficulties meeting subsistence needs (RAND Course of Homelessness Scale) at the time of the 30-day interview relative to baseline.[12,48] Exploratory outcomes include change in health status (EQ-5D-3L) at the time of the 30-day interview relative to baseline, change in quality of life (EQ-5D Visual Analogue Scale) at the time of the 30-day interview relative to baseline, leaving against medical advice at discharge, medication adherence (eight-item Morisky Medication Adherence Scale) at the time of the 30-day interview, connection to a case manager in the community at the time of the 30-day interview, attendance of any non-PCP healthcare appointment within 180-days post-discharge, and time to all-cause mortality or readmission after discharge.[49,50] Only non-PCP appointments made by the time of discharge and documented in the discharge summary will be assessed for attendance. Only participants that did not previously report contact with a case manager in the 30-days prior to the baseline interview will be eligible for the connection to a case manager outcome. A summary of outcome domains and study

instruments is provided in **Table 2** and detailed descriptions of study instruments are provided in **Appendix Table 2**.

Sample Size

No previous data are available to ascertain 14-day PCP follow-up rates after hospitalization among people experiencing homelessness under usual care. However, a previous study reported that 14-day PCP follow-up rates after hospitalization among low socioeconomic status (SES) patients was ~48%.[51] An assumption was made that 14-day PCP follow-up rates after hospitalization among people experiencing homelessness under usual care is around 2/3 that of low-SES patients (32%). This study is powered to detect an effect size of 12%, equivalent to a 37.5% increase in relative rate of follow-up with a PCP within 14 days of discharge. With an α of 0.05, 256 participants per study arm will result in an 80% power to test the study hypothesis. Given an estimated 20% attrition rate based on past studies in this population,[52] a total of 640 participants will be recruited for this study.

Blinding

It will not be possible to blind participants, HOCs, or healthcare teams given the active and collaborative nature of the intervention. However, data collectors and data analysts will be blinded to the allocation of participants. The research team member who performs study allocation for a participant will not be involved in the 30-day follow-up interview for that participant.

Statistical Analyses

All analyses will follow the intention-to-treat principle. Sample characteristics will be summarized by descriptive statistics (mean, standard deviation, median, interquartile range, and proportion). We will also construct graphs to explore relationships and estimate correlations between participant characteristics and outcomes. Descriptive comparisons between group baseline characteristics and outcomes will be performed with χ^2 or Fisher exact tests for categorical variables and with t-tests or Wilcoxon rank sum tests for continuous or count variables.

Table 2: Outcome Domains, Variables, and Instruments

Domain	Variables	Instruments
Patient-Reported Outcomes	- Health Status[a,b] - Quality of Life[a,b] - Medication Adherence[b] - Care Transition Experience[b] - Difficulties meeting subsistence needs[a,b]	- EQ-5D-3L - EQ-5D Visual Analogue Scale (VAS) - Morisky Medication Adherence Scale 8-item (MMAS-8) - Care Transitions Measure 3-item (CTM-3) - RAND Course of Homelessness Scale
Healthcare Utilization	- Follow-up with primary care provider[b,d] - Hospital readmissions within 30-days, 90-days, and 180-days post-discharge[b,d] - Emergency department visits within 30-days, 90-days, and 180-days post-discharge[b,d] - Number of days spent in hospital within 30-days, 90-days, and 180-days post-discharge[b,d] - Leaving against medical advice[c]	-
Social Service Utilization	- Connection to case manager[b]	-
Mortality[d]	-	-

[a]Self-reported from baseline interview

[b]Self-reported from 30-day interview

[c]Collected from discharge chart review

[d]Ascertained from administrative health data

The primary analysis will be performed using the χ^2 test to compare two independent proportions of 14-day PCP follow-up. The difference in proportions (risk difference, RD) and 95% confidence interval (CI) will be estimated using the Wald method.[53] Two secondary analyses will be conducted. The first is a log-binomial regression model including the intervention arm indicator as the covariate. The risk ratio and 95% CI will be estimated from the model. The second is a logistic regression model including the intervention arm indicator as the covariate. The odds ratio (OR) and 95% CI will be estimated from the model. To explore potential subgroup effects, multivariable logistic regression models for the primary outcome will be constructed including each of the following pre-specified covariates, one-at-a-time and with corresponding interaction terms with the intervention arm: age, sex, current illicit drug use, current risky alcohol use, Charlson comorbidity index score, and prior acute care utilization for a mental health reason.

For secondary and exploratory binary outcomes, logistic regression models will be used to estimate ORs and 95% CIs. For count outcomes, Poisson or negative binomial regression models (if over-dispersion is suggested by the data) will be used to estimate rate ratios and 95% CIs. For cross-sectional continuous outcomes, linear regression models will be constructed. For longitudinal continuous outcomes, we will consider linear mixed models or generalized estimating equations, depending on the outcome distribution. Models will include the intervention arm indicator, time (baseline versus 30-day interview), and the interaction of intervention arm by time. A significant interaction will indicate that the change from baseline is different between the study groups. This difference and 95% CI will be estimated. For time to all-cause mortality or readmission after discharge, a survival analysis will be performed. Cumulative event rates will be calculated with the Kaplan-Meier method, with event or censoring times calculated from the date of discharge. Differences in Kaplan-Meier survival curves between the study arms will be assessed using the log-rank test.

Any missing data will be considered, and multiple imputation will be performed if indicated either for the main analyses or as sensitivity analyses.[54] All analyses will be conducted using R, STATA, and SAS. All statistical tests will be two-sided and a p-value of 0.05 or less will indicate statistical significance. Adjustments will not be conducted for multiple comparisons.

This protocol follows guidance from the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[55]

Process Evaluation Methods and Analysis

In keeping with recommendations from the Medical Research Council on Process Evaluations of Complex Interventions,[40] we have designed a pragmatic mixed-methods process evaluation that will gather quantitative measures on program activities and qualitative data on how participants experience the intervention and how staff experience its implementation and operationalization. Three domains will be explored in this evaluation: implementation, mechanisms of impact, and context. Multiple data collection methods will be employed to better understand intervention implementation, mechanisms of change, and important contextual influences on the Navigator Program. These methods and their corresponding process evaluation domains, research questions, and data sources are outlined in **Table 3**, and include chart review, non-participant observation (NPO), semi-structured interviews, and field notes. Chart review will include data on the number and nature of interactions between HOCs and participants, community service providers, and healthcare team, collected from a database developed specifically for the Navigator Program. NPO is a process of observing participants and the program setting without actively participating, and can be helpful for assessing the finer details and spirit of implementation, mechanisms of change and program activities, and contexts.[56] In this study, NPO will entail accompanying the HOCs as they do their day-to-day work at the hospital and in the community. Semi-structured interviews will be conducted with the HOCs (n=2), the implementation team (n=4), hospital physicians and staff (n=25-50), community service providers (n=10-20) that interact with the Navigator Program, and individuals experiencing homelessness enrolled in the study in both the intervention (n=15-25) and control arms (n=15-25).

Table 3: Process Evaluation Domains, Questions, and Data Collection

Process Evaluation Domains	Research Questions	Core Information	Data Type	Data Sources	Records Kept
Across domains: What are some unanticipated consequences of the Navigator Program?					
Domain 1: Implementation	To what extent was the Navigator Program (the intervention) implemented and delivered as intended?	Fidelity: quality of the intervention delivery, capturing the nature of what was delivered and not just the specific activities	Interviews Non-participant observation Research and implementation team meetings Documentation from planning phase	Interviews with HOCs, hospital physicians and staff, and community service providers, who interact with the Navigator Program, and with the implementation team Bi-weekly research team meetings; meetings with HOC and implementation team Team records	Audio recordings and transcripts, field notes and memos, meeting notes, and memos about team records
	What was delivered in practice?	Dose: amount of and type of activity	Participant interactions with intervention: number and nature of interactions between the HOCs and participants, community service providers, and healthcare team for each participant	HOC patient chart for all study participants in the intervention arm Meetings with HOCs and implementation team to discuss participant discharge from program	Chart review and meeting notes
Domain 2: Mechanisms *2a. Mechanisms of Impact and Change*	What were the key ingredients and elements of the intervention? Which elements of the intervention supported meeting intervention goals? Which elements of the intervention challenged meeting intervention goals?	Mechanisms of impact and change (e.g. trust and rapport, relationship-building, communication, etc.) will be explored qualitatively	Interviews Non-participant observation Research and implementation team meetings	Interviews with HOCs, hospital physicians and staff, and community service providers, who interact with the Navigator Program, and with study participants in both the intervention and control arms Shadowing HOCs during their day-to-day workflow in the hospital and in the community Bi-weekly research team meetings and meetings with HOCs and implementation team	Audio recordings and transcripts, field notes and memos, and meeting notes
2b. Mechanisms of Implementation	What were the barriers and facilitators to	Mechanisms of implementation (e.g. acceptability of the	Interviews Non-participant	Interviews with HOCs; with implementation team, with hospital physicians and staff, and	Audio recordings and transcripts, field notes and memos, and meeting notes

	implementing the intervention?	intervention in the implementation setting) will be explored qualitatively	observation Research and implementation team meetings	community service providers, who interact with the Navigator program Shadowing HOCs during their day-to-day workflow in the hospital and in the community Bi-weekly research team meetings; meetings with HOC and implementation team	
Domain 3: Context	What features of context influenced the intervention implementation and reaching intervention goals?	Characteristics of implementation setting (e.g. hospital services)	Interviews Research and implementation team meetings Documentation from planning phase	Interviews with HOCs, implementation team, hospital physicians and staff, and community service providers, who interact with the Navigator Program Bi-weekly research team meetings and meetings with HOCs and implementation team Team records	Audio recordings and transcripts, field notes and memos, meeting notes, and memos about team records
	How do features of context influence intervention implementation and the activities and services delivered? How do features of the intervention shape the implementation context?	The dynamic influence between multiple domains of the internal and external domains of context (e.g. organizational setting, socioeconomic context, and community resources) and implementation and program activities delivered	Interviews Non-participant observation Research and implementation team meetings Documentation from planning phase	Interviews with HOCs, hospital physicians and staff, and community service providers, who interact with the Navigator Program, and with study participants in both the intervention and control arms Shadowing HOCs during their day-to-day workflow in the hospital and in the community Bi-weekly research team meetings and meetings with HOCs and implementation team Team records	Audio recordings and transcripts, field notes and memos, meeting notes, and memos about team records

Quantitative data from chart review will be analyzed descriptively to understand intervention fidelity and dose. All qualitative data will be analyzed as data are collected. Interviews, field notes, and NPO will be analyzed separately and then integrated to inform each other on an ongoing basis. Analyses will be conducted by multiple members of the research team and guided by a thematic analysis approach. These qualitative data will be transcribed, notable excerpts coded, and similar codes grouped into themes.[57] Field notes will be used as initial points of analysis and to contextualize interview data.

Finally, mixed-methods analyses will employ "following a thread" and "triangulation" approaches to bringing quantitative and qualitative data sets together.[58] Following separate but concurrent initial analyses of quantitative and qualitative components, key themes and interesting data points arising in one data set will be followed across and explored in other data sets. Ultimately, the data sets will be integrated for interpretation and facilitating the identification of "meta-themes" that cut across the data sets. Data source triangulation and researcher triangulation will enhance reliability of findings and provide a more complete picture.[59] Analyses throughout will also pay particular attention to the ways in which intersecting factors such as sex, gender identity, race, ethnicity, sexual orientation, culture, religion, geography, education, disability, and income shape the experiences of participants during the intervention.

Ethics and Dissemination

Ethics Approval

This study has been approved by the Unity Health Toronto Research Ethics Board (REB). All changes to the study protocol are communicated to and receive approval from the REB before implementation

Participant Safety

Study participants who are assigned to the intervention arm will receive the Navigator Program and may directly benefit from HOC services. Study participants in the usual care arm will not receive any direct benefits.

Involvement in this research poses minimal risks to participants. The baseline and 30-day interviews do not involve questions that are anticipated to cause emotional distress among participants. There is still a possibility that some participants may find certain interview questions to be challenging or uncomfortable. However, participants may decline to answer specific questions and participants may withdraw from the study at any point in time. Should an individual choose to withdraw from the study entirely, they will keep any honorariums, will still have access to usual care, and may request that their information collected up to that point be destroyed.

Dissemination

Study findings will be rapidly communicated to hospital leadership, healthcare systems, community partners, and the City of Toronto Shelter, Support, and Housing Administration Division. Other key outputs include academic publications, community reports, conference presentations, and a Town Hall that will convene people with lived experience of homelessness, hospital staff, community experts, policy makers, shelter managers and staff, researchers, and public health partners to discuss results and implications.

Data Protection and Retention

The research team will make every effort to keep personal health information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act of Ontario. All participant data that is recorded for study purposes will be de-identified with a random unique study identifier number instead of any personally identifying information. A Master Linking Log with participant identifiers will be stored on a secure computer server in a password protected file. This file will only be made available to designated members of the research team. Research assistants conducting follow-up interviews will only have access to the name of participants and their unique study identifier.

All study data will be kept on a secure hospital server that cannot be accessed by anyone outside of the research team. Only authorized members of the research team will have access to study data. All study data will be kept for a period of seven years from the end of the study and then destroyed. The research team will protect study data and keep all information confidential to the

greatest extent possible by law.

Patient and Public Involvement

The Navigator Program was reviewed by the Community Expert Group (CEG) at the MAP Centre for Urban Health Solutions, Unity Health Toronto. This group is composed of diverse individuals with lived experience of homelessness. The CEG will continue to provide guidance and input on study findings and knowledge translation and exchange.

Competing Interests:
The authors have no competing interests.

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Contributor Statement:
SWH conceived of the study. ML, KFP, and SWH led the study design and protocol development. ML, KFP, CP, RB, and SWH designed the survey instruments. CP, RB, and SV are leading recruitment, data collection, and data processing. FE and AR are leading the delivery of the intervention. ML and RN wrote statistical analysis plans and will be conducting statistical analyses. JJ led the conceptualization and development of the mixed-methods process evaluation, with contributions from ML, KFP, OD, and SWH. All authors contributed to refinement of the study protocol. ML drafted the manuscript, and all authors reviewed and approved the final manuscript.

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Appendix Table 1: Adjudication Rules for Primary Outcome

A Patient 30-day Interview Self-Report	B Primary Care Office Report[1]	C Adjudication of A and B	D ICES Administrative Data	E Final Adjudication (Yes if C=Yes or D=Yes)
Yes	Yes	Yes	Yes	Yes
Yes	Yes	Yes	No	Yes
Yes	Yes	Yes	n.d.	Yes
Yes	No	No	Yes	Yes
Yes	No	No	No	No
Yes	No	No	n.d.	No
Yes	n.d.	Yes	Yes	Yes
Yes	n.d.	Yes	No	Yes
Yes	n.d.	Yes	n.d.	Yes
No	Yes	Yes	Yes	Yes
No	Yes	Yes	No	Yes
No	Yes	Yes	n.d.	Yes
No	No	No	Yes	Yes
No	No	No	No	No
No	No	No	n.d.	No
No	n.d.	No	Yes	Yes
No	n.d.	No	No	No
No	n.d.	No	n.d.	No
n.d.	Yes	Yes	Yes	Yes
n.d.	Yes	Yes	No	Yes
n.d.	Yes	Yes	n.d.	Yes
n.d.	No	No	Yes	Yes
n.d.	No	No	No	No
n.d.	No	No	n.d.	No
n.d.	n.d.	No	Yes	Yes
n.d.	n.d.	No	No	No
n.d.	n.d.	No	n.d.	No

n.d. = no data.

[1]The primary care provider (PCP) office will be contacted under any of the following circumstances: (1) participant reports PCP visit at the 30-day interview, (2) participant reports no PCP visit at the 30-day interview AND a PCP is identified at the baseline interview or 30-day interview, or (3) participant misses the 30-day interview AND a PCP is identified at the baseline interview.

Appendix Table 2: Detailed Descriptions of Study Instruments

Instrument	Description
EQ-5D-3L and VAS	The EQ-5D-3L is a generic measure of health-related quality of life that has been widely used among the homeless population. The EQ-5D-3L includes five three-level items concerning mobility, self-care, usual activities, pain/discomfort, and anxiety/depression that are weighted to produce a single utility score between 0 and 1. The Visual Analogue Scale (VAS) of the EQ-5D-3L will also be included, which will allow participants to rate their overall health, mental health, and physical health from 0 to 100. References: 1. Janssen, M. F., Pickard, A. S., Golicki, D., Gudex, C., Niewada, M., Scalone, L., ... & Busschbach, J. (2013). Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. *Quality of life research*, *22*(7), 1717-1727. 2. Stergiopoulos, V., Hwang, S. W., Gozdzik, A., Nisenbaum, R., Latimer, E., Rabouin, D., ... & At Home/Chez Soi Investigators. (2015). Effect of scattered-site housing using rent supplements and intensive case management on housing stability among homeless adults with mental illness: a randomized trial. *JAMA*, *313*(9), 905-915.
MMAS-8	The MMAS-8 is a validated self-reported measure for medication-taking behavior that has been used among disadvantaged patients and those with chronic illnesses. The MMAS-8 consists of eight items, the first seven of which are yes/no questions, and the last of which is a five-point Likert-scale rating. Each ‘‘no” response is rated as ‘‘1” and each ‘‘yes” is rated as ‘‘0” except for item 5, in which each ‘‘yes” is rated as ‘‘1” and each ‘‘no” is rated as ‘‘0”. For item 8, if a patient chooses response ‘‘0”, the score is ‘‘1” and if they choose response ‘‘4”, the score is ‘‘0”. Responses ‘‘1, 2, 3” are respectively rated as ‘‘0.25, 0.75, 0.75”. Total MMAS-8 scores can range from 0 to 8 and are categorized into three levels of adherence: high adherence (score = 8), medium adherence (score of 6 to 8), and low adherence (score < 6). References: 1. Moon, S. J., Lee, W. Y., Hwang, J. S., Hong, Y. P., & Morisky, D. E. (2017). Accuracy of a screening tool for medication adherence: A systematic review and meta-analysis of the Morisky Medication Adherence Scale-8. *PloS one*, *12*(11), e0187139. 2. Feehan, M., Morrison, M. A., Tak, C., Morisky, D. E., DeAngelis, M. M., & Munger, M. A. (2017). Factors predicting self-reported medication low adherence in a large sample of adults in the US general population: a cross-sectional study. *BMJ open*, *7*(6), e014435.

CTM-3	The most widely used measure of care transition quality is the Care Transition Measure (CTM). The CTM-3 is an abbreviated version of the original CTM-15, which measures the extent to which the healthcare team accomplished essential care processes in preparing the patient for discharge and participating in post-hospital self-care activities. The CTM-3 consists of three items with a four-point scale with responses ranging from "Strongly Disagree" (1) to "Strongly Agree" (4) to the following questions: 3. During this hospital stay, staff took my preferences into account in deciding what my healthcare needs would be when I left. 4. When I left the hospital, I had a good understanding of the things I was responsible for in managing my health. 5. When I left the hospital, I clearly understood the purpose for taking each of my medications Items are scored by summing the responses and then linear transforming to a 0-100 range. References: 1. Parry, C., Mahoney, E., Chalmers, S. A., & Coleman, E. A. (2008). Assessing the quality of transitional care: further applications of the care transitions measure. *Medical care*, 317-322. 2. Coleman, E. A., Smith, J. D., Frank, J. C., Eilertsen, T. B., Thiare, J. N., & Kramer, A. M. (2002). Development and testing of a measure designed to assess the quality of care transitions. *International journal of integrated care*, *2*.
RAND Course of Homelessness Scale	Developed specifically for homeless populations, the RAND scale is a five-item index of self-reported difficulty in meeting the following subsistence needs over the past 30 days: frequency of difficulty in finding shelter, enough to eat, clothing, a place to wash, and a place to use the bathroom. Possible responses to each item are never (1), rarely (2), sometimes (3), or usually (4) with total scores between 5-20. Reference: 1. Gelberg, L., Gallagher, T. C., Andersen, R. M., & Koegel, P. (1997). Competing priorities as a barrier to medical care among homeless adults in Los Angeles. *American journal of public health*, *87*(2), 217-220.

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Navigator Program for hospitalized adults experiencing homelessness: protocol for a pragmatic randomized controlled trial

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Navigator Program for hospitalized adults experiencing homelessness: protocol for a pragmatic randomized controlled trial

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Abstract

Introduction: People experiencing homelessness suffer from poor outcomes after hospitalization due to systemic barriers to care, suboptimal transitions of care, and intersecting health and social burdens. Case management programs have been shown to improve housing stability, but their effects on broad post-hospital outcomes in this population have not been rigorously evaluated. The Navigator Program is a Critical Time Intervention case management program that was developed to help homeless patients with their post-discharge needs and to link them with community-based health and social services. This randomized controlled trial examines the impact of the Navigator Program on post-hospital outcomes among adults experiencing homelessness.

Methods and analysis: This is a pragmatic randomized controlled trial testing the effectiveness of the Navigator Program at an urban academic teaching hospital and an urban community teaching hospital in Toronto, Canada. Six hundred forty adults experiencing homelessness who are admitted to the hospital will be randomized to receive support from a Homeless Outreach Counsellor for 90 days after hospital discharge or to usual care. The primary outcome is follow-up with a primary care provider (physician or nurse practitioner) within 14 days of hospital discharge. Secondary outcomes include post-discharge mortality or readmission, number of days in hospital, number of emergency department visits, self-reported care transition quality, and difficulties meeting subsistence needs. Quantitative outcomes are being collected over a 180-day period through linked patient-reported and administrative health data. A parallel mixed-methods process evaluation will be conducted to explore intervention context, implementation, and mechanisms of impact.

Ethics and dissemination: Ethics approval was obtained from the Unity Health Toronto Research Ethics Board. Participants will be required to provide written informed consent. Results of the main trial and process evaluation will be reported in peer-reviewed journals and shared with hospital leadership, community partners, and policy makers.

Trial registration number: ClinicalTrials.gov, NCT04961762.

Strengths and limitations of this study

- The Navigator Program is a patient-centered case management intervention informed by a prior prospective cohort study and designed in tandem with community partners, healthcare teams, and people with lived experience of homelessness.
- Linkage of patient-reported data with administrative health data allows for rigorous assessment of a much wider range of post-hospital outcomes relative to previous case management studies for people experiencing homelessness.
- This randomized controlled trial is accompanied by a parallel mixed-methods process evaluation that will investigate intervention implementation, causal mechanisms, study context, participant experiences, and outcomes.
- Blinding of participants, Homeless Outreach Counsellors, and healthcare teams is not possible given the active and collaborative nature of the intervention.
- This study takes place at an urban academic teaching hospital and an urban community teaching hospital in Toronto, Canada, and findings may not be generalizable to individuals experiencing homelessness in other contexts and settings.

Introduction

Background and rationale

More than 235,000 Canadians experience homelessness annually, of which 27% are women, 19% are youth, and a growing number are identifying as racial, ethnic, sexual, and gender minorities.[1,2] This population experiences disproportionate intersecting physical, mental, and social burdens that greatly increase morbidity and mortality relative to the general population.[3–5] For example, rates of acute and chronic physical health problems, trauma, mental illness, and substance use are much higher among homeless adults.[6–8]

Homeless individuals often experience substantial barriers to obtaining health care and frequently suffer from unmet health needs.[9–11] Many have other immediate competing priorities such as securing food and shelter that preclude consistent engagement with healthcare services.[12,13] Homeless individuals are also much less likely to have a primary care provider (PCP) or usual source of care compared to the general population.[14,15] Lack of primary care likely contributes to poor outcomes among the homeless population, given that access to primary care is associated with lower mortality and reductions in unnecessary emergency department (ED) visits and hospital admissions.[16,17] Indeed, there is abundant evidence suggesting that homeless adults rely heavily on acute care services, and rates of ED visits and hospitalizations are much higher among homeless versus non-homeless adults.[18–21] A related problem is the high rate of hospital readmissions among homeless adults.[18,19,22,23] Many of these readmissions are thought to be potentially preventable with more complete treatment and better coordination of health and social services following hospital discharge.[24,25] In the general population, timely access to primary care follow-up after hospitalization has been consistently associated with lower rates of readmissions.[26–28] Qualitative studies have also revealed that homeless individuals face unique challenges following discharge from hospital, such as difficulties storing medication, inability to find shelter, and not being provided appropriate discharge instructions.[29–31] Altogether, systemic barriers to primary care, competing priorities, and poor care transitions all contribute toward poor post-hospital outcomes and reliance on acute care settings among homeless individuals.

Case management is a core component of care for homeless individuals, serving to help navigate and coordinate health and social services.[32] Such programs have been adapted and implemented for several subgroups of homeless individuals, including frequent users of acute healthcare services and those with complex needs and mental illness.[33–35] Systematic reviews have found that case management is effective in improving housing stability, reducing substance use, and removing barriers to securing employment in this population.[32,36] However, few studies have rigorously evaluated the effect of case management on broad post-hospital outcomes among homeless patients overall.[37] One randomized controlled trial (RCT) of a combined transitional housing, long-term housing, and case management intervention reported reductions in hospitalizations, number of hospital days, and ED visits among homeless adults with chronic illnesses.[35] Another more recent RCT of a combined permanent supportive housing and case management intervention found significant reductions in psychiatric ED visits and increases in use of outpatient mental health services.[38] However, these studies could not evaluate the independent effects of multiple intervention components and did not assess other post-hospital or patient-reported outcomes. One RCT of a physician-led model of multidisciplinary care coordination, advocacy, and hospital discharge planning found a significant increase in quality of life and reduction in street homelessness, but the intervention had no effect on length of hospital stay or post-discharge acute care utilization.[39] However, the study was underpowered with low recruitment and follow-up rates. A smaller RCT of a Critical Time Intervention (CTI) case management program focused specifically on homeless patients with severe mental illness was found to improve continuity of care, prevent homelessness, and reduce psychiatric readmissions following hospital discharge.[40–42]

Accordingly, this current RCT seeks to investigate the effectiveness of an adapted CTI case management program – the Navigator Program – in improving post-hospital outcomes among adults experiencing homelessness at an urban academic teaching hospital and an urban community teaching hospital in Toronto, Canada. CTI is a time-limited case management program which delivers focused case management at critical times or situations in the lives of clients, such as transitioning from hospital care to community care.[36] The Navigator Program features Homeless Outreach Counsellors (HOCs) – whose roles are to create strong links between community services and patients through regular contact, supporting patients in

following their post-discharge care plans, and helping patients in meeting their health- and social-related competing priorities. This intervention was informed by a recent prospective cohort study conducted at the same hospital, which found that having an active case manager, sending discharge summaries to PCPs, and informal support were associated with reduced readmissions among homeless adults.[22] The first HOC position was created in February 2019 and has since been expanded to two positions and adapted through conversations with community partners and hospital staff. Ultimately, the goal of the Navigator Program is to help homeless patients who are discharged from the hospital overcome systemic barriers and discontinuities in care that often result in poor health and high acute care utilization.

Objectives

This RCT seeks to evaluate the effectiveness of the Navigator Program in improving post-hospital outcomes among adults experiencing homelessness. It will specifically evaluate outcomes related to PCP follow-up, acute care utilization, difficulties meeting subsistence needs, care transition, and overall health following hospital discharge.

A detailed mixed-methods process evaluation will be conducted alongside the RCT. This evaluation primarily aims to provide a deeper understanding of intervention implementation, mechanisms of change within the intervention, and the way in which the Navigator Program interacts with the internal and external contexts to influence both implementation and RCT outcomes in expected or unexpected ways.[43,44] This evaluation will also aim to understand the in-hospital and post-discharge experiences of participants in the intervention and control arms, exploring differences and similarities qualitatively. It is important to investigate how RCT outcomes are shaped by intervention implementation or by the intervention itself, and to identify which parts of the Navigator Program did or did not work to achieve the intended goals and why.

Methods and analysis

Design and setting

This study is a pragmatic RCT that is being conducted at an urban academic teaching hospital (St. Michael's Hospital) and an urban community teaching hospital (St. Joseph's Health Centre)

in Toronto, Canada. Recruitment began in October 2021 and total recruitment is estimated to be completed in three years.

Eligibility criteria

To be eligible for the study, patients must meet the following criteria: (1) be 18 years of age or older, (2) be admitted to any medical or surgical service (excluding psychiatry and obstetrics), and (3) be identified as experiencing homelessness (as per the Canadian definition of homelessness) at the time of admission or anytime during the hospital admission.[45] Patients will be excluded from the study if they meet any of the following criteria: (1) are unable to provide informed consent or (2) were connected with a HOC prior to the initiation of the RCT and have received services from the HOC within 90 days preceding their current admission. Each individual patient can be randomized only once during the study period. Patients admitted to psychiatric and obstetric services are excluded from this study because optimal immediate post-discharge follow-up for these patients should be with specialists rather than with PCPs.[46,47] Furthermore, recommended follow-up timeframes for these patients are often longer than 14 days, thus rendering the primary outcome inapplicable.

Recruitment and data collection

Clinical or research staff will identify potential participants on weekdays. Once identified, the patient will be asked by a member of their circle of care for permission to be introduced to the research team. The research team will then confirm patient eligibility and explain the purpose, process, risks, and benefits of the study to potential participants. Participants may choose to enroll in the study by providing written informed consent **(online supplemental file 1)**.

A baseline interview will be conducted with participants prior to randomization and as a soon as possible after admission to the hospital upon confirmation of eligibility. Sociodemographic information will be collected, including age, gender, race, Indigenous identity, education level, housing status, and social service utilization. Participants who complete the baseline interview will receive a $20 CAD gift card to compensate them for their time. Another 30-day interview will take place at least 30 days (but no longer than 50 days) after the discharge date to assess patient-reported post-hospital outcomes. At this time, the research team will contact PCPs to

ascertain any follow-up visits. Baseline and 30-day interviews will be conducted in person or remotely. Data from interviews will be collected with tablets using electronic surveys hosted by Snap Professional Software.

The research team will also undertake a chart review of hospital records after discharge to ascertain characteristics of the admission, information about discharge, participant health information, and history of alcohol and substance use.

Plans to promote continued participation

Several strategies will be implemented to minimize attrition. At the baseline interview, study participants will be asked to provide detailed contact information, as well as the names and contact information of family, friends, and other service providers who may be contacted if the research team cannot reach the participant directly. In addition to active outreach from the research team, participants will be asked to contact the research team after discharge to schedule a 30-day interview. Participants who contact the research team 2-3 weeks following their discharge to confirm their contact information and schedule the 30-day interview will receive an additional $10 CAD honorarium upon completion of the interview. Participants who complete the 30-day interview will also receive a $40 CAD honorarium and reimbursement for any travel-related expenses, when applicable, for the interview.

Randomization

Participants will be randomized by a third-party internet randomization service (randomize.net). The program will assign participants to either the intervention or the usual care arm using permuted-block randomization, with a 1:1 allocation ratio and random permuted block sizes of 6 or 8. This process will maintain balanced group sizes between the intervention and usual care arms at intermediate points in the recruitment process and minimize the possibility of the research team predicting study allocation.[48]

Intervention

Participants randomized to the intervention arm will be assigned to work with an HOC. The HOC will connect with participants as early as possible during the admission and will provide

support for 90 days after hospital discharge. The period of support may occasionally be extended beyond 90 days for certain patients, if the HOC deems this to be necessary and appropriate. The main role of the HOC is to support continuity and comprehensiveness of care by helping participants follow their post-discharge plans and facilitating strong links with community-based health and social services. Day-to-day HOC activities fall into five main categories: 1) making connections and referrals to community-based providers, 2) supporting and advocating for patients during the hospital stay and discharge process, 3) supporting patients with health-related matters during the post-discharge period, 4) supporting patients with social-related matters during the post-discharge period, and 5) transferring patient-related information to other healthcare and community-based providers **(Table 1)**. The intensity and types of support from HOCs will be tailored to the specific needs of the individual.

Usual care

Participants in the usual care arm will be discharged without support from the HOCs. However, all participants will still receive support as usual from Care Transition Facilitators (CTFs) and/or social workers. CTFs and social workers help patients during their hospital stay to arrange discharge plans and make follow-up arrangements. However, unlike HOCs, CTFs and social workers do not typically work with patients after hospital discharge.

The typical discharge process involves counseling from the discharging physician and healthcare team, who make recommendations or appointments for follow-up care as needed. Patients will also be provided with a written discharge summary and prescription(s) as needed. If the patient has an identified PCP, a copy of the discharge summary is emailed to the PCP.

Table 1: Examples of main activities of Homeless Outreach Counsellors

Category	Examples
1. Connection to Community-Based Providers	• Referral to case managers, housing workers, harm reduction services, and shelters
2. Patient Advocacy During Hospital Stay and Discharge Process	• Link to addiction and harm reduction services within hospital and surrounding area • Help patients apply for housing, social benefits, and identification • Connect to social activities and provide other materials for in-hospital entertainment • Participate in creation of discharge plan and support patient/team in the actual discharge process
3. Health-Related Support After Discharge	• Remind patients about their medication regimes • Arrange medication storage at post-discharge setting • Help patients fill prescriptions (direct patients or accompany them to local pharmacies) • Help patients with accessing opioid agonist therapy and safer supply • Help patients procure medical aides and devices • Remind patients about upcoming medical appointments • Attend medical appointments with patients • Help patients find and connect with primary care providers • Help patients arrange for home care, wound care, eye care, and dental care • Connect patients to disease-specific programs • Purchase medical-related items to help follow through with post-discharge plans
4. Social-Related Support After Discharge	• Help patients apply for housing, social benefits, and identification • Arrange transportation to post-discharge setting • Help patients find alternative shelter based on unique needs
5. Information Transfer	• Follow-up with shelters and case managers to ensure that they have the patient discharge plan and are supporting it • Ensure that outpatient services are also aware of patient discharge plan and following through with it • Ensure that this hospital and other hospitals are aware of the hospitalization and discharge plan

Data linkage

Participant data will be linked to ICES data. ICES is an independent, non-profit research institute funded by an annual grant from the Ontario Ministry of Health and the Ministry of Long-Term Care. As a prescribed entity under Ontario's privacy legislation, ICES is authorized to collect and use health-related data for the purposes of health system analysis, evaluation, and decision support. Secure access to these data is governed by policies and procedures that are approved by the Information and Privacy Commissioner of Ontario.

Data from participants will be linked to ICES administrative health data from 3 years prior to the admission to 1 year following discharge.[49] PCP visits, outpatient visits, ED visits, inpatient hospitalizations, and mortality will be ascertained from the Ontario Health Insurance Plan (OHIP) Claims Database, Community Health Center Database, Discharge Abstract Database, Same Day Surgery Database, National Ambulatory Care Reporting System, Ontario Mental Health Reporting System databases, and the Registered Persons Database.

Outcomes

The primary outcome is follow-up with a PCP (physician or nurse practitioner) within 14 days of hospital discharge. This outcome was chosen given the unique and substantial barriers to primary care access faced by the homeless population and the fact that timely access to primary care after hospitalization is linked to better outcomes.[15,50] In-person visits, virtual encounters, and phone calls will all be considered as follow-up with a PCP. The primary outcome will be ascertained through participant self-report at the 30-day interview, phone calls to PCP offices, and verification in the OHIP and Community Health Center Databases at ICES. In the event of discrepancies between these sources of information, we will use pre-specified rules to adjudicate the primary outcome **(online supplemental file 2).**

Several other outcomes will be assessed given the multiple potential effects that are expected from this complex intervention.[44] Secondary outcomes include a composite measure of all-cause mortality or readmission, total number of days spent in hospital post-discharge, and number of ED visits within 30-, 90-, and 180-days post-discharge. Acute care utilization (readmissions and days in hospital) outcomes will not include labor and delivery visits and planned readmissions. If

a patient is transferred between services within the hospital, the entire hospital stay will be treated as a single admission. Other secondary outcomes include self-reported quality of care transition (three-item Care Transitions Measure) after hospital discharge and self-reported change in difficulties meeting subsistence needs (RAND Course of Homelessness Scale) at the time of the 30-day interview relative to baseline.[12,51] Exploratory outcomes include change in health status (EQ-5D-3L) at the time of the 30-day interview relative to baseline, change in quality of life (EQ-5D Visual Analogue Scale) at the time of the 30-day interview relative to baseline, leaving against medical advice at discharge, medication adherence (eight-item Morisky Medication Adherence Scale) at the time of the 30-day interview, connection to a case manager in the community at the time of the 30-day interview, attendance of any non-PCP healthcare appointment within 180-days post-discharge, and time to all-cause mortality or readmission after discharge.[52,53] Only non-PCP appointments made by the time of discharge and documented in the discharge summary will be assessed for attendance. Only participants that did not previously report contact with a case manager in the 30-days prior to the baseline interview will be eligible for the connection to a case manager outcome. A summary of outcome domains and study instruments is provided in **Table 2** and detailed descriptions of study instruments are provided in **online supplemental file 3.**

Table 2: Outcome domains, variables, and instruments

Domain	Variables	Instruments
Patient-Reported Outcomes	- Health Status[a,b] - Quality of Life[a,b] - Medication Adherence[b] - Care Transition Experience[b] - Difficulties meeting subsistence needs[a,b]	- EQ-5D-3L - EQ-5D Visual Analogue Scale (VAS) - Morisky Medication Adherence Scale 8-item (MMAS-8) - Care Transitions Measure 3-item (CTM-3) - RAND Course of Homelessness Scale
Healthcare Utilization	- Follow-up with primary care provider[b,d] - Hospital readmissions within 30-days, 90-days, and 180-days post-discharge[b,d] - Emergency department visits within 30-days, 90-days, and 180-days post-discharge[b,d] - Number of days spent in hospital within 30-days, 90-days, and 180-days post-discharge[b,d] - Attendance of any non-PCP health care appointment within 180-days post-discharge[b,d] - Leaving against medical advice[c]	-
Social Service Utilization	- Connection to case manager[b]	-
Mortality[d]	-	-

[a]Self-reported from baseline interview

[b]Self-reported from 30-day interview

[c]Collected from discharge chart review

[d]Ascertained from administrative health data

Sample size

No previous data are available to ascertain 14-day PCP follow-up rates after hospitalization among people experiencing homelessness under usual care. However, a previous study reported that 14-day PCP follow-up rates after hospitalization among low socioeconomic status (SES) patients was ~48%.[54] An assumption was made that 14-day PCP follow-up rates after hospitalization among people experiencing homelessness under usual care is around 2/3 that of low-SES patients (32%). This study is powered to detect an effect size of 12%, equivalent to a 37.5% increase in relative rate of follow-up with a PCP within 14 days of discharge. With an α of 0.05, 256 participants per study arm will result in an 80% power to test the study hypothesis. Given an estimated 20% attrition rate based on past studies in this population,[55] a total of 640 participants will be recruited for this study.

Blinding

It will not be possible to blind participants, HOCs, or healthcare teams given the active and collaborative nature of the intervention. However, data collectors and data analysts will be blinded to the allocation of participants. The research team member who performs study allocation for a participant will not be involved in the 30-day follow-up interview for that participant.

Statistical analyses

All analyses will follow the intention-to-treat principle. Sample characteristics will be summarized by descriptive statistics (mean, standard deviation, median, interquartile range, and proportion). We will also construct graphs to explore relationships and estimate correlations between participant characteristics and outcomes. Descriptive comparisons between group baseline characteristics and outcomes will be performed with χ^2 or Fisher exact tests for categorical variables and with t-tests or Wilcoxon rank sum tests for continuous or count variables.

The primary analysis will be performed using the χ^2 test to compare two independent proportions of 14-day PCP follow-up. The difference in proportions (risk difference, RD) and 95% confidence interval (CI) will be estimated using the Wald method.[56] Two secondary analyses will

be conducted. The first is a log-binomial regression model including the intervention arm indicator as the covariate. The risk ratio and 95% CI will be estimated from the model. The second is a logistic regression model including the intervention arm indicator as the covariate. The odds ratio (OR) and 95% CI will be estimated from the model. To explore potential subgroup effects, multivariable logistic regression models for the primary outcome will be constructed including each of the following pre-specified covariates, one-at-a-time and with corresponding interaction terms with the intervention arm: age, sex, current illicit drug use, current risky alcohol use, Charlson comorbidity index score, and prior acute care utilization for a mental health reason.

For secondary and exploratory binary outcomes, logistic regression models will be used to estimate ORs and 95% CIs. For count outcomes, Poisson or negative binomial regression models (if over-dispersion is suggested by the data) will be used to estimate rate ratios and 95% CIs. For cross-sectional continuous outcomes, linear regression models will be constructed. For longitudinal continuous outcomes, we will consider linear mixed models or generalized estimating equations, depending on the outcome distribution. Models will include the intervention arm indicator, time (baseline versus 30-day interview), and the interaction of intervention arm by time. A significant interaction will indicate that the change from baseline is different between the study groups. This difference and 95% CI will be estimated. For time to all-cause mortality or readmission after discharge, a survival analysis will be performed. Cumulative event rates will be calculated with the Kaplan-Meier method, with event or censoring times calculated from the date of discharge. Differences in Kaplan-Meier survival curves between the study arms will be assessed using the log-rank test.

Any missing data will be considered, and multiple imputation will be performed if indicated either for the main analyses or as sensitivity analyses.[57] All analyses will be conducted using R, STATA, and SAS. All statistical tests will be two-sided and a p-value of 0.05 or less will indicate statistical significance. Adjustments will not be conducted for multiple comparisons. This protocol follows guidance from the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[58]

Process evaluation methods and analysis

In keeping with recommendations from the Medical Research Council on Process Evaluations of Complex Interventions,[43] we have designed a pragmatic mixed-methods process evaluation that will gather quantitative measures on program activities and qualitative data on how participants experience the intervention and how staff experience its implementation and operationalization. Three domains will be explored in this evaluation: implementation, mechanisms of impact, and context. Multiple data collection methods will be employed to better understand intervention implementation, mechanisms of change, and important contextual influences on the Navigator Program. These methods and their corresponding process evaluation domains, research questions, and data sources are outlined in **Table 3**, and include chart review, non-participant observation (NPO), semi-structured interviews, and field notes. Chart review will include data on the number and nature of interactions between HOCs and participants, community service providers, and healthcare team, collected from a database developed specifically for the Navigator Program. NPO is a process of observing participants and the program setting without actively participating, and can be helpful for assessing the finer details and spirit of implementation, mechanisms of change and program activities, and contexts.[59] In this study, NPO will entail accompanying the HOCs as they do their day-to-day work at the hospital and in the community. Semi-structured interviews will be conducted with the HOCs (n=2), the implementation team (n=4), hospital physicians and staff (n=25-50), community service providers (n=10-20) that interact with the Navigator Program, and individuals experiencing homelessness enrolled in the study in both the intervention (n=15-25) and control arms (n=15-25).

Table 3: Process evaluation domains, questions, and data collection

Process Evaluation Domains	Research Questions	Core Information	Data Type	Data Sources	Records Kept
Across domains: What are some unanticipated consequences of the Navigator Program?					
Domain 1: Implementation	To what extent was the Navigator Program (the intervention) implemented and delivered as intended?	Fidelity: quality of the intervention delivery, capturing the nature of what was delivered and not just the specific activities	Interviews Non-participant observation Research and implementation team meetings Documentation from planning phase	Interviews with HOCs, hospital physicians and staff, and community service providers, who interact with the Navigator Program, and with the implementation team Bi-weekly research team meetings; meetings with HOC and implementation team Team records	Audio recordings and transcripts, field notes and memos, meeting notes, and memos about team records
	What was delivered in practice?	Dose: amount of and type of activity	Participant interactions with intervention: number and nature of interactions between the HOCs and participants, community service providers, and healthcare team for each participant	HOC patient chart for all study participants in the intervention arm Meetings with HOCs and implementation team to discuss participant discharge from program	Chart review and meeting notes
Domain 2: Mechanisms *2a. Mechanisms of Impact and Change*	What were the key ingredients and elements of the intervention? Which elements of the intervention supported meeting intervention goals? Which elements of the intervention challenged meeting intervention goals?	Mechanisms of impact and change (e.g. trust and rapport, relationship-building, communication, etc.) will be explored qualitatively	Interviews Non-participant observation Research and implementation team meetings	Interviews with HOCs, hospital physicians and staff, and community service providers, who interact with the Navigator Program, and with study participants in both the intervention and control arms Shadowing HOCs during their day-to-day workflow in the hospital and in the community Bi-weekly research team meetings and meetings with HOCs and implementation team	Audio recordings and transcripts, field notes and memos, and meeting notes
2b. Mechanisms of Implementation	What were the barriers and facilitators to	Mechanisms of implementation (e.g. acceptability of the	Interviews Non-participant	Interviews with HOCs; with implementation team, with hospital physicians and staff, and	Audio recordings and transcripts, field notes and memos, and meeting notes

	implementing the intervention?	intervention in the implementation setting) will be explored qualitatively	observation Research and implementation team meetings	community service providers, who interact with the Navigator program Shadowing HOCs during their day-to-day workflow in the hospital and in the community Bi-weekly research team meetings; meetings with HOC and implementation team	
Domain 3: Context	What features of context influenced the intervention implementation and reaching intervention goals?	Characteristics of implementation setting (e.g. hospital services)	Interviews Research and implementation team meetings Documentation from planning phase	Interviews with HOCs, implementation team, hospital physicians and staff, and community service providers, who interact with the Navigator Program Bi-weekly research team meetings and meetings with HOCs and implementation team Team records	Audio recordings and transcripts, field notes and memos, meeting notes, and memos about team records
	How do features of context influence intervention implementation and the activities and services delivered? How do features of the intervention shape the implementation context?	The dynamic influence between multiple domains of the internal and external domains of context (e.g. organizational setting, socioeconomic context, and community resources) and implementation and program activities delivered	Interviews Non-participant observation Research and implementation team meetings Documentation from planning phase	Interviews with HOCs, hospital physicians and staff, and community service providers, who interact with the Navigator Program, and with study participants in both the intervention and control arms Shadowing HOCs during their day-to-day workflow in the hospital and in the community Bi-weekly research team meetings and meetings with HOCs and implementation team Team records	Audio recordings and transcripts, field notes and memos, meeting notes, and memos about team records

Quantitative data from chart review will be analyzed descriptively to understand intervention fidelity and dose. All qualitative data will be analyzed as data are collected. Interviews, field notes, and NPO will be analyzed separately and then integrated to inform each other on an ongoing basis. Analyses will be conducted by multiple members of the research team and guided by a thematic analysis approach. These qualitative data will be transcribed, notable excerpts coded, and similar codes grouped into themes.[60] Field notes will be used as initial points of analysis and to contextualize interview data.

Finally, mixed-methods analyses will employ "following a thread" and "triangulation" approaches to bringing quantitative and qualitative data sets together.[61] Following separate but concurrent initial analyses of quantitative and qualitative components, key themes and interesting data points arising in one data set will be followed across and explored in other data sets. Ultimately, the data sets will be integrated for interpretation and facilitating the identification of "meta-themes" that cut across the data sets. Data source triangulation and researcher triangulation will enhance reliability of findings and provide a more complete picture.[62] Analyses throughout will also pay particular attention to the ways in which intersecting factors such as sex, gender identity, race, ethnicity, sexual orientation, culture, religion, geography, education, disability, and income shape the experiences of participants during the intervention.

Patient and public involvement

The Navigator Program was reviewed by the Community Expert Group (CEG) at the MAP Centre for Urban Health Solutions, Unity Health Toronto. This group is composed of diverse individuals with lived experience of homelessness. The CEG will continue to provide guidance and input on study findings and knowledge translation and exchange.

Ethics and dissemination

Ethics approval

This study has been approved by the Unity Health Toronto Research Ethics Board (REB). All changes to the study protocol are communicated to and receive approval from the REB before implementation.

Participant safety

Study participants who are assigned to the intervention arm will receive the Navigator Program and may directly benefit from HOC services. Study participants in the usual care arm will not receive any direct benefits.

Involvement in this research poses minimal risks to participants. The baseline and 30-day interviews do not involve questions that are anticipated to cause emotional distress among participants. There is still a possibility that some participants may find certain interview questions to be challenging or uncomfortable. However, participants may decline to answer specific questions and participants may withdraw from the study at any point in time. Should an individual choose to withdraw from the study entirely, they will keep any honorariums, will still have access to usual care, and may request that their information collected up to that point be destroyed.

Dissemination

Study findings will be rapidly communicated to hospital leadership, healthcare systems, community partners, and the City of Toronto Shelter, Support, and Housing Administration Division. Other key outputs include academic publications, community reports, conference presentations, and a Knowledge Sharing Event that will convene people with lived experience of homelessness, hospital staff, community experts, policy makers, shelter managers and staff, researchers, and public health partners to discuss results and implications.

Data protection and retention

The research team will make every effort to keep personal health information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act of Ontario. All participant data that is recorded for study purposes will be de-identified with a random unique study identifier number instead of any personally identifying information. A Master Linking Log with participant identifiers will be stored on a secure computer server in a password protected file. This file will only be made available to designated members of the research team. Research assistants conducting follow-up interviews will only have access to the name of participants and their unique study identifier.

All study data will be kept on a secure hospital server that cannot be accessed by anyone outside of the research team. Only authorized members of the research team will have access to study data. All study data will be kept for a period of seven years from the end of the study and then destroyed. The research team will protect study data and keep all information confidential to the greatest extent possible by law.

Competing interests

The authors have no competing interests.

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Contributors

SWH conceived of the study. ML, KFP, and SWH led the study design and protocol development. MJT, GEF, KAM, VS, and AP assisted with study design. ML, KFP, CP, RB, and SWH designed the survey instruments. CP, RB, and SV are leading recruitment, data collection, and data processing. FE and AR are leading the delivery of the intervention. ML, RN, and LR wrote statistical analysis plans and will be conducting statistical analyses. JJ led the conceptualization and development of the mixed-methods process evaluation, with contributions from ML, KFP, OD, and SWH. All authors contributed to refinement of the study protocol. ML drafted the manuscript, and all authors reviewed and approved the final manuscript.

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Informed Consent Form for Participation in a Research Study

Study Title: Effect of a Navigator Program on Post-Hospital Outcomes for Homeless Adults: A Pragmatic Randomized Controlled Trial

Principal Investigator: Dr. Stephen Hwang, MD MPH, Centre for Urban Health Solutions, St. Michael's Hospital, 416-864-5991(M-F, 9 AM – 5 PM)

Funder: The Navigator program is funded by the St. Michael's Hospital Foundation and this research study is funded by a CIHR Foundation Grant

INTRODUCTION

You are being asked to consider participating in this research study because you are experiencing homelessness and have been admitted to St. Michael's Hospital. All research is voluntary – you do not have to participate, and you can withdraw at any time. Before agreeing to take part in this research study, it is important that you read the information in this consent form. It includes details we think you need to know in order to decide if you wish to take part in the study. If you have any questions, ask the study doctor ot study staff. You should also be aware that it is possible that the St. Michael's Hospital Principal Investigator may also be your treating doctor.

If you choose to participate in the study, you will need to sign this Letter of Information and Consent Form. You should not sign this form until you are sure you understand the information. You may also wish to discuss the study with others, such as your case manager, family doctor, a family member, or close friend.

IS THERE A CONFLICT OF INTEREST?

The study doctors and study staff do not have any conflicts of interest, financial or otherwise, related to this study or its outcome.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Individuals experiencing homelessness often face significant challenges accessing important healthcare services and social supports during and after hospitalization. The Navigator program – a unique case management program - seeks to help participants follow their post-discharge plans, address their specific needs, and connect with community-based health and social services. This study will examine health, healthcare and social service use, and quality of care transition over 180-days after hospital discharge.

The care that you will receive in the hospital will not be changed if you decide to participate in this study. All research interventions and activities will be in addition to usual care. Usual care consists of support during your hospital stay from care transition facilitators and/or social workers. All participants will also receive counselling from their care team and will be provided with a written discharge summary and/or prescription as needed.

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WHY IS THIS STUDY BEING DONE?

The purpose of this study is to examine if the Navigator program improves post-hospital outcomes for individuals experiencing homelessness. Findings from this research will be used to design new programs to improve care and post-hospital outcomes for individuals experiencing homelessness.

WHAT OTHER CHOICES ARE THERE?

You do not need to participate in this study to receive usual care from your care team, care transition facilitators, and/or social workers. However, please note that access to the Navigator program is limited to only those that participate in this study and are assigned to the Navigator program group.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 640 people will take part in this study, with 320 participants receiving the Navigator program and 320 receiving usual care.

This study should take 2 years to complete, and the results should be known in about 2.5 years.

WHAT WILL HAPPEN DURING THIS STUDY?

This is a randomized, controlled, and unblinded study. Randomized means you will be put into a group by chance, like flipping a coin. A computer program will place you into one of two study groups after the baseline interview. Your answers to the baseline interview will NOT determine which group you are placed in and the interviewer is NOT able to decide or influence which group you are placed in. You will have an equal 1 in 2 chance of being placed in one of two study groups. Group 1 includes those receiving the Navigator program and Group 2 includes those receiving usual care. This study is controlled because it includes a comparison group (Group 2), which is the usual care group that will receive the current standard of care. Unblinded means that you and your care team will know to which group you have been assigned.

WHAT IS THE STUDY INTERVENTION?

Participants in Group 1 will be assigned to a Homeless Outreach Counsellor. Participants in Group 2 will not be assigned to a Homeless Outreach Counsellor. The Homeless Outreach Counsellor will meet participants in the hospital and work with them for up to 90-days post-discharge. Services from the Homeless Outreach Counsellors will depend on the specific needs of the participants. The broad goals of the Navigator program are to link participants with resources in the community, support participants with their post-discharge plans, and help them meet their specific needs.

WHAT ARE THE STUDY PROCEDURES?

INTERVIEWS

If you consent to participate in the study, you will be asked to do a total of 2 interviews: one after you have enrolled in the study and another 30-days after your hospital discharge. The interviews will take approximately 30-45 minutes to complete. During the interviews, we will ask you a series of questions. We will collect basic information about you, your healthcare use, social service use, health status, medication adherence, care transition, and basic needs. You can skip questions that you do not wish to answer.

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Trained research assistants will be conducting the interviews. The baseline interview may take place over the phone or in-person during your current hospitalization. The 30-day interview may take place over the phone or in-person at a location that is convenient for you.

We will ask you to provide contact information so we can reach you after your hospital discharge regarding the 30-day interview. This contact information may include your phone number and e-mail. We will also ask you to provide contact information for your friends, family members, or other agency contacts.

We will ask you to contact the research team 2-3 weeks after you are discharged from the hospital to schedule your 30-day interview.

COLLECTING HEALTH-RELATED DATA FOR RESEARCH USE

If you agree to participate in this study, the study staff will collect the following information from your medical records at Unity Health Toronto (St. Michael's Hospital): basic information about you and information about your current hospitalization. . With your permission, we will also contact your primary care provider and other healthcare providers about your appointments after hospital discharge.

For participants in the Navigator program group, we will also collect information from your Homeless Outreach Counsellor about the number and nature of interactions that your Homeless Outreach Counsellor have with you, healthcare providers, and social services.

ICES DATA LINKAGE

We also ask for your permission to securely send your study data to ICES to be linked to information collected about your healthcare service use in Ontario. We will only be looking at what kinds of healthcare services you use and how often you use these services prior to enrollment in the study and after you have been discharged from the hospital . This will be done by linking your study data using your name, date of birth, and Ontario health card number to databases held at ICES. ICES is an independent and non-profit organization, whose core purpose is to conduct research that contributes to the effectiveness, quality, equity, and efficiency of healthcare and health services in Ontario. The ICES databases store information about physicians, hospitals, home care services, and medications that are paid for by the Ontario Health Insurance Plan (OHIP). This additional information will help us understand and measure the impact of the Navigator program on healthcare service use.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study intervention will last throughout your hospital stay and for about 90 days after hospital discharge.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

Your participation in this study is completely voluntary. If you choose not to participate, there will be no impact to the medical care received, employment at, or other relationship with Unity Health now or in the future for you and your family.

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You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff. The study staff may ask you if you would like to re-join the study from time to time, but the decision is yours. You are not obligated to re-join the study.

If you withdraw from the study, no more data about you will be collected. The information you have provided us up until the time that you leave the study will still be kept for research purposes, unless you give us specific instructions to discard your data.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early, and without your consent, for reasons such as:

- If continuation in the study appears to be harmful to you
- If it is discovered that you do not meet the eligibility requirements

If you are removed from this study, the study doctor will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

Some of the interview questions may seem personal and may make you feel uncomfortable or may upset you. If this happens, you do not need to answer any question that you do not wish to, and you can let the interviewer know if you would like to take a break or stop the interview. If you would like to talk to the study staff, someone from your care team, or someone outside of St. Michael's Hospital for support after the interview, please let us know and we will help you to do that.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Participants receiving the Navigator program may benefit from the case management service.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

This section describes how your personally identifying information and study data will be accessed, disclosed, and stored during this study. Personally identifying information is any information that could be used to identify you and includes your name and date of birth. Study data is information that is generated by and/or collected for a study that has been stripped of personally identifying information.

All persons involved in study will make every effort to keep your personally identifying information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act (PHIPA) of Ontario. This information will only be used to get in touch with you and access your health records with your consent. All study data collected for research purposes will be labelled with a unique study identification number instead of your personally identifying information. The Survey Research Unit at St. Michael's Hospital is in control of the key that links your study identification number to you personally and will keep it stored separately from the study data. No personally identifying information will be allowed off site in any form, unless required by law. Other than the study team or groups described in this section, no persons will have access to your personally identifiable information without your consent, unless required by law. In addition to the

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study personnel, other employees of Unity Health Toronto may have access to your personally identifying information so that they can carry out regulatory or institutionally required duties.

Accessing and Collecting Information from Your Unity Health Toronto Medical Record
By signing this form, you are authorizing access to your medical records by the study team. The study team will also collect information from your medical record. The information that will be collected is described in the Study Procedures section. The study team will use this information to conduct the study.

You are also authorizing access to your medical records by representatives of the Unity Health Toronto Research Ethics Board. Such access will only be used to verify the authenticity and accuracy of the information collected for the study, without violating your confidentiality, to the extent permitted by applicable laws and regulations.

Accessing and Collecting Information from Providers
By signing this form, you are giving us permission to contact your healthcare providers. These providers may ask you to give separate consent to allow them to release your medical information to us. The information that will be collected from other institutions or providers is described in the Study Procedures section. The study personnel will use this information to conduct the study.

Linking to ICES
Personally identifying information will be securely transferred from St. Michael's Hospital by the study investigators to ICES so the required links can be made to collect study data. The information that will be sent is described in the Study Procedures section.

USE OF EMAIL/TEXTING FOR RESEARCH
There are common risks of using email and/or texting to communicate:

- Information travels electronically and is not secure in the way a phone call or regular mail would be.
- If someone sees these emails and/or texts they may know that you are a participant in this study or see any health information included in the email and/or text.
- Emails and/or texts may be read or saved by your internet or phone provider (i.e. Rogers, your workplace, and "free internet" providers).
- Copies of an email and/or text may continue to exist, even after efforts to delete the email and/or text have been made.
- There is always a chance with any unencrypted email and/or text, however remote, that it could be intercepted or manipulated.

Do not use email and/or text messaging for medical emergencies. If you require immediate help, call your clinic or care provider, or seek emergency services.

PERSONALLY IDENTIFYING INFORMATION AND STUDY DATA STORAGE
All data used in this study will be securely stored. At each interview, responses will be collected electronically using SNAP Professional Software. This platform has been reviewed and approved for use by St. Michael's Hospital. All electronic data will be kept on a secure server in an unreadable format for anyone outside of the study. Study data may be transferred outside of Unity Health Toronto and may be

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shared with others for purposes related to the conduct of this research study. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the Unity Health Toronto Research Ethics Board.

PERSONALLY IDENTIFYING INFORMATION RETENTION

Personally identifying information collected for research purposes will be kept by the Principal Investigator and Unity Health Toronto for as long as required by Unity Health Toronto policy (currently 7 years after the study ends), at which point any documents with personally identifying information will be destroyed.

We may wish to contact you in the next 3 years regarding additional research related to this study. You are under no obligation to participate in additional research. At the end of this consent form you can let us know if you give permission for us to contact you again. If you do not want to be contacted about future research, the list connecting your personal information (such as your name and address) to your unique study identification number will be destroyed upon completion of analysis. If you do consent to be contacted about future research, we will keep this information until the end of the 3-year period. All other electronic files will be deleted, and consent forms will be destroyed 7 years after the end of the study.

STUDY DATA RETENTION

As a reminder, study data is information that is generated by or collected for a study that has been stripped of personally identifying information. Study data may be kept indefinitely and may be used for other research or analyses by the investigators. However, the results of any research from this study will include information from many people grouped together so that no one person can be identified. No records of personal information that could be linked to you will ever be reported. The Principal Investigator will protect your records and keep all your information confidential to the greatest extent possible by law.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

On the signature page of this consent form, you will be asked to consent to allow the study team to contact your family doctor and healthcare providers about your appointments after your hospitalization.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. You may also contact the Principal Investigator after the study is completed to access and discuss results.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any direct additional costs to you. If you need to travel to and from the 30-day interview, you will also be reimbursed for the cost of round-trip public transportation fare.

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ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

If you agree to participate in the study, you will be provided with honorariums after each interview to compensate you for your time. After the baseline interview, you will be provided with a $20 Tim Horton's gift card or another type of gift card such as a Presto gift card or a grocery gift card for the same amount, if requested. After the 30-day interview, you will be provided with $40 by cash, e-transfer, or cheque. Honorariums after each completed interview will be provided to you whether or not you complete the entire study. If you contact the research team 2-3 weeks after you are discharged from the hospital to schedule your 30-day interview, you will be provided with an additional $10, and will receive this at the 30-day interview, for a total of $50. If you do not contact the research team to schedule the interview, we will contact you and you will not receive the additional $10. All participants who complete the 30-day interview will receive the same $40 compensation for their time.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. You have the right to be informed of the results of this study once the entire study is complete.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. By signing this form, you do not give up any of your legal rights against the study doctor or involved institutions for compensation, nor does this form relieve the study doctor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If at any time during the study you have questions about the study or the research activities, you should contact the Principal Investigator, Dr. Stephen Hwang, at 416-864-5991(M-F, 9 AM-5PM), or contact the Research Coordinator, Rebecca Brown, at 416-864-6060 ext. 77492 (M-F, 9 AM-5PM).

If you have any questions regarding your rights as a research participant, you may contact the Unity Health Toronto Research Ethics Board Office at 416-864-6060 ext. 42557 during business hours (9:00am to 5:00pm).

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Signature Pages: Documentation of Informed Consent

EFFECT OF A NAVIGATOR PROGRAM ON POST-HOSPITAL OUTCOMES FOR HOMELESS ADULTS: A PRAGMATIC RANDOMIZED CONTROLLED TRIAL

Participant Statement of Consent

By signing this consent form, I acknowledge that:

- This research study has been explained to me, and my questions have been answered to my satisfaction.
- I have been given sufficient time to read and understand the information in this consent form.
- I have been informed of the alternatives to participation in this study.
- I know that I have the right not to participate and the right to withdraw from this study without affecting the medical care received, employment at, or other relationship with Unity Health now or in the future for me or my family.
- The potential risks and benefits (if any) of participating in this research study have been explained to me.
- I have been told that I have not waived my legal rights nor released the investigator or involved institutions from their legal and professional responsibilities.
- I know that I may ask, now or in the future, any questions I have about this study.
- I have been told that information about me and my participation in this study will be kept confidential and that no personally identifying information will be disclosed without my permission unless required by law.
- I will be given a signed and dated copy of this consent form.

I consent to participate in this study.

Participant Name (Print)	Participant Signature	Date	Time

I have explained to the above-named participant the nature and purpose, the potential benefits, and possible risks of participation in this research study. All questions that have been raised about this study have been answered.

Name of Person Obtaining Consent (Print)	Position/Title of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date	Time

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Consent for Telephone Completion (Research Staff Only)

I have explained to the participant the nature, purpose, potential benefits, and possible risks associated with participation in this research database. I confirm that the information in the letter of information and any other written information was accurately explained to, and apparently understood by, the participant. I have answered all questions that have been raised.

I will send a copy of the letter of information to the participant for his/her records.

Name of Person Obtaining Consent (Print)	Position/Title of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date	Time

Consent signed for:		on	
	Name of Participant		Date

Letter of Information sent by:		on	
	Name of Participant		Date

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CONSENT TO CONTACT HEALTHCARE PROVIDERS

I consent to the study staff contacting my primary care provider and other healthcare providers regarding my appointments for the purpose of this study.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO REVIEW MEDICAL RECORDS AT ST. MICHAEL'S HOSPITAL

I consent to the study staff reviewing my medical records at St. Michael's Hospital regarding my medical and hospitalization history for the purpose of this study.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO THE RELEASE OF INFORMATION BY CONTACT PERSONS

I consent to the study staff contacting the individuals I have listed as alternate contacts (who have agreed to be contacted if needed), organizations, and agencies that I use when attempting to contact me for the purpose of conducting the 30-day follow-up interview. I agree to allow the study staff to link my name, gender, date of birth, and health card number to obtain information from these agencies. I authorize these people to release information regarding my up-to-date mailing address and phone number to the study staff.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO THE RELEASE OF HEALTH RECORD INFORMATION BY THE HOMELESS OUTREACH COUNSELLORS

I consent to the study staff accessing my Homeless Outreach Counsellor case notes for the purpose of this study.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO THE RELEASE OF HEALTHCARE USE INFORMATION FOR ICES DATA LINKAGE

I consent to the study staff linking my provincial health card number, my name, sex, and date of birth to Ministry of Health files to obtain information about my use of healthcare services for the past three years and for the next year.

☐ Yes _____ (initials) ☐ Declined

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Consent to be Contacted in the Future for Research Purposes

We would also like to ask that you consider providing consent to be contacted about future research studies. The information that you should consider before agreeing to this is outlined below.

The study staff may wish to contact you in the next 3 years regarding additional research related to this study and the Navigator program. Study staff may contact you through phone or e-mail. Your contact information will be stored in the Master Linking Log that will be kept separately from the study data by the Survey Research Unit at St. Michael's Hospital. This data will be stored on a secure server in a password protected file. Only members of the study staff who are not connected to any part of your care will have access to your contact information.

You are not obligated to participate in any research studies that you are contacted about. If you no longer want to be contacted about future research studies, please contact the research coordinator, Rebecca Brown, at 416-864-6060 ext. 77492 (M-F, 9 AM-5PM).

STATEMENT OF CONSENT TO BE CONTACTED IN THE FUTURE FOR RESEARCH PURPOSES

	I agree to be contacted by **email**. Email address: _____ **Please note that email is not secure. Emails can be intercepted, viewed, changed, or saved by others*
	I agree to be contacted by **telephone/text**. Telephone Number: _____
	I agree that the study staff can **leave a voicemail or message** if I do not answer the telephone.

I have read the above information, and I agree to be contacted for future research as indicated above.

Participant Name (Print)	Participant Signature	Date

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If participant is not able to read independently for any reason:

Declaration of Assistance – Witness to Consent Process

Study Participant's Name (Print): _____

ASSISTANCE DECLARATION AND SIGNATURE:
I have provided assistance during the consent discussion between the potential participant and the person obtaining consent by (please check one):

- ☐ Acting as a witness to the consent discussion
- ☐ Assisting in delivery of consent discussion (reading/oral), including communication of questions and responses
- ☐ Other: _____

I attest that the information was accurately explained, and the participant has freely given consent to participate in the research study.

Name of Person Assisting Consent (Print)	Signature of Person Assisting Consent	Date	Time
_____	_____	_____	_____

Relationship to Study Participant: _____

Contact Information of Person Assisting Consent: _____

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If participant has limited proficiency in English:

Declaration of Assistance – Interpreter

Study Participant's Name (Print): _____

INTERPRETER DECLARATION AND SIGNATURE:
I am competent in the English language and in the preferred language of the potential participant: _____ (name of language)

I am not involved in the research study or related to the participant. I agree to keep confidential all personally identifying information of the participant. I have faithfully interpreted the consent discussion and provided a sight translation of the written informed consent form as directed by the study staff obtaining consent.

_____	_____	_____	_____
Name of Interpreter (Print)	Signature of Interpreter	Date	Time

Contact Information of Interpreter: _____

Online Supplemental File 2: Adjudication Rules for Primary Outcome

A Patient 30-day Interview Self-Report	B Primary Care Office Report[1]	C Adjudication of A and B	D ICES Administrative Data	E Final Adjudication (Yes if C=Yes or D=Yes)
Yes	Yes	Yes	Yes	Yes
Yes	Yes	Yes	No	Yes
Yes	Yes	Yes	n.d.	Yes
Yes	No	No	Yes	Yes
Yes	No	No	No	No
Yes	No	No	n.d.	No
Yes	n.d.	Yes	Yes	Yes
Yes	n.d.	Yes	No	Yes
Yes	n.d.	Yes	n.d.	Yes
No	Yes	Yes	Yes	Yes
No	Yes	Yes	No	Yes
No	Yes	Yes	n.d.	Yes
No	No	No	Yes	Yes
No	No	No	No	No
No	No	No	n.d.	No
No	n.d.	No	Yes	Yes
No	n.d.	No	No	No
No	n.d.	No	n.d.	No
n.d.	Yes	Yes	Yes	Yes
n.d.	Yes	Yes	No	Yes
n.d.	Yes	Yes	n.d.	Yes
n.d.	No	No	Yes	Yes
n.d.	No	No	No	No
n.d.	No	No	n.d.	No
n.d.	n.d.	No	Yes	Yes
n.d.	n.d.	No	No	No
n.d.	n.d.	No	n.d.	No

n.d. = no data.

[1]The primary care provider (PCP) office will be contacted under any of the following circumstances: (1) participant reports PCP visit at the 30-day interview, (2) participant reports no PCP visit at the 30-day interview AND a PCP is identified at the baseline interview or 30-day interview, or (3) participant misses the 30-day interview AND a PCP is identified at the baseline interview.

Online Supplemental File 3: Detailed Descriptions of Study Instruments

Instrument	Description
EQ-5D-3L and VAS	The EQ-5D-3L is a generic measure of health-related quality of life that has been widely used among the homeless population. The EQ-5D-3L includes five three-level items concerning mobility, self-care, usual activities, pain/discomfort, and anxiety/depression that are weighted to produce a single utility score between 0 and 1. The Visual Analogue Scale (VAS) of the EQ-5D-3L will also be included, which will allow participants to rate their overall health, mental health, and physical health from 0 to 100. References: 1. Janssen, M. F., Pickard, A. S., Golicki, D., Gudex, C., Niewada, M., Scalone, L., ... & Busschbach, J. (2013). Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. *Quality of life research*, *22*(7), 1717-1727. 2. Stergiopoulos, V., Hwang, S. W., Gozdzik, A., Nisenbaum, R., Latimer, E., Rabouin, D., ... & At Home/Chez Soi Investigators. (2015). Effect of scattered-site housing using rent supplements and intensive case management on housing stability among homeless adults with mental illness: a randomized trial. *JAMA*, *313*(9), 905-915.
MMAS-8	The MMAS-8 is a validated self-reported measure for medication-taking behavior that has been used among disadvantaged patients and those with chronic illnesses. The MMAS-8 consists of eight items, the first seven of which are yes/no questions, and the last of which is a five-point Likert-scale rating. Each ‘‘no” response is rated as ‘‘1” and each ‘‘yes” is rated as ‘‘0” except for item 5, in which each ‘‘yes” is rated as ‘‘1” and each ‘‘no” is rated as ‘‘0”. For item 8, if a patient chooses response ‘‘0”, the score is ‘‘1” and if they choose response ‘‘4”, the score is ‘‘0”. Responses ‘‘1, 2, 3” are respectively rated as ‘‘0.25, 0.75, 0.75”. Total MMAS-8 scores can range from 0 to 8 and are categorized into three levels of adherence: high adherence (score = 8), medium adherence (score of 6 to 8), and low adherence (score < 6). References: 1. Moon, S. J., Lee, W. Y., Hwang, J. S., Hong, Y. P., & Morisky, D. E. (2017). Accuracy of a screening tool for medication adherence: A systematic review and meta-analysis of the Morisky Medication Adherence Scale-8. *PloS one*, *12*(11), e0187139. 2. Feehan, M., Morrison, M. A., Tak, C., Morisky, D. E., DeAngelis, M. M., & Munger, M. A. (2017). Factors predicting self-reported medication low adherence in a large sample of adults in the US general population: a cross-sectional study. *BMJ open*, *7*(6), e014435.

CTM-3	The most widely used measure of care transition quality is the Care Transition Measure (CTM). The CTM-3 is an abbreviated version of the original CTM-15, which measures the extent to which the healthcare team accomplished essential care processes in preparing the patient for discharge and participating in post-hospital self-care activities. The CTM-3 consists of three items with a four-point scale with responses ranging from "Strongly Disagree" (1) to "Strongly Agree" (4) to the following questions: 3. During this hospital stay, staff took my preferences into account in deciding what my healthcare needs would be when I left. 4. When I left the hospital, I had a good understanding of the things I was responsible for in managing my health. 5. When I left the hospital, I clearly understood the purpose for taking each of my medications Items are scored by summing the responses and then linear transforming to a 0-100 range. References: 1. Parry, C., Mahoney, E., Chalmers, S. A., & Coleman, E. A. (2008). Assessing the quality of transitional care: further applications of the care transitions measure. *Medical care*, 317-322. 2. Coleman, E. A., Smith, J. D., Frank, J. C., Eilertsen, T. B., Thiare, J. N., & Kramer, A. M. (2002). Development and testing of a measure designed to assess the quality of care transitions. *International journal of integrated care*, *2*.
RAND Course of Homelessness Scale	Developed specifically for homeless populations, the RAND scale is a five-item index of self-reported difficulty in meeting the following subsistence needs over the past 30 days: frequency of difficulty in finding shelter, enough to eat, clothing, a place to wash, and a place to use the bathroom. Possible responses to each item are never (1), rarely (2), sometimes (3), or usually (4) with total scores between 5-20. Reference: 1. Gelberg, L., Gallagher, T. C., Andersen, R. M., & Koegel, P. (1997). Competing priorities as a barrier to medical care among homeless adults in Los Angeles. *American journal of public health*, *87*(2), 217-220.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1 and 23
	5b	Name and contact information for the trial sponsor	N/A
	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	23
	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)	N/A

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	5-7
	6b	Explanation for choice of comparators	10
Objectives	7	Specific objectives or hypotheses	7
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)	7-9
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	7-8
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)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-11
	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)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
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	12-14

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)	8-9
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	15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8-9
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	9
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	9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	15
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	15
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	12-14

	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	9
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	21-22
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	15-20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15-20
	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)	17
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	N/A
	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	N/A
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	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20

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)	21
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Appendix
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	21-22
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
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	21-22
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	N/A
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	21-22
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	21-22
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix
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	N/A

*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" license.