

# BMJ Open Pragmatic trial evaluating the effectiveness of a patient navigator to decrease emergency room utilisation in transition age youth with chronic conditions: the Transition Navigator Trial protocol

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**To cite:** Samuel S, Dimitropoulos G, Schraeder K, *et al*. Pragmatic trial evaluating the effectiveness of a patient navigator to decrease emergency room utilisation in transition age youth with chronic conditions: the Transition Navigator Trial protocol. *BMJ Open* 2019;**9**:e034309. doi:10.1136/bmjopen-2019-034309

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2019-034309>).

Received 13 September 2019  
Revised 25 October 2019  
Accepted 31 October 2019



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## ABSTRACT

**Introduction** Transition to adult care is a challenging and complex process for youth with special healthcare 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 randomised controlled trial parallel group design comparing ER visit rates between patients with access to a personalised navigator intervention compared with usual care. Unit of randomisation 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 three tertiary care paediatric hospitals. Sample size will be 300 in each arm. Navigator intervention over 24 months is designed to assist participants in four 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 inpatient care utilisation measures, as well as Transition Readiness Assessment Questionnaire score, and Short-Form Health Survey 12 (SF-12) score at 6 and 18 months post-randomisation. 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 composed of diverse stakeholders who are committed

## Strengths and limitations of this study

- Population-based sample from one Canadian province with universal health coverage.
- Pragmatic randomised controlled trial design with broad inclusion criteria, and with an intervention embedded in a real world healthcare 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 prespecified sample size is anticipated to be a challenge; particular attention to youth engagement strategies is required.

to improving transition of care who will assist with dissemination of results.

**Trial registration number** NCT03342495.

## 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.<sup>1</sup> The majority (>90%) will require transfer from paediatric to adult services.<sup>1 2</sup> Suboptimal transition to adult care leads to poor adherence with ambulatory care management, health deterioration and increased use of costly emergent health services.<sup>3 4</sup> Patient navigators are a promising, but unproven intervention to facilitate planned transitions from paediatric to adult

care, and improve patient experience and outcomes.<sup>5</sup> Published studies describing patient navigator services are mostly single-centre and single-disease cohort studies, with non-randomised designs, thus, limiting generalisability to other health jurisdictions and disease populations.<sup>5</sup> Further, interventions requiring highly skilled healthcare workers tend to be expensive, and to justify such an intervention, a cost evaluation is necessary. To address these challenges, we designed a pragmatic randomised controlled trial, 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 personalised transition to adult care intervention (access to a patient navigator) compared with usual care for individuals aged 16–21 years living with chronic health conditions who are transferring to adult care with respect to: (a) emergency room (ER)/urgent care visits (*primary outcome*); and (b) inpatient and ambulatory care utilisation, transition readiness scores and patient-reported health status (*secondary outcomes*). Secondary objectives are: (a) to determine the net healthcare 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 Standard Protocol Items: Recommendations for Interventional Trials checklist<sup>6–8</sup> and Consolidated Standards of Reporting Trials statement on pragmatic trial extension<sup>9</sup> (RCT), and COREQ.<sup>10 11</sup>

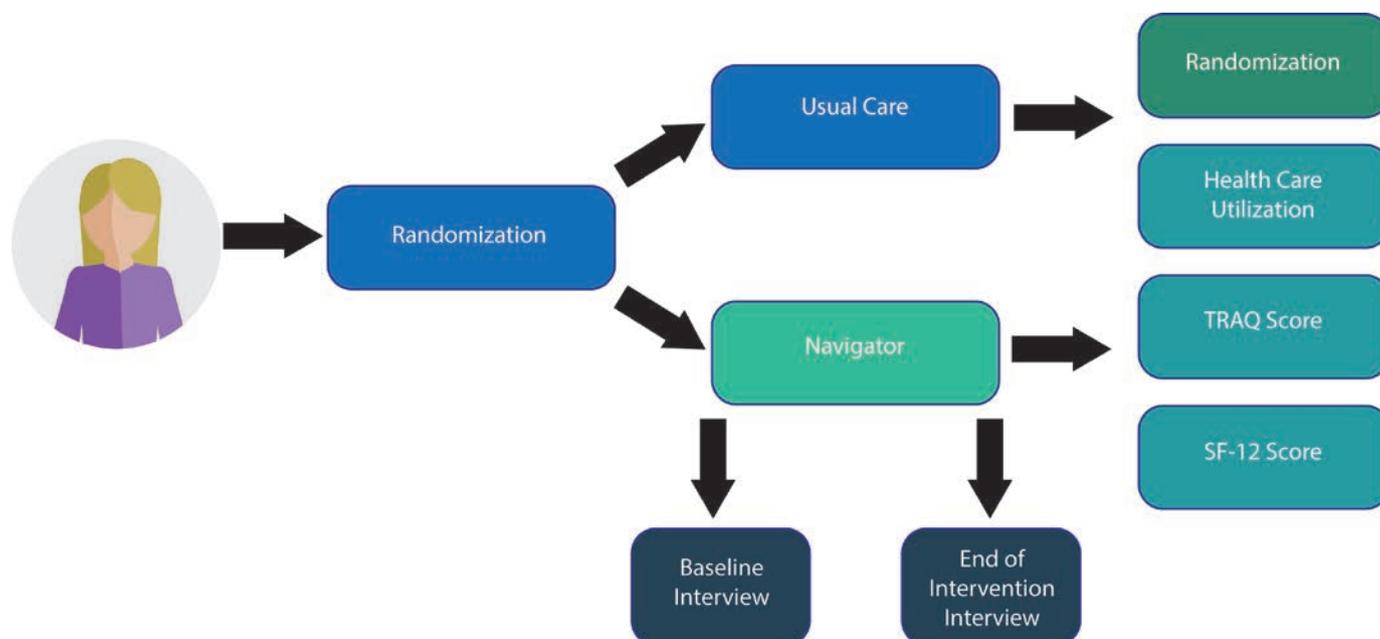
### Study design and setting

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

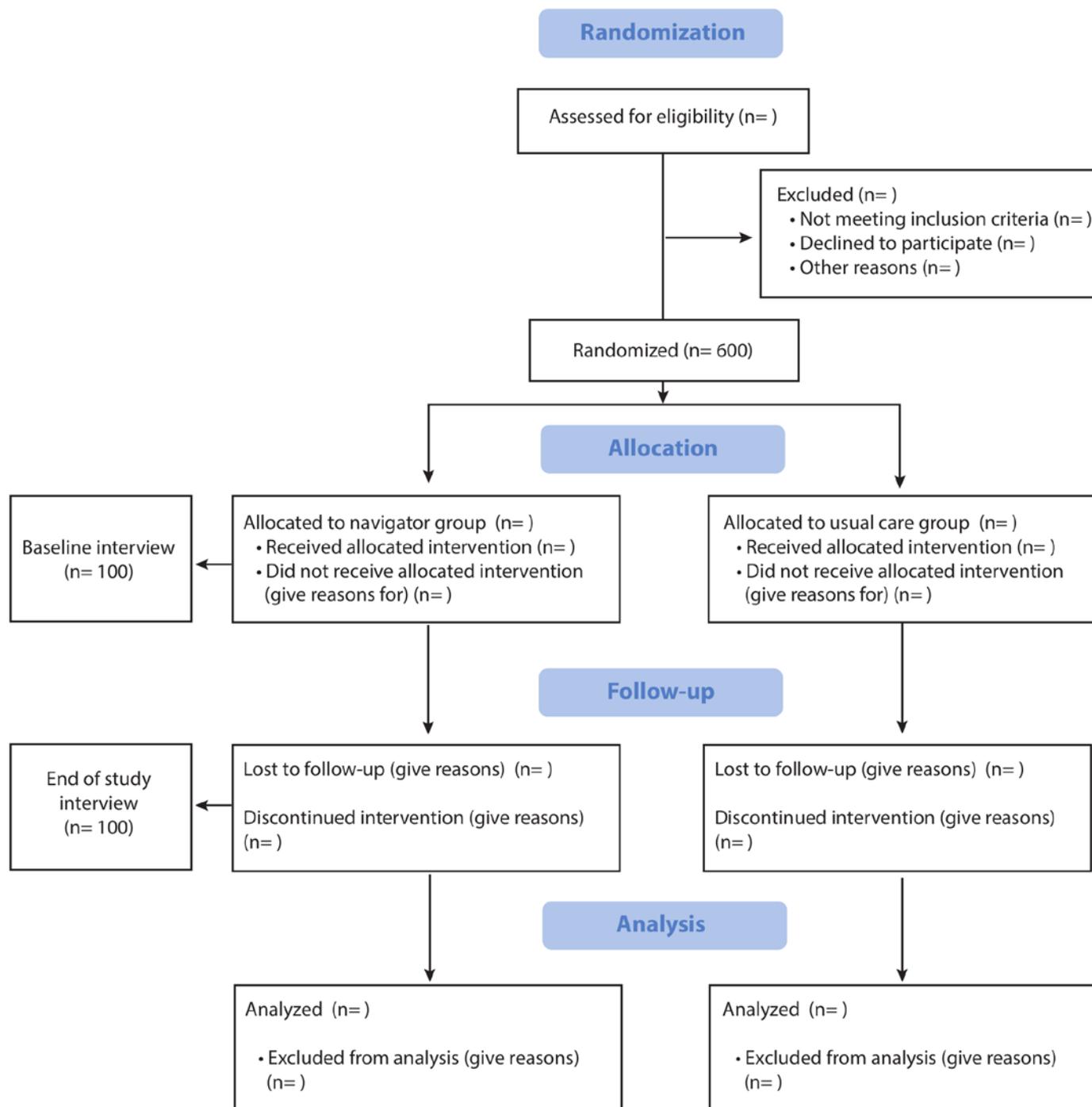
Alberta, with a population of 4.1 million, has a universal publicly funded healthcare system that covers over 99% of the population.<sup>12</sup> Patients will be recruited from three tertiary care paediatric hospitals: the Stollery Children's Hospital, Alberta Children's Hospital and Glenrose Rehabilitation Hospital.

### Recruitment

Eligible participants will be identified from 41 paediatric specialty clinics at the three 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.<sup>4 12–15</sup> Participants will have chronic health conditions in these broad categories: endocrine, gastrointestinal, neurological, neurodevelopmental, rheumatological, renal, cardiac, haematological, respiratory and metabolic/genetic. The primary caregiver



**Figure 1** Trial design. A randomised controlled trial. SF-12, Short-Form 12 Health Survey; TRAQ, Transition Readiness Assessment Questionnaire.



**Figure 2** Consolidated Standards of Reporting Trials diagram.

(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.

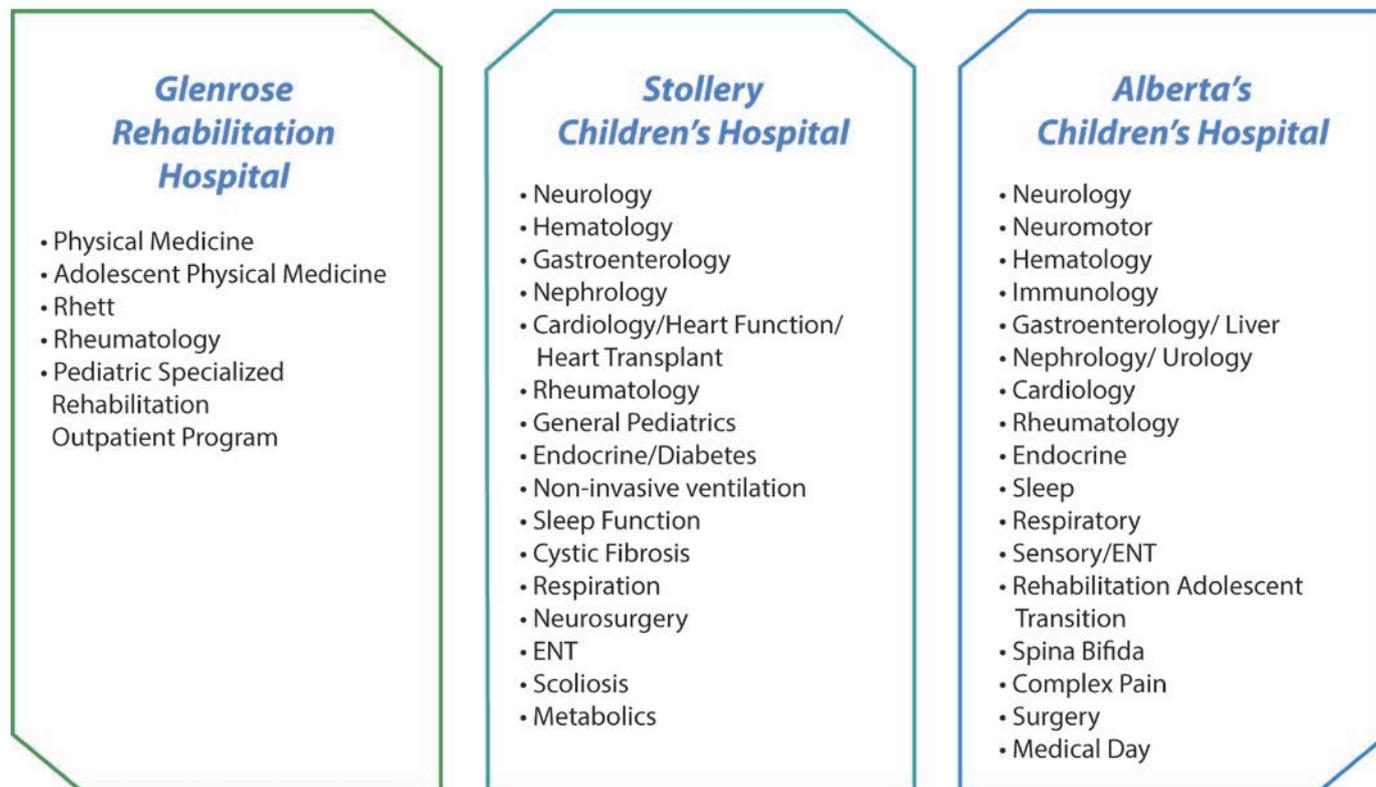
Potentially eligible participants will be recruited through various methods including: (1) clinic staff identifying potential participants and requesting consent to contact by the study team, (2) patients can directly self-refer using a generic study email or phone number provided in recruitment posters 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 enrolment 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 enrolment, (2) be receiving



**Figure 3** Participating clinics. clinics participating in the Transition Navigator Trial. ENT, ear, nose and throat.

care from at least one of the selected paediatric 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)<sup>16 17</sup> 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 (eg. 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 enrolment (see online supplementary file 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 healthcare access will be obtained, to allow examination of health service utilisation 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 enrolment 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 randomisation, 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.

#### Feasibility and sample size

There are approximately 600 prevalent patients between 16 and 18 years of age receiving care at each of the Alberta



**Figure 4** Study timeline.

Children’s Hospital and Stollery Children’s Hospital. The Glenrose Rehabilitation Hospital has approximately 250 patients aged 16–18 years. Estimated consent rate is 79% (based on our experience with transition trials).<sup>18 19</sup> 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 paediatric clinicians who have provided paediatric to adult transitional care in Alberta.

**Table 1** Schedule of assessments for participants in the trial.

Form	Screening	Enrolment	Randomisation	Baseline	Repeatable	Months postrandomisation													
						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	X	X	X	X	X	X
Fidelity Checklist						X	X	X	X	X	X	X	X	X	X	X	X	X	X
Case Closure																			X
Preintervention interview				X															
Postintervention interview																			X

SF-12, Short-Form 12 Health Survey; TRAQ, Transition Readiness Assessment Questionnaire.



Sample size calculation was based on the primary outcome (ie, 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  $\geq 18$  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,<sup>20</sup> we expect a 20%–25% relative rate reduction in the intervention group compared with 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 randomisation sequence, generated a priori by a statistician (author ANA) with varying block sizes, stratified by primary clinic affiliation. Randomisation scheme will be executed in REDCap research software.<sup>21</sup> Study coordinators at each site ascertain group allocation by clicking 'randomise' 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 hypothesised 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 minimise 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 organisation that provides government-funded healthcare 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 (personalised 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).<sup>22–23</sup> We developed a structured navigator intervention with four distinct inter-related modules based on literature highlighting the need for each,<sup>5</sup> our pretrial qualitative findings<sup>24</sup> and in collaboration with content experts in transition models, partners in AHS and patient/parent advisory committees. We also developed a 2-day training programme 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*<sup>25–28</sup>: complete needs, risk and transition readiness assessments using a structured approach with modified SSHADESS psychosocial assessment<sup>29</sup> (see online supplementary file 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*<sup>30–32</sup>: assist with data sharing between paediatric and adult service providers; work with patient and primary care providers to facilitate continuity of care; promote communication, collaboration and patient and family-centred care between all providers; and advocate with/for patient/family.
- ▶ *Module 3, Social determinants of health*<sup>33–35</sup>: 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*<sup>36–39</sup>: 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 randomised 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,<sup>40</sup> patient-centred approach that customises 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 (table 1). The navigators will record every contact and nature of assistance provided using standardised 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 five participants are enrolled into the intervention arm in each site. The knowledge gained from the review will be utilised to optimise 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 standardised fidelity checklist at the end of each patient encounter to assess their adherence to skills, interventions and pathways described in the intervention modules (see online supplementary file 3). Concomitant interventions which duplicate the intervention in whole or in part will not be permitted during the trial.

### Usual care group

Participants assigned to the usual care group will receive care as available within adult and paediatric 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 minimise 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 summarised 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 PHN to link with health service utilisation data. All ER and urgent care visits attributed to participants will be obtained from the National Ambulatory Care Reporting System,<sup>41</sup> and the Clinical Analytics Team of AHS will conduct all analysis. AHS is the custodian of all Alberta Health data for >99% of population.

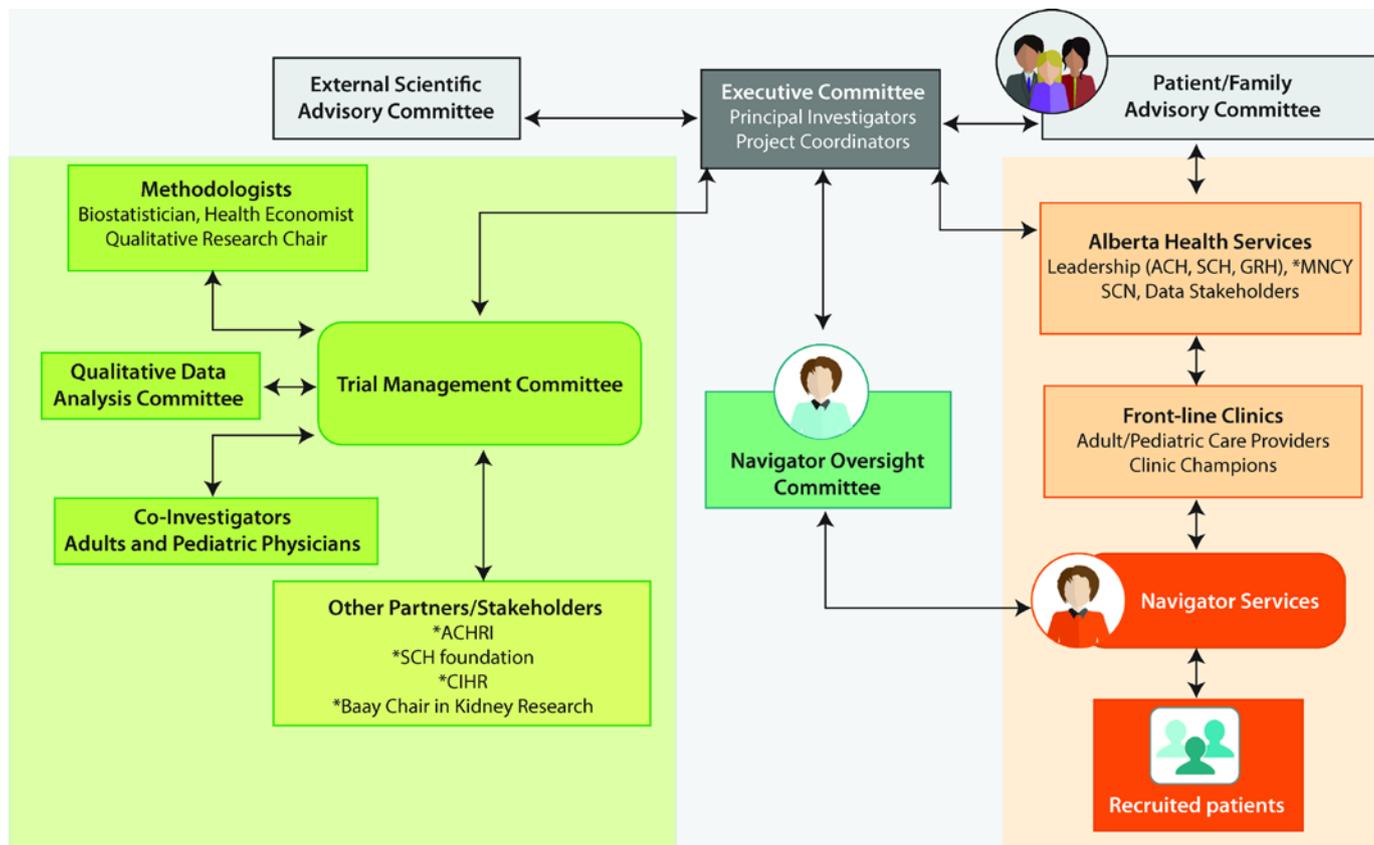
We will evaluate ambulatory and inpatient care utilisation measures as secondary outcomes (primary care visits, specialty care ambulatory care visits, inpatient admissions, intensive care unit admissions and length of hospital stay). Outcome measure will be the rate of events. This data will be obtained from the Canadian Institute for Health Information Discharge Abstract Database<sup>42</sup> and physician billing claims database.<sup>43</sup>

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.<sup>44 45</sup> The questionnaire consists of 29 items, at grade 5.7 reading level and takes ~5 min 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 SF-12 which is a validated 12-item survey that measures self-reported health status in individuals >14 years of age.<sup>46</sup> 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 microcosting methods<sup>47</sup> (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.<sup>48</sup>

### Data monitoring and trial management

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



**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.

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 three 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 rigour 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 (eg, age, primary disease, socioeconomic status, location of residence, medical and mental health comorbidity 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 utilisation outcomes will be analysed 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 healthcare payer. We will include the full cost of the navigator intervention (for intervention group) and the healthcare cost categories noted above and will use non-parametric bootstrap estimates to derive 95% CI and mean cost differences between the treatment arms.<sup>49 50</sup> 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% CIs.<sup>49</sup> We will also compare cost by category (inpatient, 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, V.10, 2012) will be used for analysis. Thematic analysis will be used to extrapolate and systematically analyse patterns in the data generated by the qualitative interviews.<sup>50</sup> We will closely adhere to the steps delineated by Braun and Clarke<sup>51</sup> for conducting thematic analysis. We will use Krueger and Casey's<sup>52</sup> constant comparative method of analysis to analyse 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 categorising 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.<sup>33</sup>

### Confidentiality

The RCT and qualitative studies will adhere to the Personal Health Information Protection Act and all other regulatory and organisational 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 deidentified in the data export prior to analysis. All identifying information stored on paper will be stored in locked cabinets.

### Knowledge Translation

We have used an integrated knowledge translation approach.<sup>54 55</sup> Our team is composed 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 composed 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 subspecialty paediatrics 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 pretrial 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 (eg, 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 TNT 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-generalisability due to diagnosis-specific inclusion criteria and non-randomised designs. The results will have the potential to change healthcare 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 healthcare 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-randomised designs. Most are single centre, single disease studies, with limited generalisability. Gabriel *et al*<sup>5</sup> 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 paediatric visit and the first adult visit<sup>56</sup>

The current study will be aligned with the Triple Aim Framework for health service evaluation.<sup>57</sup> Interventions requiring highly skilled healthcare 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 paediatric and adult healthcare providers and policy-makers regarding optimal transitional care delivery.

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**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.

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protocol and gave critical feedback on this manuscript. SS, AM and GD led the funding applications and all other authors contributed review of applications.

**Funding** Alberta Health Services (Research Number 1040209), Alberta Children's Hospital Foundation (Research Number 1042146), Stollery Children's Hospital Foundation, Canadian Institutes of Health Research (388256-CHI-CBBA-161557).

**Competing interests** None declared.

**Patient consent for publication** Not required.

**Ethics approval** 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).

**Provenance and peer review** Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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