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A pragmatic trial evaluating the effectiveness of a patient navigator to decrease emergency room utilization in transition age youth with chronic conditions: The Transition Navigator Trial

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ABSTRACT

Background: Transition to adult care is a challenging and complex process for youth with special health care needs.

Objectives: To compare effectiveness of a patient navigator service in reducing emergency room (ER) use among adolescents with chronic health conditions transitioning to adult care.

Design: Pragmatic randomized controlled trial parallel group design comparing ER visit rates between patients with access to a personalized navigator intervention compared to usual care. Unit of randomization is the patient. Treatment assignment will not be blinded. Embedded qualitative study to understand navigator's role and cost analysis attributable to the intervention will be performed.

Setting: Province of Alberta, Canada, recruitment from 3 tertiary care pediatric hospitals

Participants: Patients age 16-21 years, followed within a chronic disease clinic, and expected to be transferred to adult care within 12 months and reside in Alberta during study period. Sample size is determined to be 300 in each arm.

Intervention: Navigator intervention over 24 months is designed to assist participants in 4 domains: transition preparation, health system brokering, socioeconomic determinants of health, and self-management.

Primary and secondary outcome measures: Primary outcome is ER visit rate during observation period. Secondary outcomes are ambulatory and in-patient care utilization measures, as well as Transition Readiness Assessment Questionnaire score, and Short-Form Health Survey 12 (SF-12) score at 6 and 18 months post-randomization.

Analysis: Intention to treat analysis will be used. Poisson regression will compare rates of ER/urgent care visits between navigator and control participants. A cost analysis of the intervention will be conducted using high quality administrative health datasets. Thematic analysis will be used to identify perceptions of stakeholders regarding the role of navigators in reducing barriers to care.

Conclusion: The study results have the potential to change health care delivery and improve health outcomes and transition experiences of youth with special health care needs.

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Strengths and Limitations of this study

[5 short bullet points]

- Population based sample
- Pragmatic randomized controlled trial design
- Innovative navigator intervention, provided within the healthcare setting
- Inclusion of youth having a broad range of chronic health conditions

INTRODUCTION

Approximately 15-20% of adolescents in North America live with a chronic health condition, defined as a condition that lasts at least 3 months, is not yet curable, affects a child's normal activities, and requires ongoing care.[1] The majority (>90%) will require transfer from pediatric to adult services.[1,2] Sub-optimal transition to adult care leads to poor adherence with ambulatory care management, health deterioration and increased use of costly emergent health services.[3,4] Patient navigators are a promising, but unproven intervention to facilitate planned transitions from pediatric to adult care, and improve patient experience and outcomes.[5] Published studies describing patient navigator services are mostly single centre and single disease cohort studies, with non-randomized designs, thus, limiting generalizability to other health jurisdictions and disease populations.[5] Further, interventions requiring highly skilled health care workers tend to be expensive, and to justify such an intervention, a cost evaluation is necessary. To address these challenges we designed a pragmatic RCT, the Transition Navigator Trial (TNT), the protocol for which is described in this paper.

Trial Objectives

The primary objective is to evaluate the impact of a personalized transition to adult care intervention (access to a patient navigator) compared to usual care for 16-21 year olds living with chronic health conditions who are transferring to adult care with respect to: a) ER/urgent care visits (*primary outcome*); and b) inpatient and ambulatory care utilization, transition readiness scores, and patient-reported health status (*secondary outcomes*). Secondary objectives are: a) to determine the net health care cost impact attributable to the patient navigator intervention; and b) to obtain perceptions of stakeholders regarding the role of patient navigators in reducing barriers to adult-oriented ambulatory care.

Hypotheses

The patient navigator intervention will reduce all-cause ER/urgent care visit rates, improve transition readiness scores and patient-reported health status, and generate cost savings for the health system.

METHODS AND ANALYSIS

This study will be conducted in accordance with the SPIRIT checklist[6-8] and CONSORT statement on pragmatic trial extension[9] (RCT), and COREQ.[10,11] Ethics approval was obtained from the University of Calgary Conjoint Health Research Ethics Board (REB #162561) and the University of Alberta Health Research Ethics Board (Pro00077325).

Study Design and Setting

This study will use a parallel group**,** pragmatic RCT[9] design (Figures 1 and 2) with an embedded qualitative study. The RCT involves random allocation of young adults (ages 16 to 21 years) with a chronic medical/mental health condition to either a personalized transition intervention (access to a patient navigator) or usual transitional care at one of three tertiary care pediatric hospitals in

Alberta, Canada.

Alberta, with a population of 4.1 million, has a universal publicly funded health care system that covers over 99% of the population.[12] Patients will be recruited from 3 tertiary care pediatric hospitals: the Stollery Children's Hospital, Alberta Children's Hospital, and Glenrose Rehabilitation Hospital.

Recruitment

Eligible participants will be identified from 41 pediatric specialty clinics at the 3 participating hospitals (Figure 3). These clinics were selected after extensive stakeholder input, as these patient groups have high potential for adverse outcomes if transitions are not managed optimally.[4,12-15] Participants will have chronic health conditions in these broad categories: endocrine, gastrointestinal, neurologic, neurodevelopmental, rheumatologic, renal, cardiac, hematologic, respiratory, and metabolic/genetic. The primary caregiver (legal guardian or parent) of the young adult will also be considered a study participant if he/she is willing; however, parent/guardian involvement is not a requirement. Primary caregiver will also provide information required for the study should the patient be non-verbal or lack capacity to participate in the study.

Potentially eligible participants will be recruited through various methods including: 1) clinic staff identifying potential participants and requesting consent to contact by the study team, 2) patients can directly self-refer using a generic study email or phone number provided in recruitment posters, and 3) using mail-outs to potentially eligible participants who have used health services at the participating hospitals.

Trained research assistants are responsible for responding to any queries for enrollment via telephone or email. These research assistants are also responsible for screening potential participants for eligibility. The screening process is being conducted in person or by phone.

Inclusion criteria

To be eligible, participants must: (1) be between 16 and 21 years of age at the time of enrollment, (2) be receiving care from at least one of the selected pediatric outpatient hospital and community clinics (Figure 3), (3) have a chronic medical condition (defined as conditions which are >3 months in duration and/or lifelong with multiple morbidities and/or multi-organ/system manifestations or conditions which typically affect a single organ/system)[16,17] and (4) be expected to be transferred to adult specialty care in the next 12 months.

Exclusion criteria

Exclusion criteria will be: (1) enrolled in another transition-related study involving a navigator or similar intervention; (2) transfer will not occur during the time interval for the study; (3) will be moving out of Alberta during the study (e.g., going away for college) resulting in inability to report on primary outcome (ER visits) within the province; (4) inability to read and write in English.

Consent

Informed written consent will be obtained from all participants prior to enrollment. For patients who are minors (age 16-17), informed assent will be obtained where appropriate. When the patient is considered a mature minor (after a capacity assessment by the responsible physician) or at age 18, we will obtain consent. If a patient is consenting for him/herself, then consent forms will ask participants for permission to contact their parents/guardians as needed to facilitate care, and also for permission to disclose medical information to parents/guardians. Should the participant decline parent involvement in the study, parents will not be contacted nor will health information be provided to the parent.

The primary caregiver will consent for his/her own respective participation. Primary caregivers will also consent on behalf of young adult participants who lack capacity to do so themselves due to developmental delay. Consent for disclosure of personal health numbers (PHN) assigned by Alberta Health for universal health care access will be obtained, to allow examination of health service utilization at the patient level by linkage to administrative health datasets.

Participation will be voluntary and participants will be free to withdraw at any time. A small incentive will be offered to participants ($25 at enrollment and $25 at study end), as a token of appreciation of their participation.

Study Timeline

Participants will be recruited over ~42 months. Recruitment started in January 2018, and will continue until target enrolment is reached. The duration of navigator support for participants in the intervention arm will be up to 24 months after randomization, and a minimum of 12 months for those enrolled later in the recruitment period. All participants will be observed for a minimum of 12, and maximum of 42 months. See timeline in Figure 4. A schematic diagram outlining the schedule of enrolment, assessments, and visits is shown in Table 1.

Form	Screening	Enrollment	Randomi-zation	Baseline	Repeat-able	Months Post-Randomization							
						3	6	9	12	15	18	21	24
CONSENT - Participant	X												
CONSENT - Caregiver	X												
ASSENT - Participant	X												
Screening Form	X												
Participant Demographics		X											
Caregiver Demographics		X											
Contact Information		X											
Baseline Medical		X											

Allocation			X										
End of Study Form													X
TRAQ 5.0				X			X		X		X		X
SF-12				X			X		X		X		X
Navigator Initial Encounter				X									
Navigator Encounter Form					X								
Navigator Critical Encounter					X								
Navigator Review						X	X	X	X	X	X	X	X
Fidelity Checklist						X	X	X	X	X	X	X	X
Case Closure													X
Pre-Intervention Interview				X									
Post-Intervention Interview													X

Table 1: Schedule of assessments for participants in the trial. TRAQ: Transition Readiness Assessment Questionnaire, SF-12: Short-Form 12 Health Survey.

Feasibility and Sample Size

There are approximately 600 prevalent patients between 16-18 years of age receiving care at each of the Alberta Children's Hospital and Stollery Children's Hospital. The Glenrose Rehabilitation Hospital has approximately 250 patients age 16-18 years. Estimated consent rate is 79% (based on our experience with transition trials).[18,19] We expect to recruit approximately 14-15 patients per month to reach our target sample size in 42 months. Clinic "champions" (physician, nurse or social worker leads) have been identified at all participating clinics to liaise with the study team and facilitate recruitment. A maximum case-load of 140-150 patients per patient navigator (one each in Edmonton and Calgary) is anticipated. This volume is considered feasible based on a similar case load of pediatric clinicians who have provided pediatric to adult transitional care in Alberta.

Sample size calculation was based on the primary outcome (i.e., ER/urgent care visit rate) during the period of observation. The baseline ER/urgent care visit rate observed within a diverse cohort of transitioning patients in Calgary, as identified using available administrative data, is 51 per 100 person years of follow-up, for age ≥18 years. Our team, composed of stakeholders from various levels of health service delivery, confirmed that a minimum clinically important difference between groups is a 20% (relative change) drop in ER visits. Based on effect size seen in a prior study evaluating transition navigators' impact on diabetic ketoacidosis admissions in diabetic patients,[20] we expect a 20-25% relative rate reduction in the intervention group compared to the control group. Assuming an ER/urgent care visit rate of 40 per 100 person years (21% rate reduction) in the intervention group, with significance level of alpha = 0.05 and 80% power, with an average follow-up of 2.04 years based on 24 months of recruitment and 36 months of maximum observation for outcomes, based on comparison between two Poisson rates, the needed sample size

in each arm is 300. Loss to follow-up will not affect our ability to measure the primary outcome, as we are using administrative health data. We have extended our recruitment time from 24 months to 42 months, in response to slow recruitment at the beginning of the study.

Allocation and Blinding

Participants will be randomly allocated after consent to either the patient navigator intervention or usual care in a 1:1 ratio using a computer-stratified generated randomization sequence, generated a priori by a statistician (author ANA) with varying block sizes, stratified by primary clinic affiliation. Randomization scheme will be executed in REDCap research software.[21] Study coordinators at each site ascertain group allocation by clicking 'randomize' on REDCap, and inform participants of their assigned study arm.

Intervention assignment will not be blinded from trial participants, family members, research assistants, or clinical teams. All patients/family participants will be blinded to the primary outcome (ER/urgent care visit) and hypothesized effects of the study. The navigators will not be blinded to the primary hypothesis. Full details of the navigator intervention will not be available to clinic staff/control participants to minimize contamination of the intervention to the control group. Data analysts will be blinded to group allocation and the nature of the intervention.

Study Intervention

There will be one navigator in each of Calgary and Edmonton serving approximately 150 participants. These navigators are employees of Alberta Health Services (AHS), the organization that provides government-funded health care to >99% of Alberta residents. Individuals eligible for the patient navigator position will have a minimum of a Bachelor's degree in Social Work and 5 years of clinical experience, including experience working with adolescents and/or young adults. The navigator will be familiar with resources and health services available within AHS and the community. The intervention group will also receive usual care.

The intervention (personalized transition support, access to a patient navigator) is designed to overcome barriers and challenges experienced by transferring patients by facilitating a coordinated entry into the adult system, to increase appropriate use of adult-oriented ambulatory primary and specialty care, and reduce ER/urgent care visits (primary outcome).[22,23] We developed a structured navigator intervention with four distinct inter-related modules based on literature highlighting the need for each[5], our pre-trial qualitative findings[24], and in collaboration with content experts in transition models, partners in Alberta Health Services, and patient/parent advisory committees. We also developed a 2-day training program for the navigators to complete prior to start of the trial. The training consists of readings, case scenarios, and role plays. The modules are:

- **Module 1 Prepare for transfer of care**[25-28] complete needs, risk and transition readiness assessments using a structured approach with modified SSHADESS psychosocial assessment[29] (see supplementary material); create medical passport; help establish relationships with primary care providers and appropriate specialty care providers; and enable timely attendance at first adult clinic visit.
- **Module 2 Navigator as a health system broker**[30-32]: assist with data sharing between

pediatric and adult service providers; work with patient and primary care providers to facilitate continuity of care; promote communication, collaboration, and patient and family centered care between all providers; and advocate with/for patient/family.

- **Module 3 Social determinants of health**[33-35]: assist families with barriers related to social and economic determinants of health to reduce modifiable barriers to accessing ambulatory medical care after transfer.
- **Module 4 Promote self-management of medical conditions**[36-39]: provide information and access to tools, educational resources, and peer support groups; track follow-up clinic visits, medication refills and laboratory testing in order to flag non-adherence early and provide coaching to reduce barriers to adherence; and plan for medical and/or mental health crisis management.

Once a participant is randomized to the intervention group, the navigators will contact the participant within 7 days to schedule a face-to-face (or phone meeting if necessary for rural dwelling patients) meeting during which the navigator will complete tasks in Module 1. Using information obtained at this initial assessment, the navigators will use an adaptive[40], patient-centered approach that customizes delivery of services based on needs of the patient, and consistent with principles and practice outlined in Modules 2-4. Navigators will use telephone, text messages, email messages, and in-person visits to maintain contact with participants as needed during the course of the intervention. Navigators will be alerted to ER/urgent care visits of participants by either the participants, caregivers (if appropriate), clinical providers, or through use of electronic medical record alerts. The navigator will review circumstances related to ER/urgent care visits, and inform preventative actions based on the intervention modules. Scheduled patient reviews (in person, or by telephone contact) will occur every 3 months (see Schedule of Assessments, Table 1). The navigators will record every contact and nature of assistance provided using standardized forms.

Fidelity

Procedures for monitoring adherence to intervention fidelity by the navigators will be managed by the Operational Oversight Committee (investigators, policy makers, navigator's supervisors), and its role will be to assess and enhance fidelity to the intervention throughout the trial. The committee will review the patient navigator intervention using qualitative interviews of stakeholders and participants after the first 5 participants are enrolled into the intervention arm in each site. The knowledge gained from the review will be utilized to optimize the intervention protocol and address barriers to intervention fidelity across all sites.

Deviations will be carefully documented by navigators during their course of the trial. The navigators will complete a standardized fidelity checklist at the end of each patient encounter to assess their adherence to skills, interventions and pathways described in the intervention modules (Supplementary Material). Concomitant interventions which duplicate the intervention in whole or in part will be not be permitted during the trial.

Usual care group: Participants assigned to the usual care group will receive care as available within adult and pediatric clinics and the health region. However, this group is *not* a 'no intervention' group; in addition to care provided by their clinical teams, the study team will

provide usual care participants with information in the form of infographics and quarterly newsletters, regarding transition to adult care resources such as young-adult oriented transition websites, self-management tools, and the opportunity to attend transition-focused workshops. Significant variation in transitional care is expected in this group within and across sites (based on our prior stakeholder engagement work).

To minimize attrition, all participants in the intervention and usual care group will receive electronic newsletters every 4 months, letters thanking them for their participation to date and email and phone reminders for follow-up data collection.

Outcome and outcome measures

Outcome measures and the assessment schedule are summarized in Table 1. The primary outcome is the rate of all-cause ER and urgent care visits during the observation period. Patients, providers, and policy makers on our team considered ER/urgent care visits to be relevant, and measureable in a blinded fashion across all clinical groups. We will obtain consent from trial participants to use their personal health numbers to link with health service utilization data. All ER and urgent care visits attributed to participants will be obtained from the National Ambulatory Care Reporting System[41], and the Clinical Analytics Team of AHS will conduct all analysis. AHS is the custodian of all Alberta Health data for >99% of population.

We will evaluate ambulatory and inpatient care utilization measures as secondary outcomes (primary care visits, specialty care ambulatory care visits, in-patient admissions, ICU admissions, and length of hospital stay). Outcome measure will be the rate of events. This data will be obtained from the Canadian Institute for Health Information Discharge Abstract Database[42], and physician billing claims database[43].

Other secondary outcomes are the Transition Readiness Assessment Questionnaire (TRAQ), and patient reported health status as measured by the 12-Item Short Form Health Survey (SF-12). The TRAQ is the best-validated transition readiness scale for adolescents[44,45]. The questionnaire consists of 29 items, at grade 5.7 reading level, and takes ~5 minutes to complete. Participants will complete the TRAQ online at baseline, 6, 12, 18 and 24 months. Regarding general health, participants will complete the 12-Item Short Form Health Survey (SF-12) which is a validated 12 item survey that measures self-reported health status in individuals >14 years of age.[46] The survey includes questions concerning physical functioning, role limitations because of physical health problems, bodily pain, general health perceptions, vitality (energy/fatigue), social functioning, role limitations because of emotional problems, and general mental health (psychological distress and psychological well-being). Participants will complete the SF-12 at baseline, 6, 12, 18 and 24 months.

We will prospectively capture the cost of the navigator intervention using micro-costing methods[47] (identification, measurement, and valuation) that include one time and ongoing costs (development of materials, capital costs, wage rates for navigators, number of patients in caseload), enabling estimation of the cost of this intervention per patient served, using high quality administrative datasets from the AHS Clinical Analytics data repository.[48]

Data monitoring and trial management

The trial protocol is registered at www.clinicaltrials.gov (NCT03342495). The trial is governed by multiple stakeholder groups, including clinicians and policy makers at each of the recruiting sites, study team members, and youth and family members. The Executive Trial Team is composed of the principal investigators and research team members, as well as site representatives and a patient representative. The team is supported by the larger Trial Management Committee, Operational Oversight Committee, Data Safety Monitoring Board (DSMB), Patient and Family Advisory Council and Scientific Advisory Board. A governance chart is provided in Figure 5.

Potential adverse events will be monitored in both study groups, however, the intervention is considered to be of minimal risk. No interim analysis is planned. The DSMB consists of 3 individuals who are familiar with the patient population and study question, but unfamiliar with the research team. The board will meet at least twice a year and monitor the trial in terms of safety of the participants and rigor of the data collection procedures.

Analytical Plan

All analyses will be intention-to-treat. We will use Poisson regression to compare rates of ER/urgent care visits between the navigator and usual control groups, with fixed as well as random effects per site, and random effect by primary clinic. Demographic and medical characteristics that could be potential confounders or independent risk factors (e.g. age, primary disease, socioeconomic status, location of residence, medical and mental health co-morbidity in participant, ethnicity, immigrant status, demographic characteristics and medical/mental health of parents/caregivers obtained with consent) will be collected *a priori*, and used for adjusting the Poisson model. All other health utilization outcomes will be analyzed using descriptive statistical methods and by key demographic variables. For TRAQ and SF-12 scores we will assess the effect of time (baseline, 6, 12, 18 and 24 months) on the scores using linear regression with random effects for subject and clinic.

For the economic evaluation, we will use established methods to enable comparisons of mean costs, as these are easily interpretable and relevant to health care payer. We will include the full cost of the navigator intervention (for intervention group) and the health care cost categories noted above and will use non-parametric bootstrap estimates to derive 95% confidence interval and mean cost differences between the treatment arms.[49,50] We will use 1000 bias-corrected bootstrap replications (including sampling with replacement from the original data) to estimate the distribution of a sampling statistic to derive 95% confidence intervals.[49] We will also compare cost by category (in-patient, ER, ambulatory care, physician claims) between both groups.

Qualitative data analysis

All interviews and focus groups will be audio-taped and transcribed verbatim, and NVivo software (QSR International Pty Ltd., Version 10, 2012) will be used for analysis. Thematic analysis will be used to extrapolate and systematically analyze patterns in the data generated by the qualitative interviews.[50] We will closely adhere to the steps delineated by Braun and Clarke[51] for conducting thematic analysis. We will use Krueger and Casey's[52] constant comparative method of analysis to

analyze the focus group data. This method involves "cutting, sorting, and arranging through comparing and contrasting." The coding process consists of grouping similar concepts and ideas, while identifying themes and categorizing results. The research team will engage in established steps to increase the validity, credibility, transferability, and dependability of findings by adhering to guidelines for publication of qualitative research studies.[53]

Confidentiality

The RCT and qualitative studies will adhere to the Personal Health Information Protection Act and all other regulatory and organizational standards for privacy, confidentiality and security of database information. All patient-identifiable electronic data will be stored in password protected encrypted files on a secure network. Any identifiable information stored on REDCap will only be accessed by the investigative team and will be de-identified in the data export prior to analysis. All identifying information stored on paper will be stored in locked cabinets.

Dissemination

We have used an integrated knowledge translation approach.[54,55] Our team is comprised of patient representatives, researchers, clinical service providers and senior policy makers who are committed to improving transition and transfer of care within Alberta. At the end of the study, we will conduct face to face stakeholder meetings to develop a holistic understanding of the barriers and facilitators to transitional care and the effectiveness of the patient navigator service using both quantitative and qualitative data obtained in this study.

Discussion

The Transition Navigator Trial is a unique pragmatic population based trial which will address a significant gap in knowledge in the area of transition to adult care. The study will overcome previous methodological limitations including small sample sizes, non-generalizability due to diagnosis- specific inclusion criteria, and non- randomized designs. The results will have the potential to change health care delivery, improve health outcomes, and enhance experiences of young adults transitioning to adult care. The study will also provide a better understanding of the barriers and facilitators to transitional care and the effectiveness of the patient navigator service using both quantitative and qualitative data. We will determine what elements of the navigator service are most beneficial to participants, and whether the intervention is cost saving.

The evidence base for health care interventions during transition to adult care is limited by a paucity of data from controlled studies. Various interventions have been described and tested to a limited extent, mostly using non-randomized designs. Most are single centre, single disease studies, with limited generalizability. Gabriel *et al.*[5] performed a systematic review of evidence focused on transition interventions. They report that structured transition interventions led to improvement in patient reported quality of life and perceived health status in several studies, suggesting potential publication bias. No studies have found significant cost savings; several studies found that having a structured transition process resulted in increased visits to the new adult provider, and a reduced time lag between the last pediatric visit and the first adult visitpstein[56]

The current study will be aligned with the Triple Aim Framework for health service evaluation[57]. Interventions requiring highly skilled health care workers tend to be expensive, and to justify such an intervention, a cost evaluation is necessary. Complex interventions require assessment of fidelity to examine whether the intervention was delivered as intended, including a description of the interventions. This study will address these challenges.

In conclusion, this pragmatic RCT will evaluate the impact of a patient navigator service on rates of urgent care/ER visits and will provide patient, family and provider perceptions of the transition experience and the navigator service. This study will provide urgently needed data to guide pediatric and adult health care providers and policy makers regarding optimal transitional care delivery.

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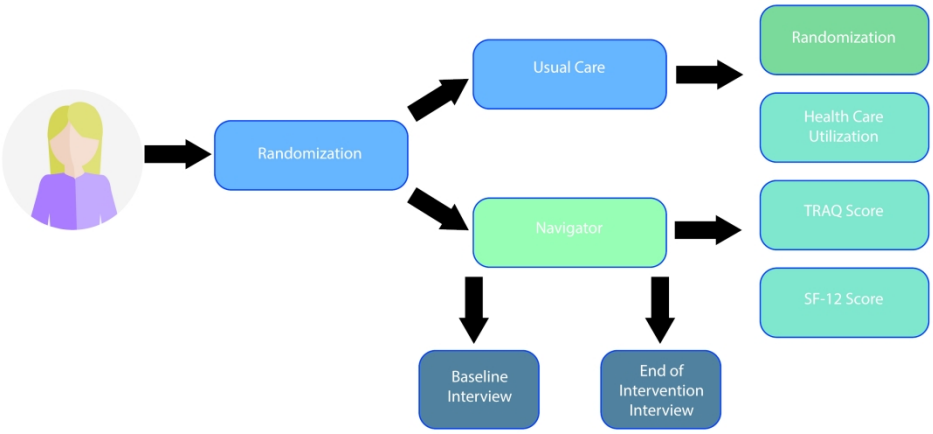

Figure 1 Trial Design

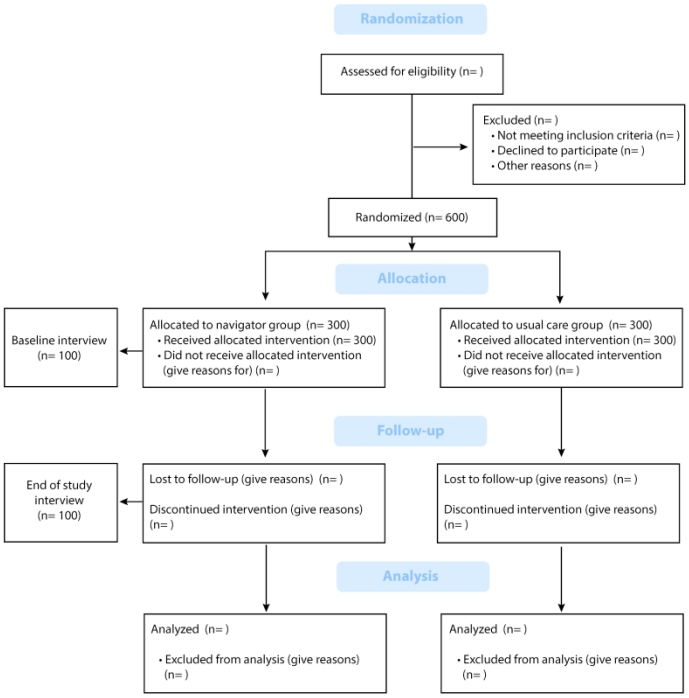

Figure 2 CONSORT Diagram

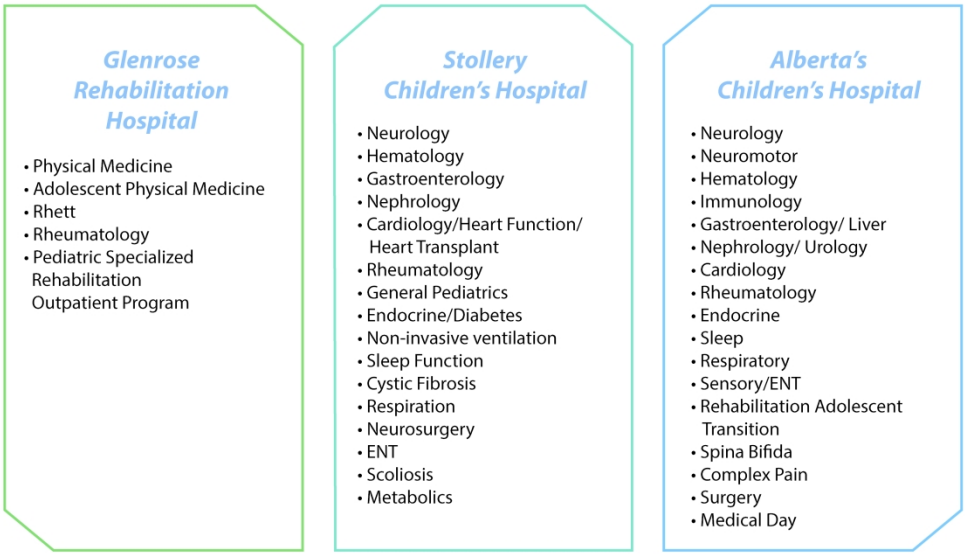

Figure 3 Participating Clinics

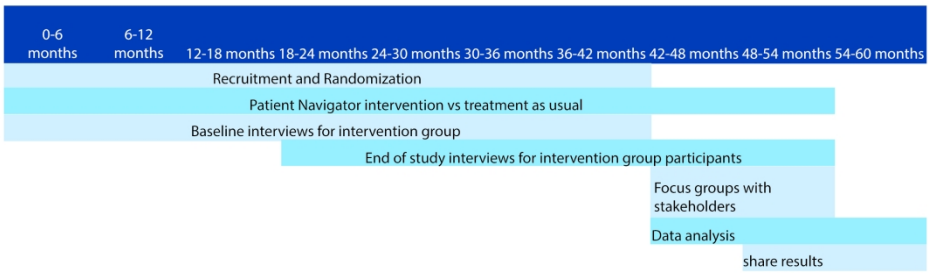

Figure 4 Study Timeline

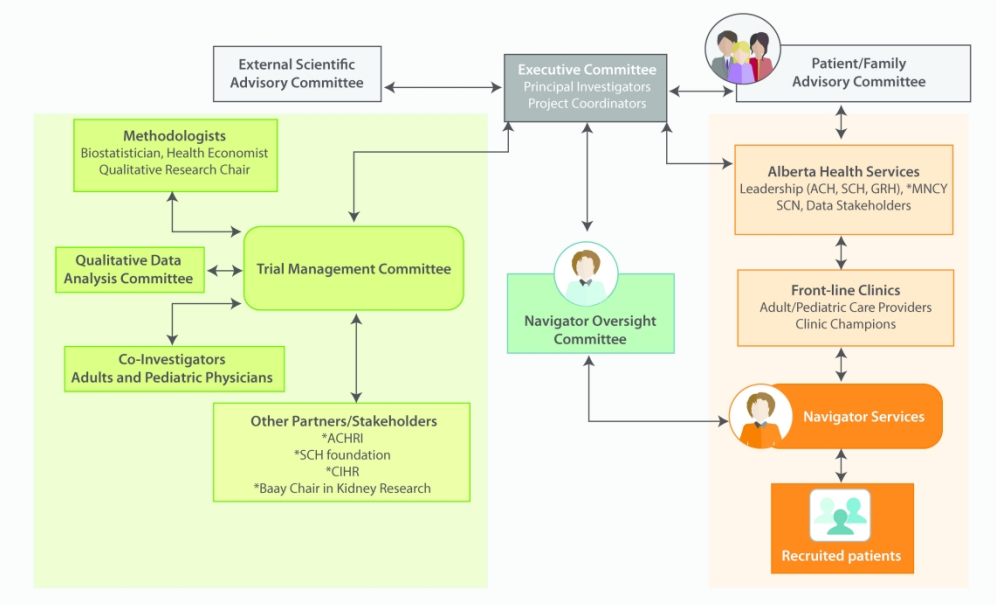

Figure: Governance of the Transition Navigator Trial. ACH: Alberta Children's Hospital; **ACHRI:** Alberta Children's Hospital Research Institute; **GRH:** Glenrose Rehabilitation Hospital; **MNCY SCN:** Maternal Newborn Child Youth Strategic Clinical Network; **SCH:** Stollery Children's Hospital

Figure 5. Trial Governance

Supplementary Material

Navigator Fidelity Checklist

Date of Transfers

In how many clinics is this participant being transferred?

- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6

Date of Reviews

Date of 3 Month Review _____ (YYYY-MM-DD)

Date of 6 Month Review _____ (YYYY-MM-DD)

Date of 9 Month Review _____ (YYYY-MM-DD)

Date of 12 Month Review _____ (YYYY-MM-DD)

Date of 15 Month Review _____ (YYYY-MM-DD)

Date of 18 Month Review _____ (YYYY-MM-DD)

Date of 21 Month Review _____ (YYYY-MM-DD)

Date of 24 Month Review _____ (YYYY-MM-DD)

Module 1: Preparing for transfer of care

	3 month	6 Month	9 month	12 month	15 month	18 month	21 month	24 month	N/A
Explained the ROLE of the navigation service	☐	☐	☐	☐	☐	☐	☐	☐	☐
Discussed/provided RESOURCES on patient and family-centered care	☐	☐	☐	☐	☐	☐	☐	☐	☐
Completed psychosocial ASSESSMENTS (HEADSS, SSHADESS)	☐	☐	☐	☐	☐	☐	☐	☐	☐
Completed a comprehensive TRANSITION PLAN	☐	☐	☐	☐	☐	☐	☐	☐	☐
Facilitated TRANSFER of medical and psychosocial DATA	☐	☐	☐	☐	☐	☐	☐	☐	☐
Helped participant prepare succinct COMMUNICATION TOOLS (e.g., medical passport, 3 sentence health summary)	☐	☐	☐	☐	☐	☐	☐	☐	☐

Assisted with SCHEDULING adult oriented medical appointments	☐	☐	☐	☐	☐	☐	☐	☐	☐
Assisted with ACCESSING RESOURCES/SERVICES within the community and/or adult-oriented health services	☐	☐	☐	☐	☐	☐	☐	☐	☐
Helped participant find a FAMILY DOCTOR or primary care clinic	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments:

_____

Module 2: Promote self-management

	3 month	6 Month	9 month	12 month	15 month	18 month	21 month	24 month	N/A
COACHED self-management skills and identified strategies to promote adherence to medical care plans (e.g., role play, checklists)	☐	☐	☐	☐	☐	☐	☐	☐	☐
Directed participant to TOOLS/RESOURCES to support self-management	☐	☐	☐	☐	☐	☐	☐	☐	☐
Worked with participant (also caregivers and providers as appropriate) to ADDRESS BARRIERS to adherence with medical care plans	☐	☐	☐	☐	☐	☐	☐	☐	☐
MONITORED ADHERENCE to medical care plans by direct report from participant (caregivers and/or providers as appropriate) or indirectly by reviewing medical records	☐	☐	☐	☐	☐	☐	☐	☐	☐
Established PLAN to address medical CRISIS	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments:

_____

Module 3: Health systems broker

	3 month	6 Month	9 month	12 month	15 month	18 month	21 month	24 month	N/A
Facilitated CONTINUITY OF CARE across adult providers	☐	☐	☐	☐	☐	☐	☐	☐	☐

Supported ongoing, appropriate ENGAGEMENT with health and mental health services	☐	☐	☐	☐	☐	☐	☐	☐	☐
Advocated for timely and appropriate ACCESS to primary care and adult services	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments:

_____

Module 4: Social determinants of health

	3 month	6 Month	9 month	12 month	15 month	18 month	21 month	24 month	N/A
Identified SOCIO-ECONOMIC BARRIERS interfering with participant's adherence to medical care plans	☐	☐	☐	☐	☐	☐	☐	☐	☐
Helped participant find ADDITIONAL RESOURCES/PROGRAMS to address modifiable barriers related to service access	☐	☐	☐	☐	☐	☐	☐	☐	☐
Assisted with educational, vocational, housing, and/or financial NEEDS for the participant	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments:

_____

Supplementary Material 2: Initial encounter assessment template used by patient navigators

Study ID
Family physician
Current pediatric specialists
Pending adult specialists- list or summary
Other services (including mental health)
Community agencies currently involved in care
Medical status -medical diagnoses and medical history summary -psychiatric/mental health diagnoses -neurodevelopmental diagnoses -past surgical history -medication summary -laboratory frequencies, investigations

-medical devices, required assistance (oxygen, CPAP) -special adaptations required in adult care centre -funding/medical costs
Functional status -communication -activities of daily living -mobility

Modified SSHADES Psychosocial Assessment:

Strengths **tell me about the things you are good at* **what would others say you are good at* **what do you think are your best qualities?*
School and Employment **is client currently in school* **how much school has client missed due to illness* **how does illness affect schooling* **what are client's thoughts about school? (shy, lots of friends, bullied, conflict?)* **school achievement* **participation in school activities and/or sport* **goals after school* **does participant have a SIN number* **past employment* **employment goals*
Home and Environment Housing and Immediate family -**housing security/safety* **who resides in the home* **who frequents the home* **future housing plans* **court orders/custody documents- impact on medical planning* Supports **relationship function* **family supports* **peer supports* **spirituality/religion* **professional supports* **who do you turn to when condition worsens* Finances **income sources* **monthly income* **health insurance and extended health coverage* **food security* **does participant have a bank account (sole or joint? Must be sole to receive AB Works unless trusteeship)* **does participant have photo ID*

Transportation **how do you get around?* **is transportation a barrier to obtaining medical care OR adhering to medical plan?*
Activities **organized activities* **informal leisure* **solo versus social activities* **financial barriers to participating in activities*
Drugs/Substance Use **use harm-reduction approach* **is there anyone in your life who has issue with substance abuse?* **participant's history of substance use/abuse, including legal, illicit and prescription* **does participant have insight into how substances impact general health and his/her particular medical condition(s)* **do you know where to get information on substance abuse?* **complete AADIS if appropriate*
Emotions/Depression **how is your mood* **self-harm, suicidal ideation* **coping and adjustment to illness* **relationship between mental health and condition*
Sexuality **relationship status and history* **gender identity and sexual orientation* ** reproductive sexual health* **do you know where to get information on safe sex and sexual health*
Safety **how safe do you feel at school/home/work* **domestic violence history* **neighbourhood and community safety* **history of involvement with legal system* **do safety concerns affect medical care or adherence to medical plan?*

Transition Plan:

TRAQ Summary -notify study staff if not completed
Preparation -summary -goals (patient-specific) -actions (navigator)
Self-management -summary -goals -actions
Systems brokering -summary -goals -actions
Social determinants of health

-summary -goals -actions
Navigator prospective estimate of case complexity at assessment: low/med/high

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	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	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	1
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-3

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	
Roles and responsibilities: sponsor and funder	#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	1
Roles and responsibilities: committees	#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)	3-4
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	7
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7
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, non-inferiority, exploratory)	7
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	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: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11
Interventions: modifications	#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)	12
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	12
Interventions: concomitant care	#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	13
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)	9, 13
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	10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8
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	11
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	11

Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#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	13
Data collection plan: retention	#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	13
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	
Statistics: outcomes	#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	14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14
Statistics: analysis population and missing data	#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)	
Methods: Monitoring			
Data monitoring: formal committee	#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	14

		found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#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, no interim analyses planned
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	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	7
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)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
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	9
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
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	

Dissemination policy: trial results	#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	15
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Not included in 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

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A pragmatic trial evaluating the effectiveness of a patient navigator to decrease emergency room utilization in transition age youth with chronic conditions: The Transition Navigator Trial Protocol

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Competing interest statement:

There are no competing interests for authors relevant to this manuscript.

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Key Words: adolescence, emerging adulthood, transition to adult care, pragmatic trial

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ABSTRACT

Introduction:

Transition to adult care is a challenging and complex process for youth with special health care needs. We aim to compare effectiveness of a patient navigator service in reducing emergency room (ER) use among adolescents with chronic health conditions transitioning to adult care.

Methods and Analysis:

Pragmatic randomized controlled trial parallel group design comparing ER visit rates between patients with access to a personalized navigator intervention compared to usual care. Unit of randomization is the patient. Treatment assignment will not be blinded. Embedded qualitative study to understand navigator's role and cost analysis attributable to the intervention will be performed.

Patients aged 16-21 years, followed within a chronic disease clinic, expected to be transferred to adult care within 12 months and residing in Alberta during study period will be recruited from 3 tertiary care pediatric hospitals. Sample size will be 300 in each arm. Navigator intervention over 24 months is designed to assist participants in 4 domains: transition preparation, health system brokering, socioeconomic determinants of health, and self-management. Primary outcome is ER visit rate during observation period. Secondary outcomes are ambulatory and in-patient care utilization measures, as well as Transition Readiness Assessment Questionnaire score, and Short-Form Health Survey 12 (SF-12) score at 6 and 18 months post-randomization.

Poisson regression will compare rates of ER/urgent care visits between navigator and control participants, using intention to treat principle. Cost analysis of the intervention will be conducted. Thematic analysis will be used to identify perceptions of stakeholders regarding the role of navigators.

Ethics and Dissemination: Ethics approval was obtained from the University of Calgary Conjoint Health Research Ethics Board (REB #162561) and the University of Alberta Health Research Ethics Board (Pro00077325). Our team is comprised of diverse stakeholders who are committed to improving transition of care who will assist with dissemination of results.

Abstract word count: 300

Trial Registration: Clinicaltrials.gov NCT03342495

Strengths and Limitations of this study

[5 short bullet points]

- Population based sample from one Canadian province with universal health coverage
- Pragmatic randomized controlled trial design with broad inclusion criteria, and with an intervention embedded in a real world health care setting
- Participants are not blinded to the treatment arms, but blinded to primary outcome
- Contamination may occur from clinic based interventions which may duplicate some of the services the patient navigator may provide
- Participant recruitment to achieve the pre-specified sample size is anticipated to be challenge; particular attention to youth engagement strategies is required

INTRODUCTION

Approximately 15-20% of adolescents in North America live with a chronic health condition, defined as a condition that lasts at least 3 months, is not yet curable, affects a child's normal activities, and requires ongoing care.[1] The majority (>90%) will require transfer from pediatric to adult services.[1,2] Sub-optimal transition to adult care leads to poor adherence with ambulatory care management, health deterioration and increased use of costly emergent health services.[3,4] Patient navigators are a promising, but unproven intervention to facilitate planned transitions from pediatric to adult care, and improve patient experience and outcomes.[5] Published studies describing patient navigator services are mostly single centre and single disease cohort studies, with non-randomized designs, thus, limiting generalizability to other health jurisdictions and disease populations.[5] Further, interventions requiring highly skilled health care workers tend to be expensive, and to justify such an intervention, a cost evaluation is necessary. To address these challenges we designed a pragmatic RCT, the Transition Navigator Trial (TNT), the protocol for which is described in this paper.

Trial Objectives

The primary objective is to evaluate the impact of a personalized transition to adult care intervention (access to a patient navigator) compared to usual care for 16-21 year olds living with chronic health conditions who are transferring to adult care with respect to: a) ER/urgent care visits (*primary outcome*); and b) inpatient and ambulatory care utilization, transition readiness scores, and patient-reported health status (*secondary outcomes*). Secondary objectives are: a) to determine the net health care cost impact attributable to the patient navigator intervention; and b) to obtain perceptions of stakeholders regarding the role of patient navigators in reducing barriers to adult-oriented ambulatory care.

Hypotheses

The patient navigator intervention will reduce all-cause ER/urgent care visit rates, improve transition readiness scores and patient-reported health status, and generate cost savings for the health system.

METHODS AND ANALYSIS

This study will be conducted in accordance with the SPIRIT checklist[6-8] and CONSORT statement on pragmatic trial extension[9] (RCT), and COREQ.[10,11]

Study Design and Setting

This study will use a parallel group**,** pragmatic RCT[9] design (Figures 1 and 2) with an embedded qualitative study. The RCT involves random allocation of young adults (ages 16 to 21 years) with a chronic medical/mental health condition to either a personalized transition intervention (access to a patient navigator) or usual transitional care at one of three tertiary care pediatric hospitals in Alberta, Canada.

Alberta, with a population of 4.1 million, has a universal publicly funded health care system that covers over 99% of the population.[12] Patients will be recruited from 3 tertiary care pediatric hospitals: the Stollery Children's Hospital, Alberta Children's Hospital, and Glenrose Rehabilitation Hospital.

Recruitment

Eligible participants will be identified from 41 pediatric specialty clinics at the 3 participating hospitals (Figure 3). These clinics were selected after extensive stakeholder input, as these patient groups have high potential for adverse outcomes if transitions are not managed optimally.[4,12-15] Participants will have chronic health conditions in these broad categories: endocrine, gastrointestinal, neurologic, neurodevelopmental, rheumatologic, renal, cardiac, hematologic, respiratory, and metabolic/genetic. The primary caregiver (legal guardian or parent) of the young adult will also be considered a study participant if he/she is willing; however, parent/guardian involvement is not a requirement. Primary caregiver will also provide information required for the study should the patient be non-verbal or lack capacity to participate in the study.

Potentially eligible participants will be recruited through various methods including: 1) clinic staff identifying potential participants and requesting consent to contact by the study team, 2) patients can directly self-refer using a generic study email or phone number provided in recruitment posters, and 3) using mail-outs to potentially eligible participants who have used health services at the participating hospitals.

Trained research assistants are responsible for responding to any queries for enrollment via telephone or email. These research assistants are also responsible for screening potential participants for eligibility. The screening process is being conducted in person or by phone.

Inclusion criteria

To be eligible, participants must: (1) be between 16 and 21 years of age at the time of enrollment, (2) be receiving care from at least one of the selected pediatric outpatient hospital and community clinics (Figure 3), (3) have a chronic medical condition (defined as conditions which are >3 months in duration and/or lifelong with multiple morbidities and/or multi-organ/system manifestations or conditions which typically affect a single organ/system)[16,17] and (4) be expected to be transferred to adult specialty care in the next 12 months.

Exclusion criteria

Exclusion criteria will be: (1) enrolled in another transition-related study involving a navigator or similar intervention; (2) transfer will not occur during the time interval for the study; (3) will be moving out of Alberta during the study (e.g., going away for college) resulting in inability to report on primary outcome (ER visits) within the province; (4) inability to read and write in English.

Consent

Informed written consent will be obtained from all participants prior to enrollment (see supplementary material 1). For patients who are minors (age 16-17), informed assent will be obtained where appropriate. When the patient is considered a mature minor (after a capacity assessment by the responsible physician) or at age 18, we will obtain consent. If a patient is consenting for him/herself, then consent forms will ask participants for permission to contact their parents/guardians as needed to facilitate care, and also for permission to disclose medical information to parents/guardians. Should the participant decline parent involvement in the study, parents will not be contacted nor will health information be provided to the parent.

The primary caregiver will consent for his/her own respective participation. Primary caregivers will also consent on behalf of young adult participants who lack capacity to do so themselves due to developmental delay. Consent for disclosure of personal health numbers (PHN) assigned by Alberta Health for universal health care access will be obtained, to allow examination of health service utilization at the patient level by linkage to administrative health datasets.

Participation will be voluntary and participants will be free to withdraw at any time. A small incentive will be offered to participants ($25 at enrollment and $25 at study end), as a token of appreciation of their participation.

Study Timeline

Participants will be recruited over ~42 months. Recruitment started in January 2018, and will continue until target enrolment is reached. The duration of navigator support for participants in the intervention arm will be up to 24 months after randomization, and a minimum of 12 months for those enrolled later in the recruitment period. All participants will be observed for a minimum of 12, and maximum of 42 months. See timeline in Figure 4. A schematic diagram outlining the schedule of enrolment, assessments, and visits is shown in Table 1.

Form	Screening	Enrollment	Randomi-zation	Baseline	Repeat-able	Months Post-Randomization							
						3	6	9	12	15	18	21	24
CONSENT - Participant	X												
CONSENT - Caregiver	X												
ASSENT - Participant	X												
Screening Form	X												
Participant Demographics		X											
Caregiver Demographics		X											
Contact Information		X											
Baseline Medical		X											
Allocation			X										

End of Study Form													X
TRAQ 5.0				X			X		X		X		X
SF-12				X			X		X		X		X
Navigator Initial Encounter				X									
Navigator Encounter Form					X								
Navigator Critical Encounter					X								
Navigator Review						X	X	X	X	X	X	X	X
Fidelity Checklist						X	X	X	X	X	X	X	X
Case Closure													X
Pre-Intervention Interview				X									
Post-Intervention Interview													X

Table 1: Schedule of assessments for participants in the trial. TRAQ: Transition Readiness Assessment Questionnaire, SF-12: Short-Form 12 Health Survey.

Feasibility and Sample Size

There are approximately 600 prevalent patients between 16-18 years of age receiving care at each of the Alberta Children's Hospital and Stollery Children's Hospital. The Glenrose Rehabilitation Hospital has approximately 250 patients age 16-18 years. Estimated consent rate is 79% (based on our experience with transition trials).[18,19] We expect to recruit approximately 14-15 patients per month to reach our target sample size in 42 months. Clinic "champions" (physician, nurse or social worker leads) have been identified at all participating clinics to liaise with the study team and facilitate recruitment. A maximum case-load of 140-150 patients per patient navigator (one each in Edmonton and Calgary) is anticipated. This volume is considered feasible based on a similar case load of pediatric clinicians who have provided pediatric to adult transitional care in Alberta.

Sample size calculation was based on the primary outcome (i.e., ER/urgent care visit rate) during the period of observation. The baseline ER/urgent care visit rate observed within a diverse cohort of transitioning patients in Calgary, as identified using available administrative data, is 51 per 100 person years of follow-up, for age ≥18 years. Our team, composed of stakeholders from various levels of health service delivery, confirmed that a minimum clinically important difference between groups is a 20% (relative change) drop in ER visits. Based on effect size seen in a prior study evaluating transition navigators' impact on diabetic ketoacidosis admissions in diabetic patients,[20] we expect a 20-25% relative rate reduction in the intervention group compared to the control group. Assuming an ER/urgent care visit rate of 40 per 100 person years (21% rate reduction) in the intervention group, with significance level of alpha = 0.05 and 80% power, with an average follow-up of 2.04 years based on 24 months of recruitment and 36 months of maximum observation for outcomes, based on comparison between two Poisson rates, the needed sample size in each arm is 300. Loss to follow-up will not affect our ability to measure the primary outcome,

as we are using administrative health data. We have extended our recruitment time from 24 months to 42 months, in response to slow recruitment at the beginning of the study.

Allocation and Blinding

Participants will be randomly allocated after consent to either the patient navigator intervention or usual care in a 1:1 ratio using a computer-stratified generated randomization sequence, generated a priori by a statistician (author ANA) with varying block sizes, stratified by primary clinic affiliation. Randomization scheme will be executed in REDCap research software.[21] Study coordinators at each site ascertain group allocation by clicking 'randomize' on REDCap, and inform participants of their assigned study arm.

Intervention assignment will not be blinded from trial participants, family members, research assistants, or clinical teams. All patients/family participants will be blinded to the primary outcome (ER/urgent care visit) and hypothesized effects of the study. The navigators will not be blinded to the primary hypothesis. Full details of the navigator intervention will not be available to clinic staff/control participants to minimize contamination of the intervention to the control group. Data analysts will be blinded to group allocation and the nature of the intervention.

Study Intervention

There will be one navigator in each of Calgary and Edmonton serving approximately 150 participants. These navigators are employees of Alberta Health Services (AHS), the organization that provides government-funded health care to >99% of Alberta residents. Individuals eligible for the patient navigator position will have a minimum of a Bachelor's degree in Social Work and 5 years of clinical experience, including experience working with adolescents and/or young adults. The navigator will be familiar with resources and health services available within AHS and the community. The intervention group will also receive usual care.

The intervention (personalized transition support, access to a patient navigator) is designed to overcome barriers and challenges experienced by transferring patients by facilitating a coordinated entry into the adult system, to increase appropriate use of adult-oriented ambulatory primary and specialty care, and reduce ER/urgent care visits (primary outcome).[22,23] We developed a structured navigator intervention with four distinct inter-related modules based on literature highlighting the need for each[5], our pre-trial qualitative findings[24], and in collaboration with content experts in transition models, partners in Alberta Health Services, and patient/parent advisory committees. We also developed a 2-day training program for the navigators to complete prior to start of the trial. The training consists of readings, case scenarios, and role plays. The modules are:

- **Module 1 Prepare for transfer of care**[25-28] complete needs, risk and transition readiness assessments using a structured approach with modified SSHADESS psychosocial assessment[29] (see supplementary material 2); create medical passport; help establish relationships with primary care providers and appropriate specialty care providers; and enable timely attendance at first adult clinic visit.
- **Module 2 Navigator as a health system broker**[30-32]: assist with data sharing between pediatric and adult service providers; work with patient and primary care providers to facilitate

continuity of care; promote communication, collaboration, and patient and family centered care between all providers; and advocate with/for patient/family.

- **Module 3 Social determinants of health**[33-35]: assist families with barriers related to social and economic determinants of health to reduce modifiable barriers to accessing ambulatory medical care after transfer.
- **Module 4 Promote self-management of medical conditions**[36-39]: provide information and access to tools, educational resources, and peer support groups; track follow-up clinic visits, medication refills and laboratory testing in order to flag non-adherence early and provide coaching to reduce barriers to adherence; and plan for medical and/or mental health crisis management.

Once a participant is randomized to the intervention group, the navigators will contact the participant within 7 days to schedule a face-to-face (or phone meeting if necessary for rural dwelling patients) meeting during which the navigator will complete tasks in Module 1. Using information obtained at this initial assessment, the navigators will use an adaptive[40], patient-centered approach that customizes delivery of services based on needs of the patient, and consistent with principles and practice outlined in Modules 2-4. Navigators will use telephone, text messages, email messages, and in-person visits to maintain contact with participants as needed during the course of the intervention. Navigators will be alerted to ER/urgent care visits of participants by either the participants, caregivers (if appropriate), clinical providers, or through use of electronic medical record alerts. The navigator will review circumstances related to ER/urgent care visits, and inform preventative actions based on the intervention modules. Scheduled patient reviews (in person, or by telephone contact) will occur every 3 months (see Schedule of Assessments, Table 1). The navigators will record every contact and nature of assistance provided using standardized forms.

Fidelity

Procedures for monitoring adherence to intervention fidelity by the navigators will be managed by the Operational Oversight Committee (investigators, policy makers, navigator's supervisors), and its role will be to assess and enhance fidelity to the intervention throughout the trial. The committee will review the patient navigator intervention using qualitative interviews of stakeholders and participants after the first 5 participants are enrolled into the intervention arm in each site. The knowledge gained from the review will be utilized to optimize the intervention protocol and address barriers to intervention fidelity across all sites.

Deviations will be carefully documented by navigators during their course of the trial. The navigators will complete a standardized fidelity checklist at the end of each patient encounter to assess their adherence to skills, interventions and pathways described in the intervention modules (see supplementary material 3). Concomitant interventions which duplicate the intervention in whole or in part will be not be permitted during the trial.

Usual care group: Participants assigned to the usual care group will receive care as available within adult and pediatric clinics and the health region. However, this group is *not* a 'no intervention' group; in addition to care provided by their clinical teams, the study team will provide usual care participants with information in the form of infographics and quarterly

newsletters, regarding transition to adult care resources such as young-adult oriented transition websites, self-management tools, and the opportunity to attend transition-focused workshops. Significant variation in transitional care is expected in this group within and across sites (based on our prior stakeholder engagement work).

To minimize attrition, all participants in the intervention and usual care group will receive electronic newsletters every 4 months, letters thanking them for their participation to date and email and phone reminders for follow-up data collection.

Outcome and outcome measures

Outcome measures and the assessment schedule are summarized in Table 1. The primary outcome is the rate of all-cause ER and urgent care visits during the observation period. Patients, providers, and policy makers on our team considered ER/urgent care visits to be relevant, and measureable in a blinded fashion across all clinical groups. We will obtain consent from trial participants to use their personal health numbers to link with health service utilization data. All ER and urgent care visits attributed to participants will be obtained from the National Ambulatory Care Reporting System[41], and the Clinical Analytics Team of AHS will conduct all analysis. AHS is the custodian of all Alberta Health data for >99% of population.

We will evaluate ambulatory and inpatient care utilization measures as secondary outcomes (primary care visits, specialty care ambulatory care visits, in-patient admissions, ICU admissions, and length of hospital stay). Outcome measure will be the rate of events. This data will be obtained from the Canadian Institute for Health Information Discharge Abstract Database[42], and physician billing claims database[43].

Other secondary outcomes are the Transition Readiness Assessment Questionnaire (TRAQ), and patient reported health status as measured by the 12-Item Short Form Health Survey (SF-12). The TRAQ is the best-validated transition readiness scale for adolescents[44,45]. The questionnaire consists of 29 items, at grade 5.7 reading level, and takes ~5 minutes to complete. Participants will complete the TRAQ online at baseline, 6, 12, 18 and 24 months. Regarding general health, participants will complete the 12-Item Short Form Health Survey (SF-12) which is a validated 12 item survey that measures self-reported health status in individuals >14 years of age.[46] The survey includes questions concerning physical functioning, role limitations because of physical health problems, bodily pain, general health perceptions, vitality (energy/fatigue), social functioning, role limitations because of emotional problems, and general mental health (psychological distress and psychological well-being). Participants will complete the SF-12 at baseline, 6, 12, 18 and 24 months.

We will prospectively capture the cost of the navigator intervention using micro-costing methods[47] (identification, measurement, and valuation) that include one time and ongoing costs (development of materials, capital costs, wage rates for navigators, number of patients in caseload), enabling estimation of the cost of this intervention per patient served, using high quality administrative datasets from the AHS Clinical Analytics data repository.[48]

Data monitoring and trial management

The trial protocol is registered at www.clinicaltrials.gov (NCT03342495). The trial is governed by multiple stakeholder groups, including clinicians and policy makers at each of the recruiting sites, study team members, and youth and family members. The Executive Trial Team is composed of the principal investigators and research team members, as well as site representatives and a patient representative. The team is supported by the larger Trial Management Committee, Operational Oversight Committee, Data Safety Monitoring Board (DSMB), Patient and Family Advisory Council and Scientific Advisory Board. A governance chart is provided in Figure 5.

Potential adverse events will be monitored in both study groups, however, the intervention is considered to be of minimal risk. No interim analysis is planned. The DSMB consists of 3 individuals who are familiar with the patient population and study question, but unfamiliar with the research team. The board will meet at least twice a year and monitor the trial in terms of safety of the participants and rigor of the data collection procedures.

Analytical Plan

All analyses will be intention-to-treat. We will use Poisson regression to compare rates of ER/urgent care visits between the navigator and usual control groups, with fixed as well as random effects per site, and random effect by primary clinic. Demographic and medical characteristics that could be potential confounders or independent risk factors (e.g. age, primary disease, socioeconomic status, location of residence, medical and mental health co-morbidity in participant, ethnicity, immigrant status, demographic characteristics and medical/mental health of parents/caregivers obtained with consent) will be collected *a priori*, and used for adjusting the Poisson model. All other health utilization outcomes will be analyzed using descriptive statistical methods and by key demographic variables. For TRAQ and SF-12 scores we will assess the effect of time (baseline, 6, 12, 18 and 24 months) on the scores using linear regression with random effects for subject and clinic.

For the economic evaluation, we will use established methods to enable comparisons of mean costs, as these are easily interpretable and relevant to health care payer. We will include the full cost of the navigator intervention (for intervention group) and the health care cost categories noted above and will use non-parametric bootstrap estimates to derive 95% confidence interval and mean cost differences between the treatment arms.[49,50] We will use 1000 bias-corrected bootstrap replications (including sampling with replacement from the original data) to estimate the distribution of a sampling statistic to derive 95% confidence intervals.[49] We will also compare cost by category (in-patient, ER, ambulatory care, physician claims) between both groups.

Qualitative data analysis

All interviews and focus groups will be audio-taped and transcribed verbatim, and NVivo software (QSR International Pty Ltd., Version 10, 2012) will be used for analysis. Thematic analysis will be used to extrapolate and systematically analyze patterns in the data generated by the qualitative interviews.[50] We will closely adhere to the steps delineated by Braun and Clarke[51] for conducting thematic analysis. We will use Krueger and Casey's[52] constant comparative method of analysis to analyze the focus group data. This method involves "cutting, sorting, and arranging through

comparing and contrasting." The coding process consists of grouping similar concepts and ideas, while identifying themes and categorizing results. The research team will engage in established steps to increase the validity, credibility, transferability, and dependability of findings by adhering to guidelines for publication of qualitative research studies.[53]

Confidentiality

The RCT and qualitative studies will adhere to the Personal Health Information Protection Act and all other regulatory and organizational standards for privacy, confidentiality and security of database information. All patient-identifiable electronic data will be stored in password protected encrypted files on a secure network. Any identifiable information stored on REDCap will only be accessed by the investigative team and will be de-identified in the data export prior to analysis. All identifying information stored on paper will be stored in locked cabinets.

Ethics and Dissemination

Ethics approval was obtained from the University of Calgary Conjoint Health Research Ethics Board (REB #162561) and the University of Alberta Health Research Ethics Board (Pro00077325).

We have used an integrated knowledge translation approach.[54,55] Our team is comprised of patient representatives, researchers, clinical service providers and senior policy makers who are committed to improving transition and transfer of care within Alberta. At the end of the study, we will conduct face to face stakeholder meetings to develop a holistic understanding of the barriers and facilitators to transitional care and the effectiveness of the patient navigator service using both quantitative and qualitative data obtained in this study.

Patient and Public Involvement

Our team is comprised of patient representatives, researchers, clinical service providers and senior policy makers who are committed to improving transition and transfer of care within Alberta. We developed the intervention and strategy for implementation and evaluation after extensive consultation and engagement with stakeholders in sub-specialty pediatrics and adult chronic disease clinics, emergency medicine, the Well on Your Way Transition Program at ACH, Calgary Zone Primary Care Networks, the Calgary Zone Primary Care & Chronic Disease Management Program, the SCH Family-Centered Care Team, and senior leadership within each tertiary care hospital. We conducted pre-trial qualitative interviews and focus groups with relevant stakeholders (patients and families who recently transitioned to adult care, providers and policy makers) to understand their perspectives regarding contextual variables affecting transition and refined the intervention based on results of this work. We engaged the Child and Youth Advisory Council (a patient council) at the Alberta Children's Hospital and through a ranking exercise we found that patients valued interventions with personal contact (e.g. patient navigator, peer mentor support) more than those with less personal contact (social media, electronic apps). We are continuing to engage patient council groups such as these in Alberta. They will be informed of the results periodically during the study and also at the end of study through newsletters and news releases.

Discussion

The Transition Navigator Trial is a unique pragmatic population based trial which will address a significant gap in knowledge in the area of transition to adult care. The study will overcome previous methodological limitations including small sample sizes, non-generalizability due to diagnosis- specific inclusion criteria, and non- randomized designs. The results will have the potential to change health care delivery, improve health outcomes, and enhance experiences of young adults transitioning to adult care. The study will also provide a better understanding of the barriers and facilitators to transitional care and the effectiveness of the patient navigator service using both quantitative and qualitative data. We will determine what elements of the navigator service are most beneficial to participants, and whether the intervention is cost saving.

The evidence base for health care interventions during transition to adult care is limited by a paucity of data from controlled studies. Various interventions have been described and tested to a limited extent, mostly using non-randomized designs. Most are single centre, single disease studies, with limited generalizability. Gabriel *et al.*[5] performed a systematic review of evidence focused on transition interventions. They report that structured transition interventions led to improvement in patient reported quality of life and perceived health status in several studies, suggesting potential publication bias. No studies have found significant cost savings; several studies found that having a structured transition process resulted in increased visits to the new adult provider, and a reduced time lag between the last pediatric visit and the first adult visitpstein[56]

The current study will be aligned with the Triple Aim Framework for health service evaluation[57]. Interventions requiring highly skilled health care workers tend to be expensive, and to justify such an intervention, a cost evaluation is necessary. Complex interventions require assessment of fidelity to examine whether the intervention was delivered as intended, including a description of the interventions. This study will address these challenges.

In conclusion, this pragmatic RCT will evaluate the impact of a patient navigator service on rates of urgent care/ER visits and will provide patient, family and provider perceptions of the transition experience and the navigator service. This study will provide urgently needed data to guide pediatric and adult health care providers and policy makers regarding optimal transitional care delivery.

Acknowledgements:

We would like to acknowledge Sarah Gil for the creation of the figures used in this paper. We thank the patients and families who contributed to the development of this intervention and the design of the trial.

Figure Legends:

Figure 1. Trial Design. A randomized control trial.

Figure 2. CONSORT Diagram

Figure 3. Participating Clinics. Clinics participating in the Transition Navigator Trial

Figure 4. Study Timeline.

Figure 5. Governance of the Transition Navigator Trial. ACH: Alberta Children's Hospital; ACHRI: Alberta Children's Hospital Research Institute; GRH: Glenrose Rehabilitation Hospital; MNCY SCN: Maternal Newborn Child Youth Strategic Clinical Network; SCH: Stollery Children's Hospital

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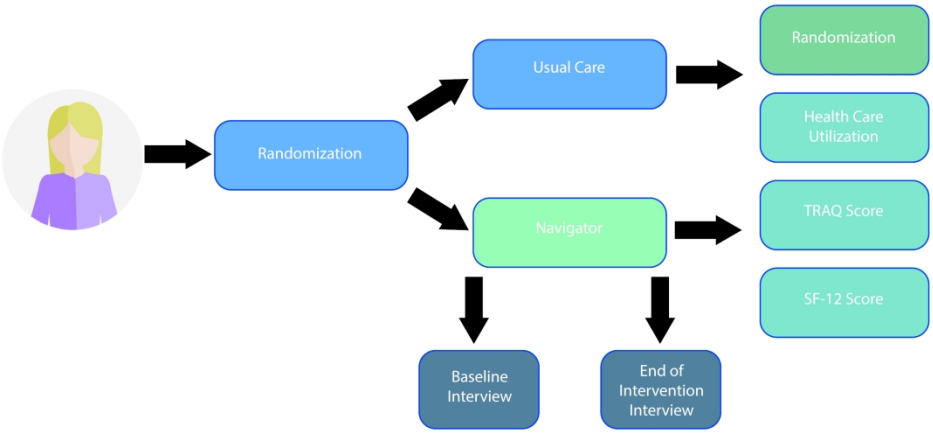


Figure 1 Trial Design

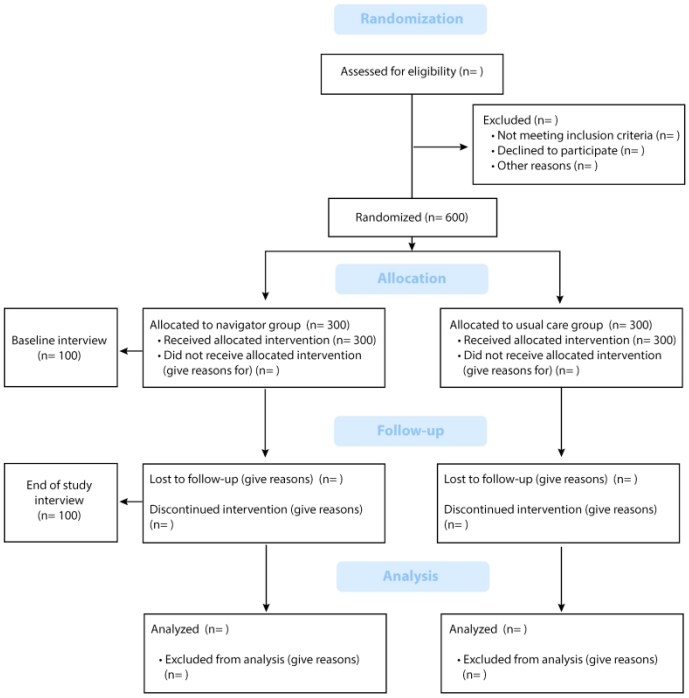


Figure 2 CONSORT Diagram

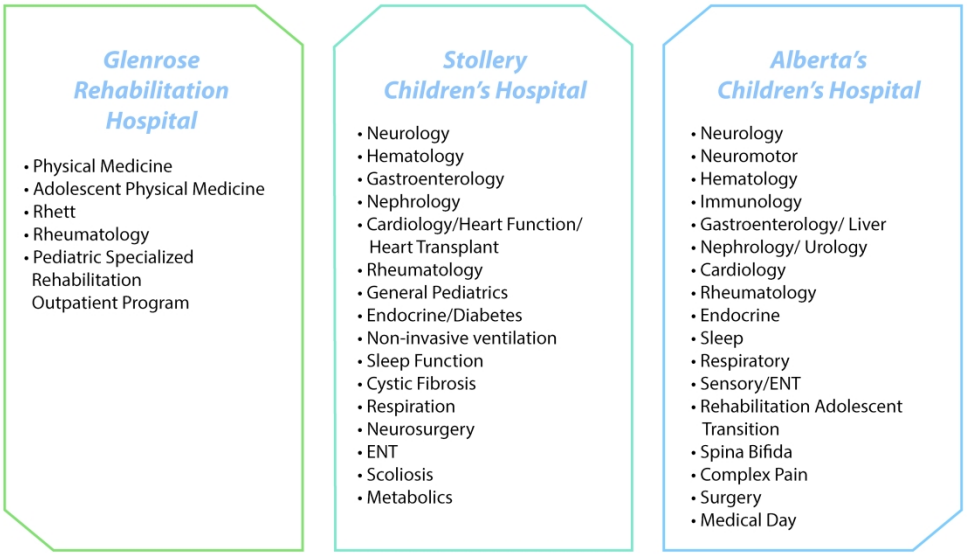


Figure 3 Participating Clinics

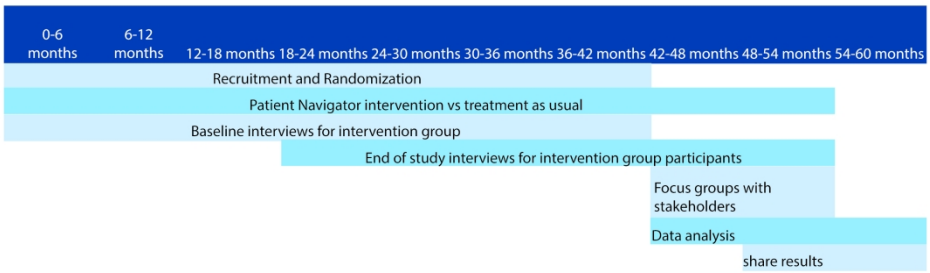


Figure 4 Study Timeline

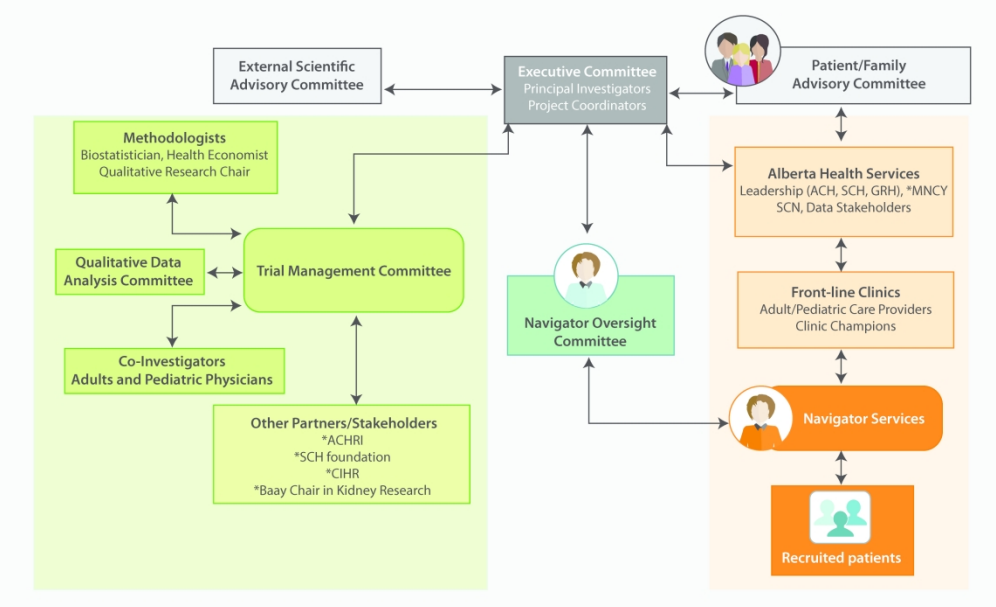


Figure: Governance of the Transition Navigator Trial. ACH: Alberta Children's Hospital; **ACHRI:** Alberta Children's Hospital Research Institute; **GRH:** Glenrose Rehabilitation Hospital; **MNCY SCN:** Maternal Newborn Child Youth Strategic Clinical Network; **SCH:** Stollery Children's Hospital

Figure 5. Trial Governance

Supplementary Material 1: Example of participant consent form

CONSENT TO PARTICIPATE IN RESEARCH

TRANSITION AGE YOUTH

TITLE

Evaluating Innovations in Transition to Adult Care: Transition Navigator Trial

SPONSORS

- Alberta Children's Hospital Research Institute BMO Endowed Award for Healthy Living
- Alberta Health Services, Maternal Newborn Child and Youth Strategic Clinical Network, Health Outcomes Improvement Fund
- Canadian Institutes for Health Research

PRINCIPAL INVESTIGATORS

Susan Samuel, MD, MSc — Alberta Children's Hospital
(403) 955-7950

Andrew Mackie, MD, MSc — Stollery Children's Hospital
(780) 407-8361

Gina Dimitropoulos, MSW, PhD — University of Calgary
(403) 220-7332

CO-INVESTIGATORS: Please see attached list.

*In the sections that follow, the word "**we**" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "**you**" refers to your child (if your child is not capable of legal consent).*

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask the research staff. Take the time to read this carefully and to understand the information. You will receive a copy of this form.

BACKGROUND

Transition to adult care is a difficult time for youth and young adults with chronic health conditions. Many youth and families struggle to get used to the adult care settings, and report difficulties accessing needed services to manage their health conditions into adulthood.

WHAT IS THE PURPOSE OF THE STUDY?

We are evaluating whether a patient navigator service will improve patient health and experience, after transfer to adult care. A navigator is an individual who will be able to provide help and refer you to different services and resources as you transition from pediatric to adult care. We will interview patients and their families to understand needs and difficulties during transition in Alberta and to understand whether a navigator will help overcome barriers to care. We will perform a cost analysis to determine if providing the navigator involvement is cost-saving to the health system.

We intend to recruit 600 youth/young adults and their families over three years, 300 in each major urban area, Edmonton and Calgary. Of these, approximately half will receive the navigator service, and half will receive the usual care in the health system by random selection (meaning a computer will decide which participant goes into which group).

Participants will be contacted and be fully informed of the results of the trial at the end of the study. Everyone in the study will receive periodic newsletters regarding current resources within Alberta for transition to adult care.

WHAT WOULD I HAVE TO DO?

If you consent to be a part of this trial, this is what will happen:

1) You will be asked to provide some basic information about yourself.
2) You will be asked to provide your Alberta Health Care number and residence postal code, in order for us to find your medical records within Alberta Health Services health records. Examining data from these records will help us understand how you will use the health care system after transfer to adult care.
3) You will be asked to complete standardized assessments at enrollment,periodically thereafter and at study end. These assessments will take approximately 10 minutes each.
    a. Transition Readiness Assessment Questionnaire (20 questions)
    b. SF-12 (Health Survey) (12 questions)

    Only a sample of the participants will be contacted. See Figure 1 below.
4) If you are randomized into the "patient navigator" group, you will be contacted by a patient navigator to assist in your transition and transfer process. The navigator will work with you to ensure that you are able to access appropriate healthcare services in the adult system, and guide you to resources you may need. The navigator will be available to you

for up to 24 months. If you are assigned to this group, you will receive further information regarding this service. You may be contacted at the beginning of the study for a telephone interview (approximately 45 minutes) by research staff to ask you some questions about your upcoming move from pediatric to adult healthcare. At the end of the study, you may be asked to participate in another telephone interview (approximately 45 minutes) to reflect on your experiences around the transition to adult healthcare. Only a sample of the participants will be contacted for these interviews. See Figure 1 below.

5) If you are randomized into the "usual care" group, you will receive the usual support that your clinic and healthcare teams provide.

6) We will observe your progress through the adult health care system by tracking how you use the health system (hospitalizations, emergency room visits, primary care visits).

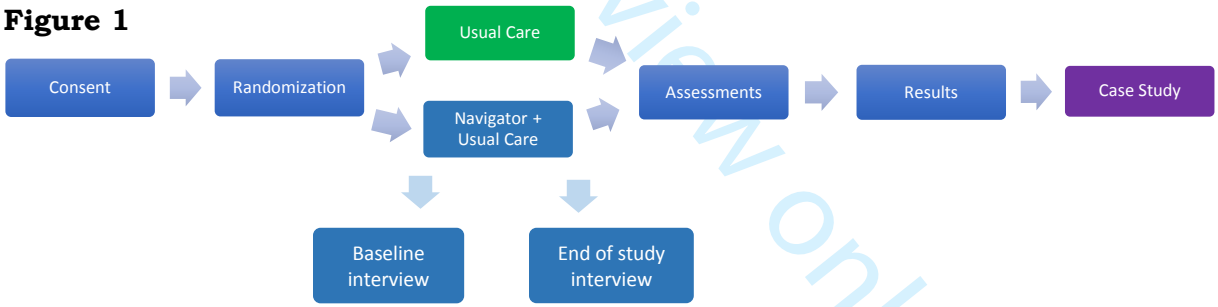
7) A small number of participants (5 to 10) who experience a good or bad transition outcome will be asked to participate in more detailed interviews to understand the root cause of the outcomes. This is called a case study (approximately 1-2 hours).

8) You will have the opportunity to journal/ write your story during transition on the researcher's database (REDCap). This is optional.

9) At the end of the study, we will contact you or your nominated delegate (parent or guardian) to complete an End of Study form which will ask you the some basic questions about your life at that time (education, employment, satisfaction with health care, income, extended medical insurance etc.)

10) This study does not affect routine care.

Figure 1



WHAT ARE THE RISKS?

There are no known risks to you associated with this study, and in particular when receiving support from the patient navigator. You are always in control of the information you share with study staff/researchers and your health care professionals.

If you experience discomfort, distress or get upset during your interactions with the navigator, you can decline navigator assistance at any time, yet you may choose to continue in the study. Should you be asked to participate in interviews or focus groups, you may experience a range of responses during and after the interview process, including feelings of discomfort and for some, distress. If you become upset during or after completing the interview, please mention it to the researcher. A member of the research team will be available to find you support if needed. We will also provide you with a list of community resources that can be accessed if you need additional support.

WILL I BENEFIT IF I TAKE PART?

If you agree to participate in this study there may or may not be a direct benefit to you. There is no guarantee that this research will help you. The information we get from this study may help us to provide better services and support in the future for youth and their families who are transitioning into the adult healthcare system.

DO I HAVE TO PARTICIPATE?

Participation in this study is voluntary and you may withdraw from the study at any time without jeopardizing your health care. If you wish to withdraw, please contact the study coordinator, listed on the last page.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will be given a gift card or cash value of $25 after you have enrolled in the study and completed the baseline questionnaires. You will receive another gift card or cash value of $25 at the end of the study. You will be reimbursed if you incur parking costs while you are participating in research.

WILL MY RECORDS BE KEPT PRIVATE?

Your personal and health information will be only accessible to the research team members who are conducting the data analysis. We will use the personal health information number provided to find records with Alberta Health Services administrative datasets (healthcare records), in order to understand how the health care system is being used to get medical care. All the data will be kept on password protected network computers, with controlled access. All paper documents will be locked up in a secured research area. In addition, authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your identifiable medical/clinical study records held at the Alberta Children's Hospital for quality assurance purposes.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the researchers or sponsors. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

Signature page follows.

SIGNATURES

Your signature on this form indicates that you understood to your satisfaction the information regarding your participation in the research project and agree to participate. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact: Dr. Susan Samuel (403) 955-7950 or Study Coordinator: Gurkeet Lalli (403) 955-2769.

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

I agree to allow the researchers and/or navigator to contact my parents or guardians as needed to facilitate care and to disclose medical information to my parents/guardians. My parent or guardian can participate in the study if they are interested.

☐ YES ☐ NO

I agree to allow the researchers to contact me at the end of the study. (See number 9 above). If I am unable to respond, I hereby nominate the following person to answer in my stead, and you have my permission to contact the delegate.

☐ YES ☐ NO

Name of Delegate: _____

Contact Information for Delegate: _____

I agree to allow the researchers to contact me for future studies related to transition to adult care.

☐ YES ☐ NO

_____

Printed name of participant (or legal representative on behalf of participant)

_____ _____

Signature of participant (or legal representative on behalf of participant) *Date*

_____ _____ _____

Printed name of person who explained consent *Signature* *Date*

Supplementary Material 2: Initial encounter assessment template used by patient navigators

Study ID
Family physician
Current pediatric specialists
Pending adult specialists- list or summary
Other services (including mental health)
Community agencies currently involved in care
Medical status -medical diagnoses and medical history summary -psychiatric/mental health diagnoses -neurodevelopmental diagnoses -past surgical history -medication summary -laboratory frequencies, investigations -medical devices, required assistance (oxygen, CPAP) -special adaptations required in adult care centre -funding/medical costs
Functional status -communication -activities of daily living -mobility

Modified SSHADES Psychosocial Assessment:

Strengths **tell me about the things you are good at* **what would others say you are good at* **what do you think are your best qualities?*
School and Employment **is client currently in school* **how much school has client missed due to illness* **how does illness affect schooling* **what are client's thoughts about school? (shy, lots of friends, bullied, conflict?)* **school achievement* **participation in school activities and/or sport* **goals after school* **does participant have a SIN number* **past employment* **employment goals*
Home and Environment Housing and Immediate family -**housing security/safety* **who resides in the home* **who frequents the home* **future housing plans* **court orders/custody documents- impact on medical planning* Supports

**relationship function* **family supports* **peer supports* **spirituality/religion* **professional supports* **who do you turn to when condition worsens* Finances **income sources* **monthly income* **health insurance and extended health coverage* **food security* **does participant have a bank account (sole or joint? Must be sole to receive AB Works unless trusteeship)* **does participant have photo ID* Transportation **how do you get around?* **is transportation a barrier to obtaining medical care OR adhering to medical plan?*
Activities **organized activities* **informal leisure* **solo versus social activities* **financial barriers to participating in activities*
Drugs/Substance Use **use harm-reduction approach* **is there anyone in your life who has issue with substance abuse?* **participant's history of substance use/abuse, including legal, illicit and prescription* **does participant have insight into how substances impact general health and his/her particular medical condition(s)* **do you know where to get information on substance abuse?* **complete AADIS if appropriate*
Emotions/Depression **how is your mood* **self-harm, suicidal ideation* **coping and adjustment to illness* **relationship between mental health and condition*
Sexuality **relationship status and history* **gender identity and sexual orientation* ** reproductive sexual health* **do you know where to get information on safe sex and sexual health*
Safety **how safe do you feel at school/home/work* **domestic violence history* **neighbourhood and community safety* **history of involvement with legal system* **do safety concerns affect medical care or adherence to medical plan?*

Transition Plan:

TRAQ Summary -notify study staff if not completed
Preparation -summary -goals (patient-specific) -actions (navigator)
Self-management -summary -goals -actions
Systems brokering -summary -goals -actions
Social determinants of health -summary -goals -actions
Navigator prospective estimate of case complexity at assessment: low/med/high

Supplementary Material 3

Navigator Fidelity Checklist

Date of Transfers

In how many clinics is this participant being transferred?

- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6

Date of Reviews

Date of 3 Month Review _____ (YYYY-MM-DD)

Date of 6 Month Review _____ (YYYY-MM-DD)

Date of 9 Month Review _____ (YYYY-MM-DD)

Date of 12 Month Review _____ (YYYY-MM-DD)

Date of 15 Month Review _____ (YYYY-MM-DD)

Date of 18 Month Review _____ (YYYY-MM-DD)

Date of 21 Month Review _____ (YYYY-MM-DD)

Date of 24 Month Review _____ (YYYY-MM-DD)

Module 1: Preparing for transfer of care

	3 month	6 Month	9 month	12 month	15 month	18 month	21 month	24 month	N/A
Explained the ROLE of the navigation service	☐	☐	☐	☐	☐	☐	☐	☐	☐
Discussed/provided RESOURCES on patient and family-centered care	☐	☐	☐	☐	☐	☐	☐	☐	☐
Completed psychosocial ASSESSMENTS (HEADSS, SSHADESS)	☐	☐	☐	☐	☐	☐	☐	☐	☐
Completed a comprehensive TRANSITION PLAN	☐	☐	☐	☐	☐	☐	☐	☐	☐
Facilitated TRANSFER of medical and psychosocial DATA	☐	☐	☐	☐	☐	☐	☐	☐	☐
Helped participant prepare succinct COMMUNICATION TOOLS (e.g., medical passport, 3 sentence health summary)	☐	☐	☐	☐	☐	☐	☐	☐	☐

Assisted with SCHEDULING adult oriented medical appointments	☐	☐	☐	☐	☐	☐	☐	☐	☐
Assisted with ACCESSING RESOURCES/SERVICES within the community and/or adult-oriented health services	☐	☐	☐	☐	☐	☐	☐	☐	☐
Helped participant find a FAMILY DOCTOR or primary care clinic	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments:

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Module 2: Promote self-management

	3 month	6 Month	9 month	12 month	15 month	18 month	21 month	24 month	N/A
COACHED self-management skills and identified strategies to promote adherence to medical care plans (e.g., role play, checklists)	☐	☐	☐	☐	☐	☐	☐	☐	☐
Directed participant to TOOLS/RESOURCES to support self-management	☐	☐	☐	☐	☐	☐	☐	☐	☐
Worked with participant (also caregivers and providers as appropriate) to ADDRESS BARRIERS to adherence with medical care plans	☐	☐	☐	☐	☐	☐	☐	☐	☐
MONITORED ADHERENCE to medical care plans by direct report from participant (caregivers and/or providers as appropriate) or indirectly by reviewing medical records	☐	☐	☐	☐	☐	☐	☐	☐	☐
Established PLAN to address medical CRISIS	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments:

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Module 3: Health systems broker

	3 month	6 Month	9 month	12 month	15 month	18 month	21 month	24 month	N/A
Facilitated CONTINUITY OF CARE across adult providers	☐	☐	☐	☐	☐	☐	☐	☐	☐

Supported ongoing, appropriate ENGAGEMENT with health and mental health services	☐	☐	☐	☐	☐	☐	☐	☐	☐
Advocated for timely and appropriate ACCESS to primary care and adult services	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments:

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Module 4: Social determinants of health

	3 month	**6 Month**	**9 month**	**12 month**	**15 month**	**18 month**	**21 month**	**24 month**	**N/A**
Identified SOCIO-ECONOMIC BARRIERS interfering with participant's adherence to medical care plans	☐	☐	☐	☐	☐	☐	☐	☐	☐
Helped participant find ADDITIONAL RESOURCES/PROGRAMS to address modifiable barriers related to service access	☐	☐	☐	☐	☐	☐	☐	☐	☐
Assisted with educational, vocational, housing, and/or financial NEEDS for the participant	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments:

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	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	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	1
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-3

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	
Roles and responsibilities: sponsor and funder	#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	1
Roles and responsibilities: committees	#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)	3-4
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	7
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7
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, non-inferiority, exploratory)	7
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	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: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11
Interventions: modifications	#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)	12
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	12
Interventions: concomitant care	#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	13
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)	9, 13
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	10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8
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	11
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	11

Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#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	13
Data collection plan: retention	#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	13
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	
Statistics: outcomes	#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	14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14
Statistics: analysis population and missing data	#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)	
Methods: Monitoring			
Data monitoring: formal committee	#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	14

		found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#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, no interim analyses planned
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	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	7
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)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
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	9
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
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	

Dissemination policy: trial results	#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	15
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Not included in 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