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# Integrated collaborative care teams to enhance service delivery to youth with mental health and substance use challenges: protocol for a pragmatic randomised controlled trial

Joanna L Henderson,[1] Amy Cheung,[2] Kristin Cleverley,[3] Gloria Chaim,[1] Myla E Moretti,[4] Claire de Oliveira,[1] Lisa D Hawke,[1] Andrew R Willan,[5] David O'Brien,[6] Olivia Heffernan,[1] Tyson Herzog,[1] Lynn Courey,[7] Heather McDonald,[8] Enid Grant,[9] Peter Szatmari[1]

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For numbered affiliations see end of article.

**Correspondence to**
Dr Joanna L Henderson;
joanna.henderson@camh.ca

## ABSTRACT

**Introduction:** Among youth, the prevalence of mental health and addiction (MHA) disorders is roughly 20%, yet youth are challenged to access evidence-based services in a timely fashion. To address MHA system gaps, this study tests the benefits of an Integrated Collaborative Care Team (ICCT) model for youth with MHA challenges. A rapid, stepped-care approach geared to need in a youth-friendly environment is expected to result in better youth MHA outcomes. Moreover, the ICCT approach is expected to decrease service wait-times, be more youth-friendly and family-friendly, and be more cost-effective, providing substantial public health benefits.

**Methods and analysis:** In partnership with four community agencies, four adolescent psychiatry hospital departments, youth and family members with lived experience of MHA service use, and other stakeholders, we have developed an innovative model of collaborative, community-based service provision involving rapid access to needs-based MHA services. A total of 500 youth presenting for hospital-based, outpatient psychiatric service will be randomised to ICCT services or hospital-based treatment as usual, following a pragmatic randomised controlled trial design. The primary outcome variable will be the youth's functioning, assessed at intake, 6 months and 12 months. Secondary outcomes will include clinical change, youth/family satisfaction and perception of care, empowerment, engagement and the incremental cost-effectiveness ratio (ICER). Intent-to-treat analyses will be used on repeated-measures data, along with cost-effectiveness and cost-utility analyses, to determine intervention effectiveness.

**Ethics and dissemination:** Research Ethics Board approval has been received from the Centre for Addiction and Mental Health, as well as institutional ethical approval from participating community sites. This study will be conducted according to Good Clinical Practice guidelines. Participants will provide informed consent prior to study participation and data confidentiality will be ensured. A data safety monitoring panel will monitor the study. Results will be disseminated through community and peer-reviewed academic channels.

**Trial registration number:** Clinicaltrials.gov NCT02836080.

## Strengths and limitations of this study

- Pragmatic randomised controlled trial design to test the benefits of the integrated collaborative care team model involving multiple community and academic collaborators.
- Inclusion of economic evaluation, patient-oriented outcomes and minimal exclusion criteria.
- Involvement of youth, family members and other stakeholders through all stages of project design.
- Inability to identify the differential impact of the systems of care or specific service components for individuals with specific mental health/addiction challenges.
- Inability to assess long-term impact past 1 year.

## BACKGROUND

Research has shown that ~20% of Canadian adolescents are affected by mental health and addiction (MHA) disorders.[1] Most mental disorders begin early in life and persist, either as the same or as a new disorder. It is estimated that 75% of all adult mental disorders arise before the age of 16 years.[2] Some 10% of individuals seeking specialised addictions treatment in Ontario, Canada are youth under the age of 18 years.[3] The disease burden associated with MHA

disorders is more than 1.5 times that of all cancers and more than seven times that of all infectious diseases.[4] Adolescence is an optimal time to intervene for MHA challenges, to reduce both individual suffering and long-term population burden.[5 6]

Two recent landmark publications on primary mental healthcare for youth concluded that service reach is substantially limited by multiple access barriers and by a dearth of evidence-based services designed for this developmental stage.[2 7] Many models of service delivery fail to consider the particular contexts in which youth find themselves, for example, schools, youth protection settings, the youth justice system, homeless shelters and colleges or universities. Models also fail to consider the lack of engagement that youth feel with a 'children's' mental health agency or an 'adult' psychiatric service. Further, waiting lists for youth mental health services are unacceptably long in many jurisdictions.[8 9] Exacerbating this series of problems, many services impose arbitrary limitations on access, such as excluding youth with multiple diagnoses. The perspectives of youth and family members are rarely integrated in service planning, development and research, thereby missing out on the benefits that have been shown to be provided through patient-oriented research and care.[10]

Currently, Canadian youth have great difficulty accessing effective evidence-based mental healthcare that is timely and user-friendly. In Ontario, youth and their families have characterised the adolescent mental health system as fragmented, under-resourced, unresponsive, and inefficient.[11] Only 25-30% of youth with MHA challenges access specialised treatment, and most do not receive evidence-based treatment in a timely manner, resulting in functional impairment, poor quality of life and negative impacts on attaining important developmental milestones.[1 4]

Taken together, these problems create a crisis of access and engagement for youth needing developmentally sensitive, youth-oriented mental health services.[12] This crisis is not due to a lack of research evidence. On the contrary, the previous decade has seen a plethora of new studies on effective mental health interventions for youth, with accompanying clinical practice guidelines and consensus statements.[13] The critical problem lies with inadequate implementation of evidence-based interventions across multiple real world settings and jurisdictions.[13] The youth mental health system urgently needs transformative change that simultaneously addresses all system levels and meaningfully integrates youth and family members.

We propose to address the service gap for youth with MHA challenges within Ontario's current MHA system by developing and implementing an Integrated Collaborative Care Team (ICCT) model. This new model for Ontario consists of several linked, evidence-informed components, including solution-focused brief therapy (SFBT)[14–16] on a scheduled and walk-in basis; access to primary care; care navigators; dialectical behavioural therapy (DBT) skills groups for youth,[17] family-focused interventions[18]; e-health support tools; and peer mentorship/support,[19] all colocated in youth-friendly, community-based walk-in clinics. In addition to these services, some youth with more severe problems may need to be fast-tracked to immediate medical and specialised mental health services, including psychiatric consultation and medication management. The main ingredients of the model (a 'stepped care' process, short wait times, multiple standardised evidence-informed interventions in a single setting) are hypothesised to provide better outcomes compared to the usual treatment typically provided in local hospital outpatient clinics.

Each of these components is an evidence-informed intervention identified as holding promise for the healthcare system. SFBT is an evidence-informed treatment approach that has demonstrated efficacy for youth internalising and externalising symptoms in only a few sessions, especially as an early, low-intensity intervention.[15 20] The SFBT approach is strengths-based and guides the individual toward concrete solutions to the issues at hand. The evidence for SFBT suggests that it may be cost-effective and feasible for use in community mental health sites. DBT is a treatment that has been demonstrated effective in reducing self-harm and chronic suicidality, notably among individuals with borderline personality disorder.[21] Core foci of the intervention include decreasing emotional dysregulation, teaching mindfulness skills, enhancing distress tolerance and improving interpersonal effectiveness. Based on the success of the model, DBT has been modified and expanded for use as an effective transdiagnostic treatment for youth with other MHA concerns, with a focus on emotional dysregulation.[17] Family-focused applications of DBT have also demonstrated substantial benefits.[18] Peer support, which was identified as a priority in our recent review of youth mental health services in Ontario,[22] has been shown to increase a sense of hope, empowerment and social functioning, while reducing stigma and possibly even hospitalisation.[19] Collaborative mental healthcare spaces that bring these and other services together have been shown to produce strong outcomes for presenting youth.[23 24] By combining low, moderate and high-intensity services in a youth-friendly space, this new stepped-care ICCT model may provide a timely, well-rounded response to youth with MHA challenges.

## STUDY OBJECTIVES

The current study will evaluate the intervention effectiveness and cost-effectiveness of the above-described multicomponent ICCT model compared to hospital-based outpatient treatment as usual (TAU) for youth with mental health and/or addictions challenges using a pragmatic randomised controlled trial (RCT) design. In addition, it will document the process of cocreating and implementing the ICCT model.

### Primary objective

1. Following a patient-oriented research model, to work together with youth, family members and stakeholders to test the benefits of an ICCT model in improving functioning among youth aged 14–18 years with MHA challenges, compared to TAU

### Secondary objectives

2. To assess clinical improvement under the ICCT compared to TAU
3. To determine whether youth and participating family members experience greater satisfaction, engagement and empowerment with the treatments provided under the ICCT model compared to TAU
4. To determine the cost-effectiveness of the ICCT model compared to TAU
5. To document the co-creation and implementation of the ICCT model by youth, family members, community and hospital service providers, researchers and other stakeholders

## METHODS

### Study design

This study implements a pragmatic RCT design with random allocation of youth aged 14–18 years to either TAU at one of four outpatient hospital sites or ICCT treatment at one of three community-based sites, all in Toronto, Canada. The hospitals include the Centre for Addiction and Mental Health (CAMH), the Hospital for Sick Children (SickKids), Sunnybrook Health Sciences Centre and Michael Garron Hospital (MGH). The ICCT services will be provided by East Metro Youth Services (EMYS), Skylark Children, Youth and Families, LOFT Community Services and Sashbear Foundation, in collaboration with the South East Toronto Family Health Team, and the Anne Johnston Health Station.

### Project management and participation plan

The project is governed by multistakeholder groups, including representatives of the four hospital sites, community agencies, youth and family members. The Core Team is composed of the principal investigators and research team members, as well as site representatives and youth and family member coinvestigators. This team is supported by four working groups focusing on (1) community services, (2) study methodology, (3) hospital processes and (4) implementation science. Participating in each working group are also two youth advisors to provide the youth voice to the project. Youth and family advisory groups have also been established to facilitate patient-oriented research. The full project team includes collaborators from various research, clinical and broader community specialties ensuring that the necessary expertise is available for all aspects of the project. This represents an academic-stakeholder cocreation model that can maximise relevance and impact of the study and intervention design.[25]

### Participant selection and withdrawal

*Participant recruitment*: Participant recruitment will be conducted at the four Toronto hospital sites. Recruitment will take place over a 12-month period. A total of 500 youth will be randomised into the study; 250 will be randomised to ICCT and 250 to TAU. For each youth, the participation of one family member (ie, a primary caregiver) in the study process will be encouraged, but is optional. Across hospitals, the following procedures will be used as appropriate and feasible: hospital intake staff will identify new referrals for appropriateness for referral to the project; standardised telephone screening calls will be conducted by clinical research assistants (RAs); a visit will then be scheduled at a neutral community site with the youth and family member (if any) for consent, enrolment, intake assessments and randomisation. Those who do not meet the criteria or who do not agree to participate in the study will be immediately connected with a regular hospital appointment outside of the research study. For participants who are randomised to the ICCT arm, Consent for Disclosure of Personal Health Information will be completed to enable the clinical RA to forward referral information to the ICCT, as well as a standardised letter indicating referral to the ICCT to the referring physician, to ensure adequate information sharing. Participating youth will receive honoraria in the form of gift cards valued at $50 at time 1, time 2 and time 3. Caregivers will receive $25 in gift cards at each time point, as well as entry into a random draw for a $250 gift card. The study is currently in the recruitment phase; the first participant was enrolled on 19 September 2016.

*Inclusion and exclusion criteria*. To be eligible, youth must be between 14 and 18 years of age at the time of presentation (the common age range of services at the four hospital sites), referred to one of the four participating hospitals with MHA challenges and be among the population regularly accepted for outpatient adolescent psychiatric services at that hospital. An individual meeting any of the following criteria will be excluded from participation in the study: referral for specialty forensic or firesetting treatment; autism without MHA problems; primary diagnosis of an eating disorder; active psychosis or imminent risk of self-harm requiring immediate intervention; inability to read and write in English due to the self-report assessment component; and inability to consent to the study. As a pragmatic trial, exclusion criteria are intentionally minimised to ensure an inclusive sample representative of the youth who would normally be targeted by this service delivery model. Family member participants must be a primary caregiver of the youth and aware of the youth's everyday functioning. Exclusion criteria are the inability to read and write in English or to consent to the study.

*Consent and withdrawal from study*: Informed, signed consent will be obtained from all study participants at the intake visit prior to study enrolment and randomisation (see online supplementary appendix A and B). If

youth/family members wish more time to consider participation, a second intake visit will be scheduled. Youth will provide consent rather than assent regardless of age, as they are considered to play an equal role in the decision to participate in research. The family member will consent for his/her own respective participation. Copies of the signed consent forms will be given to the youth and family member; originals will be filed securely in study files. Participation will be voluntary and participants will be free to withdraw from the study at any time without affecting their treatment. Whether assigned to the TAU or ICCT arm, youth will be able to continue receiving full treatment within that model if they withdraw from the study. If youth randomised to the ICCT arm withdraw from the study and wish to receive treatment as usual in the hospital setting, the research team will assist them in returning to the original hospital to schedule treatment. Other youth who withdraw from the research project and request community services will be provided with information about available services.

## Study interventions

*Integrated collaborative care teams*: ICCT treatments and services are summarised in table 1. ICCTs are housed in the community in three neighbourhoods across Toronto, Canada. Each ICCT will include MHA care providers (eg, youth worker, social worker, psychiatrist, nurse practitioner), trained peer support workers, access to a primary care providers and a care navigator responsible for working with the various specialists to coordinate care. For each intervention, standardised intervention protocols will be used, employing evidence-informed sources wherever possible. All participants will begin with rapid access to a SFBT session[14 15] as a gateway to the ICCT services; this will serve as a brief intervention, as well as to identify the needs and preferences of the youth and his or her family member and to develop a treatment plan. Subsequent interventions will then be selected based on need, using clinical assessments and selected by the ICCT service provider in a stepped-care manner.

Youth will be offered higher or lower intensity services, following a needs-based staging model.[26] The Columbia Suicide Scale Clinical Practice Screener[27] and PRIME Screen[28] prodrome screener will be used clinically with all youth across ICCT sites to identify risk suggesting the need for high-intensity/high-risk psychiatric services in the presence of psychotic prodromal or suicidal symptoms. The HEADS-ED[29] will be used clinically by ICCT service providers to identify the functional level of the youth, suggesting moderate intensity when both risk and functioning are low, but low intensity when risk is low and functioning is high. These scales will be followed to inform treatment planning based on a treatment algorithm provided to the community sites, in conjunction with the service provider's judgement of treatment response and youth/family preference or expressed need.

**Table 1** Summary of ICCT study interventions and the treatment selection pathway

| | |
|---|---|
| Intake (all youth) | Randomisation to ICCT intake:<br>▶ Solution-Focused Brief Therapy Session[14–16]<br>▶ Assessment and treatment planning<br>▶ Care Navigator<br>▶ *Assertive Outreach (as needed)* |
| Low-intensity interventions | Intake interventions, plus:<br>▶ Continued Solution-Focused Brief Therapy[14–16]<br>▶ Family Connections DBT-based group for family members[18]<br>▶ *Primary Care (as needed)*<br>▶ *Assertive Outreach (as needed)* |
| Moderate-intensity interventions | Intake interventions, plus:<br>▶ DBT-based skills group[17]<br>▶ Family Connections DBT-based group for family members[18]<br>▶ *Primary Care (as needed)*<br>▶ *Assertive Outreach (as needed)* |
| High-intensity interventions | Intake interventions, plus:<br>▶ High-intensity psychiatric response—Psychiatrist/Nurse Practitioner<br>▶ Family Connections DBT-based group for family members[18]<br>▶ *Primary Care (as needed)*<br>▶ *Assertive Outreach (as needed)* |
| Additional options within the ICCT model | ▶ Peer support mentor[19]<br>▶ Peer support drop-in group<br>▶ E-health support tools<br>▶ 24/7 crisis text support |
| Additional options available through participating agencies | ▶ Drop-in activity area<br>▶ Group/individual DBT<br>▶ Group/individual CBT<br>▶ Support groups (various)<br>▶ Family-specific interventions<br>▶ External agency service<br>▶ Other counselling |

CBT, cognitive-behavioral therapy; DBT,dialectical behavioural therapy; ICCT,Integrated Collaborative Care Team.

The low-intensity intervention will consist of SFBT, a goal-directed single-session intervention that focuses on the youth's strengths and identifies concrete solutions; this will be provided by the ICCT service provider. Youth will receive an established number of single-session SFBT sessions based on need and will have ongoing access to the SFBT model through the ICCT walk-in services. The moderate-intensity intervention will be a modular DBT skills group, provided by group facilitators at each site and consisting of modules focusing on developing the emotional regulation, distress tolerance and interpersonal effectiveness skills of the youth. The high-intensity psychiatric response will consist of management by a child and adolescent psychiatrist within the ICCT environment, and/or a Nurse Practitioner, focusing on psychiatric assessment, medication management and

other interventions deemed clinically appropriate; treatment duration will be based on need, as assessed by the clinician. Family members will be offered participation in Family Connections, a DBT-based skills and support group designed for families,[17] regardless of the youth's risk and functional level. Additional community services will be offered to youth/family members where appropriate. Since the study aims to evaluate the effectiveness of the pathway rather than the specific effectiveness of each individual intervention, intervention fidelity will be monitored at the level of delivery of intervention modules, components and subcomponents; service providers will document the delivery of intervention modules, components and subcomponents for each youth and/or family member using detailed self-report intervention logs and checklists.

*Treatment as usual*: The TAU condition consists of the standard outpatient treatment provided at each participating hospital site. This typically entails assessment and treatment planning by a psychiatrist at the participating hospital, and may include medication, psychotherapy and/or internal and external referrals to treatment and other services, guided by local service standards. The hospital services used in the TAU condition will be tracked for each participant using chart review (based on medical record numbers).

*Application of interventions*: Each hospital and ICCT site will be responsible for the application of the appropriate clinical interventions. Training in core ICCT interventions (SFBT, DBT Skills Group, Family Connections) has been conducted together in a single group, using the same treatment manual. It is expected that interventions will be selected for each youth based on the clinical assessments and the related treatment algorithm provided to the clinical sites, complemented by the clinical judgement of the site staff and drawing from the available services, taking into consideration youth and family member preferences.

## Outcome measures

Outcome measures are summarised in table 2. For psychometric properties, see online supplementary appendix C.

*Sample description*: To describe the basic characteristics of the sample recruited into the study, a custom demographic information form will be administered to the youth and family member. In addition, a clinical description of the sample will be provided by the Diagnostic Interview for Affective and Anxiety Spectrum Disorders—Child Version (DIAS-C)[30], which is an interview that will be administered by a trained clinical RA. Risk for psychosis will be assessed by the self-report PRIME.[28] Youth will also complete the PTSD CheckList—Civilian Version (PCL-C)[31] and a checklist indicating any comorbid physical health conditions.

*Clinical/functional outcome*: The primary objective, to test the benefits of the ICCT model in improving functioning among youth aged 14–18 years with MHA challenges, will be measured using the Columbia Impairment Scale (CIS)[32]. This self-report scale includes 13 items, versions for both youth and family members, is reliable and valid, has been used in several clinical trials[33–35] and was chosen by youth in focus groups as the main measure of interest to them. Youth CIS scores will represent the primary outcome variable, with caregiver CIS scores serving as a secondary outcome variable.

Our second objective, to assess clinical improvement, will be measured using the Strengths and Difficulties Questionnaire (SDQ)[36] in its versions for youth self-report and parental report. Further symptom profiles, including problematic substance use, will be assessed using the GAIN Short Screener,[37] which will be supplemented by the substance use table of the Adolescent Alcohol and Drug Involvement Scale.[38] An additional clinical outcome will include caregiver burden, measured using the self-report Burden Assessment Scale (BAS)[39] administered to family members only.

*Satisfaction, goal achievement, engagement, empowerment, burden*: Our third study objective, satisfaction with the service models, will be assessed using the Ontario Perception of Care Tool for Mental Health and Addictions, client and family versions (OPOC)[40]. To provide insight into goal achievement, each youth and parent will be asked to determine his or her own goals at intake; we will then use an 11-point progress scale based on the Goal Progress Chart[41] at the 6-month and 12-month assessments to determine the average extent to which these goals were met. Further information on client empowerment and engagement will be collected using the self-report Family Empowerment Scale[42] for family members, the Youth Efficacy/Empowerment Scale[43] for youth and the Continuity of Care in Children's Mental Health questionnaire[44] in its family member and youth versions.

*Economic evaluation*: Our final objective is to determine the cost-effectiveness of the ICCT model compared to TAU. We will perform two analyses, a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA), to determine the incremental costs of ICCT compared to TAU in modifying health outcomes as measured by the CIS and quality-adjusted life years (QALYs) measured with a validated utility instrument, the Assessment of Quality of Life-6D (AQOL-6D)[45]. The AQOL-6D will be administered at baseline and at 6 and 12 months to determine the change in utility for the duration of the intervention, and will be used to calculate QALYs. Custom data collection tools have been developed to measure direct costs to the youth/family member, as well as indirect costs (eg, lost income due to appointments; see table 3 for a detailed description of each cost category). These tools will be completed by treatment teams in the respective treatment arms and by the youth and their family member (if applicable). This data will be collected at all three assessment times. Additional data regarding health services use and direct costs to the

Table 2 Summary of research assessment tools selected for the study

| Objective | Instrument | Reporter | Key construct | Subscales | Measurement time(s) |
|---|---|---|---|---|---|
| Sample description | Custom questionnaire | Youth, Family member | Demographic characteristics | None | Intake |
| | DIAS-C[30] | Clinical Research Assistant | Clinical Improvement | Mood disorders, anxiety disorders, externalising disorders | Intake |
| | Custom checklist | Youth, Family member | Physical health variables | None | Intake |
| | PRIME[28] | Youth | Prodrome for psychosis | None | Intake |
| | PCL-C[31] | Youth | PTSD symptoms | None | Intake |
| Functional improvement | Columbia Impairment Scale[32] | Youth, Family member | Impairment | None | Intake, 6 months, 12 months |
| Clinical improvement | Strengths and Difficulties Questionnaire[36] | Youth, Family member | Clinical Improvement | Emotional problems, conduct problems, hyperactivity, peer problems, prosocial | Intake, 6 months, 12 months |
| | GAIN SS[37] | Youth | Clinical symptoms | Internalising disorders, externalising disorders, substance use disorders, crime/violence | Intake, 6 months, 12 months |
| | Adolescent Alcohol and Drug Involvement Scale[38] | Youth | Problematic substance use | None | Intake, 6 months, 12 months |
| | Burden Assessment Scale[39] | Family member | Family Burden | Objective burden, subjective burden | Intake, 6 months, 12 months |
| Economic Evaluation | Assessment of Quality of Life-6D[45] | Youth | Quality Adjusted Life Years | Physical ability, social/family relationships, mental health, coping, pain, vision/hearing/communication | Intake, 6 months, 12 months |
| | Participant/Family member Health Services Use and Out-of-Pocket Expense Diary (Custom questionnaire) | Youth, Family member | Direct and Indirect Costs | Health services usage, participant/family member out-of-pocket expenses, lost time (employment and leisure), third party payer costs | Intake, 6 months, 12 months |
| | Care provider interactions with participants (TAU and ICCT versions) | TAU and ICCT clinical staff | Direct and Indirect Costs | Health services usage participant/family member out-of-pocket expenses, lost time | Intake, 6 months, 12 months |
| Service experiences | Continuity of Care in Children's Mental Health[44] | Youth, Family member | Continuity of care | Experiences at this agency, multiple providers at agency, primary provider at agency | Intake, 6 months, 12 months |
| | Custom questionnaire | Youth, Family member | Goals | None | Intake, 6 months, 12 months |
| Satisfaction | Ontario Perception of Care Tool for Mental Health and Addictions[40] | Youth, Family member | Satisfaction | Access to service, services provided, participation/rights, therapists/support workers/staff, environment, discharge, recovery outcome, service quality | 6 months, 12 months |
| Empowerment/ Engagement | Youth Efficacy/ Empowerment Scale[43] | Youth | Empowerment | Self, services, system | Intake, 6 months, 12 months |
| | Family Empowerment Scale[42] | Family member | Empowerment | Family, child's services, involvement in community | Intake, 6 months, 12 months |

DIAS-C,Diagnostic Interview for Affective and Anxiety Spectrum Disorders Child Version; GAIN SS, GAIN Short Screener; ICCT,Integrated Collaborative Care Team; PCL-C,PTSD CheckList Civilian Version; PTSD, post-traumatic stress disorder; TAU,treatment as usual.

Table 3 Summary of data collected for evaluation of the economic impact of the two intervention arms

| Direct costs | | | |
|---|---|---|---|
| | Youth/family† | | |
| System* | Out-of-pocket | Time | Indirect costs‡ |
| ▶ Acute inpatient hospitalisations<br>▶ Psychiatric inpatient hospitalisations<br>▶ Same-day surgeries<br>▶ ED visits<br>▶ Other ambulatory care (chemo clinic visits, dialysis clinic visits)<br>▶ Physician services<br>▶ Diagnostic/laboratory tests<br>▶ Outpatient prescription drugs covered under the ODB programme<br>▶ Home care<br>▶ Complex continuing care<br>▶ Long-term care<br>▶ Inpatient rehabilitation<br>▶ Assistive devices (not available from 2010-onwards) | ▶ OOP costs spent visiting health professionals<br>▶ Outpatient prescription drugs not covered under the ODB programme<br>▶ Equipment<br>▶ Community services<br>▶ Household help | ▶ Time costs spent visiting health professionals<br>▶ Time lost from work and leisure | ▶ Lost productivity |

*Available through ICES.
†To be collected from youth and caregiver.
‡To be estimated and/or obtained from the literature.
ED, emergency department; ICES, Institute for Clinical Evaluative Sciences; ODB, Ontario Drug Benefit; OOP, out-of-pocket.

healthcare system will be obtained through the Institute for Clinical Evaluative Sciences (ICES), which holds administrative healthcare use and cost data, such as physician billings, hospital emergency services and inpatient stays, for the province of Ontario. Since participants will not be prevented from engaging in concomitant service use during the trial period, all service use will be documented using the data collection tool. Follow-up data will be collected from participants regardless of the amount of time during which they receive services.

## Randomisation

*Sequence generation*: Participants will be block-randomised to the TAU or ICCT arms using random block sizes for two treatments within each of the two strata defined by sex, separately at each of the four hospital sites (62–63 participants in each of the 8 strata, for sex and site). Randomisation will be executed using computer algorithms generated by REDCap research software.[46]

*Allocation concealment*: Participants will be randomised to the two study arms at entry into the trial. The allocation sequence will be concealed from the clinical RAs responsible for consenting, registering and assessing participants until all intake assessments are complete and the clinical RA accesses the website to obtain the randomisation result.

*Implementation*: The allocation sequence will be generated centrally by REDCap system and accessed by the clinical RA at the time of randomisation. Clinical RAs will receive a training session on the randomisation process prior to study launch. To randomise, the clinical RA will enter the sex of the participant into the software to obtain stratified randomisation within that hospital site.

*Blinding*: Clinical RAs will be blind to treatment allocation at intake, as intake assessments will be conducted prior to randomisation. Data analysts will be blind as to the treatment arms.

## Data collection procedures

*Clinical data*: Clinical data will be collected by clinical RAs at the intake visit. The intake meeting will be ~2½ hours in length based on pilot tests. The clinical RA will have access to an on-call clinician at all times during appointments to provide support for emergent issues. The assessment process will be repeated at 6 months and 12 months. Data from assessments will be directly collected into the electronic data capture system REDCap[46] using a tablet application and stored on a secure server hosted at CAMH.

*Economic evaluation*: Data will be collected by clinical RAs at baseline, 6-month and 12-month follow-up points. Site measures will be collected at each treatment site. Additional information on clinical contacts will be collected by clinical RAs from patient files (number, duration, type of service provider). At the end of the follow-up period, and once data is available, the health card number will be used to link the patient to their healthcare usage data from the Ministry of Health and Long-Term Care (MOHLTC). This data will be accessed through the Institute for Clinical Evaluative Sciences. The data will remain de-identified throughout the analysis (healthcare visits, emergency department visits, hospitalisations, specialist referrals, etc; see Statistical Plan below).

## Statistical plan

Analysis will be by intention to treat, and every attempt will be made to collect outcome data from all participants, including those who do not complete treatment. General linear models with repeated observations per youth (6 and 12 months) will be used to compare treatment and TAU groups with respect to outcome variables. Generalised estimation equations will be employed for parameter estimation. The respective baseline values will be added to the model as a covariate. For the primary outcome, a two-sided level of 0.05 will be used to examine for statistical significance. To control type I error probabilities, the analyses of secondary outcomes and the subgroup analyses will employ a two-sided level of 0.005. Subgroup analyses for the primary and secondary outcomes will be performed based on the following variables: age (14–16.5 vs 16.5–18 years old), severity of functional impairment (CIS) at baseline, disorder duration/age of onset and comorbidity of mental health symptoms (DAIS-C and self-report measures), all dichotomised depending on the distribution. Additional analyses will include examining, within treatment arms, the between-site heterogeneity and identifying baseline predictors of treatment response. Participants will also be asked to report their impression of the change observed, as an indication of clinical significance.[47]

*Sample size determination and statistical power*: A sample size of 500 participants will provide 80% power for the primary outcome, that is, the CIS.[32] This is based on the alternative hypothesis that the arms differ by 0.15 SD at 6 months and 0.3 SD at 12 months, $\alpha$=0.05 (two-sided), and an intraclass correlation coefficient $\leq$0.4 between the 6-month and 12-month observation periods. An effect size of 0.3 SD is considered the smallest that is clinically relevant and represents at most a 3-point difference on a scale of 0–52.

*Economic evaluation*: The economic evaluations will take both a healthcare system and societal perspective; these will include a CEA and a CUA. The time horizon will be the youth's lifetime. For the CEA, we will account for direct costs to the healthcare system and to the youth/family members, as well as indirect costs. Costs will be adjusted for inflation to 2018 Canadian dollars using the Statistics Canada Consumer Price Index for health and personal care.[48] All health outcomes and costs will be discounted at 5%/year.[49] We will account for all costs associated with delivering the proposed intervention. This will include costs with personnel, supplies and services, equipment and programme resources, among others. We will make use of a decision model in our CEA to help incorporate the benefits and costs beyond the time horizon of the existing data, and to help evaluate hypothetical scenarios. Health-related costs for the standard care costing cohort will be determined through linkage to population-based administrative databases at ICES using encrypted unique patient identifiers.[50] For each youth, we will determine the total usage of health resources and respective costs during the observation window in addition to the data collected directly from participants.

The incremental cost-effectiveness ratio (ICER), the primary outcome of the CEA, will be calculated as the difference in discounted mean costs between the ICCT and TAU groups divided by the difference in functional impairment on the CIS. Similarly, for the CUA the ICER will be a measure of the difference in costs divided by the difference in QALYs between the treatment arms. A 95% CI around these estimates will be estimated non-parametrically using 1000 bootstrap replications.

One-way deterministic sensitivity analyses will be performed to evaluate the robustness of our results. The ranges for the sensitivity analysis will be obtained from 95% CIs. We will also perform a probabilistic sensitivity analysis using a second-order Monte Carlo simulation with 1000 iterations. Using a net-benefit framework,[51] a cost-effectiveness acceptability curve (CEAC) will be produced using varying willingness-to-pay thresholds. A CEAC describes the probability that an intervention is cost-effective, compared with the alternative, for a range of maximum monetary values that a decision-maker may be willing to pay for a particular unit change in the outcome analysed. We will derive the CEAC from the joint distribution of incremental costs and incremental effects; we will use non-parametric bootstrapping of the observed data to estimate these joint distributions.

For the CUA, we will measure the change in utility as obtained from the AQOL-6D[45] instrument, which will allow us to calculate quality adjusted life years (QALYs). The AQoL-6D is a validated, self-reported instrument that contains 20 items that cover six domains of quality of life, including 'independent living', 'relationships', 'mental health', 'coping', 'pain' and 'senses'. The advantage of the CUA approach is that QALYs capture general well-being/disease burden directly from study participants. In addition, because the QALY is a widely used measure in economic evaluations across all clinical disciplines, the results generated from this study will be easily compared to the results of other, different healthcare interventions.

As a subsequent analysis to the economic evaluation, we also propose to examine the real world budget impact of implementing ICCTs for hospitals that treat adolescents across the province. One of the main objectives of this analysis will be to determine how much the Ontario Ministry of Health and Long-Term Care would need to spend to implement this model of care either in the entire province or in a given jurisdiction. Another outcome of interest will be an estimate of the potential savings achieved by the system by implementing this intervention.

## Confidentiality

The study will adhere to the Personal Health Information Protection Act[52] and all other regulatory and organisational standards for privacy, confidentiality

and security of database information. All study investigators will sign confidentiality agreements with ICES, following their guidelines, as PHI will be used to access ICES data.

All identifying information will be stored in locked cabinets separate from the study data. All study data will be coded numerically and password protected in the case of electronic data and stored on a secure server at CAMH. Only study personnel will have access to this data (including keys to cabinets for hard copies, knowledge of passwords for data).

*Records retention*: Study data will be stored in compliance with appropriate regulations.

### Ethical considerations

This study will be conducted according to the guidelines established by Good Clinical Practice (Food and Drug Administration, http://www.fda.gov/oc/gcp/regulations.html). Any protocol modifications will be communicated to all relevant parties immediately as they are made.

*Adverse events*: Adverse events will be clearly documented at the central study site in an Adverse Event Log immediately on notification and duly reported to the Research Ethics Board. An independent data safety monitoring panel will track and consider any adverse events to ensure participant safety.

### Regulatory binder

A regulatory Standard Operating Procedures binder will be kept in a secure location in the project coordinator's office. A separate binder containing personal health information will also be kept in a locked drawer within the project coordinator's office.

## DISCUSSION

Our model of an ICCT addresses the current deficiencies of the youth mental health system without replacing any existing services. Rather, ICCTs will be a state-of-the-art interface between existing agencies to improve practices and service access, co-created with the agencies themselves, youth, family members and other important stakeholders.[25] These teams will build interagency and cross-sectoral linkages to provide a seamless pathway of care from the identification of a mental health concern through transitions to low-intensity and high-intensity mental health interventions, depending on the needs of the youth and family members.

This ICCT model is innovative, brings together evidence-informed interventions and combines input from all stakeholders. Our partnership with youth and family members, community service providers, outreach services and targeted intervention programmes offer key outcomes at all levels. Coupled with our strong focus on research and evaluation, our model is expected to be of significant interest to the global youth mental health community as this will be the first RCT of similar models now in use in Australia, Ireland and the UK.[53–57] At the local community level, we expect to strengthen mental health awareness, capacity in delivering low-intensity interventions and the ability and willingness of mental health professionals to support high-risk youth in the community using collaborative care models. Evidence-informed treatments are expected to be used more frequently, delivered earlier in the course of a problem, with anticipated shorter waits to service. We may experience savings to the healthcare system if equivalent clinical outcomes can be achieved with less expensive services. At the individual level, youth and their families are expected to be more engaged in the services available for their MHA concerns in their community and more satisfied when they interact with such services. Youth and family members are expected to feel more empowered as they contribute to and receive services. Results will be disseminated through community and peer-reviewed academic channels, including publication in peer-reviewed journals, presentation at academic and service provider conferences and reports to community partners. Authorship will be determined based on standard protocols regarding the substantial contributions to study design, data analysis and interpretation and article preparation.

### Limitations

This study has several limitations that should be kept in mind. First, since this project is focused on evaluating models and systems of care complete efficacy and fidelity analyses will not be available for individual interventions within these systems. In addition, given the intentionally broad inclusion criteria, this pragmatic study will include individuals with a wide range of mental/addiction health challenges; although the sample size may allow for analysing data of youth grouped into broad MHA groups, it will not be possible to identify the differential impact of the systems of care or specific service components for individuals with specific mental health/addiction challenges. With the follow-up period limited to 1 year, it will not be possible to assess long-term impacts of each system of care. Given the relatively small sample size it is possible that there might be important differences between the recruitment sites in participant characteristics and or treatments provided. The inability to assess the degree of collaboration and sustainability of the interventions are additional limitations.

## CONCLUSION

This Integrated Collaborative Care Team model is innovative in many respects and holds substantial promise for the MHA system. By involving youth, family members and other stakeholders through all phases of the project, we have developed a service pathway that will meet the wide variety of needs with which youth with MHA challenges present. The multitude of services available in the pathway include evidence-informed community interventions, peer mentorship and phone/text-based crisis

support as well as rapid access to psychiatric care and primary care services. By providing integrated, highly collaborative care geared to need, goals and preferences, situated in youth-friendly environments within the community, this model is expected to substantially improve the mental health of this vulnerable population, making Ontario a leader in innovative systems of care.

**Author affiliations**
[1]Centre for Addiction and Mental Health (CAMH), Toronto, Ontario, Canada
[2]Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada
[3]Bloomberg Faculty of Nursing, University of Toronto, Toronto, Ontario, Canada
[4]Clinical Trials Unit, The Hospital for Sick Children, Toronto, Ontario, Canada
[5]SickKids Research Institute, Hospital for Sick Children, Toronto, Ontario, Canada
[6]East Metro Youth Services, Scarborough, Ontario, Canada
[7]Sashbear Foundation, Toronto, Ontario, Canada
[8]LOFT Community Services, Toronto, Ontario, Canada
[9]Youth and Families, Toronto, Ontario, Canada

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