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# ED to EPI: protocol for a pragmatic randomised controlled trial of an SMS (text) messaging intervention to improve the transition from the emergency department to early psychosis intervention for young people with psychosis

Alexia Polillo,[1,2] George Foussias,[1,2] Albert H C Wong,[2,3] Augustina Ampofo,[4] Vicky Stergiopoulos,[2,4] Kelly K Anderson,[5] Sarah Bromley,[1] Jessica D'Arcey,[1,6] Claire de Oliveira,[7,8] Lillian Duda,[4] Joanna Henderson ,[2,9] Sean Kidd,[2,4] Paul Kurdyak,[2,7] Wei Wang,[2,4] Juveria Zaheer,[2,7] Aristotle N Voineskos,[1,2] Nicole Kozloff [1,2]

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For numbered affiliations see end of article.

**Correspondence to**
Dr Nicole Kozloff;
n.kozloff@mail.utoronto.ca

## ABSTRACT

**Introduction** While nearly half of all new psychotic disorders are diagnosed in the emergency department (ED), most young people who present to the ED with psychosis do not receive timely follow-up with a psychiatrist, and even fewer with evidence-based early psychosis intervention (EPI) services. We aim to test an intervention delivered using short message service (SMS), a low-cost, low-complexity, youth-friendly approach, to improve transitions from the ED to EPI services.

**Methods and analysis** This is a protocol for a pragmatic randomised, single blind, controlled trial with accompanying economic and qualitative evaluations conducted at the Centre for Addiction and Mental Health (CAMH) in Toronto, Canada. A consecutive series of 186 participants aged 16–29 referred by the ED to CAMH's EPI programme will be recruited for a trial of a two-way intervention involving reminders, psychoeducation and check-ins delivered via SMS. The primary outcome will be attendance at the first consultation appointment within 30 days of study enrolment assessed through chart reviews in the electronic health record. We will also extract routine clinical measures, including the Brief Psychiatric Rating Scale, Clinical Global Impression and Service Engagement Scale, and link with provincial health administrative data to examine system-level outcomes, including ED visits and psychiatric hospitalisations, 6 months and up to 2 years after baseline. We will perform a cost-effectiveness analysis of the primary study outcome and costs incurred, calculating an incremental cost effectiveness ratio. Web-based surveys and qualitative interviews will explore intervention user experience. Patients and families with lived experience will be engaged in all aspects of the project.

**Ethics and dissemination** Research Ethics Board approval has been obtained. Findings will be reported in scientific journal articles and shared with key stakeholders including youth, family members, knowledge users and decision makers.

## Strengths and limitations of this study

- ► Pragmatic randomised controlled trial leveraging mobile health technology, chart reviews, routinely collected administrative data, and economic and qualitative evaluations.
- ► Intervention well-positioned for local adoption as well as scale and spread to other early psychosis intervention programmes and youth mental health services more broadly.
- ► Collaboration with health system decision-makers, clinical stakeholders, knowledge users, team members with clinical and research expertise, people with lived experience of psychosis, and key relationships with organisations well-positioned to support widespread implementation.
- ► Conducting the trial at a single site will support streamlined recruitment but may limit generalisability of our findings.
- ► The pragmatic data collection methods being used, particularly chart review, may be subject to unreliable extraction and missing data.

**Trial registration number** NCT04298450.

## INTRODUCTION

Psychosis, characterised by delusions and/or hallucinations, typically manifests during adolescence or early adulthood. It is the characteristic presentation of schizophrenia and schizoaffective disorder, and often occurs in bipolar disorder.[1] These disorders can cause significant dysfunction: in disability weighting surveys used to establish global disease burden, participants rated schizophrenia as

the disorder most disabling for individuals.[2] Young people experience greater mortality by up to 24-fold in the year following a first psychotic disorder diagnosis compared with peers in the general population.[3] In the long term, psychotic disorders are associated with ongoing increased mortality particularly by suicide,[4] substance use disorders, homelessness, victimisation, acts of violence[5] and high economic costs due to healthcare use as well as lost productivity.[6 7] Early psychosis intervention (EPI) is a model developed to provide treatment early in the course of illness to improve patients' long-term trajectories and reduce the burden on individuals and their families. The rationale for EPI has been strengthened by consistent findings that long duration of untreated psychosis is associated with greater symptom burden, lower likelihood of remission and poor social functioning and global outcomes.[8] Members of our team have shown that EPI service use is associated with a fourfold reduction in all-cause mortality for young people with psychosis compared with those who do not access EPI services.[9] EPI services have also been associated with improved access to psychiatric care, reduced risk of relapse, fewer hospital readmissions and increased employment rates.[9–13] EPI can be a lifechanging and lifesaving intervention for young people with psychosis.

EPI programmes are well-established in Ontario and provide services to young people with early psychosis across the province.[14] Despite this, and the clear mandate for EPI programmes to promote their services and minimise barriers to care, many youth with psychosis in Ontario either never access these services, or enter them far later than indicated.[15] In Canada, nearly half of all new psychotic disorders are diagnosed in the emergency department (ED).[16] We recently found that among young people across Ontario presenting with psychotic disorders to the ED for the first time, 40% received no outpatient mental health follow-up within 30 days and only 45% saw a psychiatrist.[17] The reasons young people with psychosis discharged from the ED did not receive follow-up were unclear in this study: both issues of access (availability and awareness of services) and engagement (youth following through on referrals) are potential explanations. Our experience at the Centre for Addiction and Mental Health (CAMH) in Toronto, where our EPI programme sees referred patients for consultation within 2 weeks on average, suggests a problem of engagement: according to clinic data, 50% of the youth referred from the ED do not attend their first EPI consultation appointment (compared with approximately 30% from all other referral sources). It is clear that new approaches are required to engage this population in accessing evidence-based care that is life-saving and improves illness outcomes. In surveys of patients and families in EPI services, appointment reminders are cited as a top factor that would improve service engagement, with a preference for email and text communication.[18–20]

Mobile health technologies are increasingly being tested to improve outcomes, including symptoms, appointment attendance and medication adherence, among young people with mental illness, particularly psychosis.[21–23] Short message service (SMS) or text message is a commonly used mode of communication by adolescents and young adults: in a survey of users of community mental health services, access to mobile phones approached 100%.[24] SMS is associated with low user and financial burden. SMS does not require people to own a smartphone, have data plans, or have access to wireless internet. In a study of people with psychosis, participants were found to be highly engaged with an SMS intervention.[25] SMS reminders have been associated with improved service engagement in psychosis across studies,[22] including twice the attendance rates for initial appointments in an EPI programme.[26] An ongoing pilot study at CAMH investigating the effect of a weekly two-way SMS intervention on service engagement during the first year of EPI treatment found this approach to be feasible and valued by participants.[27] We are unaware of any studies examining interventions specifically to improve the transition in care from the ED to EPI for young people with psychosis, using mobile health technologies or otherwise.

## Objectives and hypotheses

'ED to EPI', a pragmatic randomised, single blind, controlled trial[28] with accompanying economic and qualitative evaluations, aims to improve the transition from the ED to EPI services for youth with psychosis using an SMS text messaging intervention. It is pragmatic in its participant eligibility criteria (broad and inclusive), comparison intervention (usual care), follow-up intensity (low), primary trial outcome (objective, meaningful and assessed under usual conditions), measurement of participant compliance and practitioner adherence to study protocol (unobtrusive) and analysis of primary outcome (inclusive, ie, intention-to-treat).[29] We also leverage linked routinely collected data through ICES (previously known as the Institute for Clinical Evaluative Sciences), which holds data on all hospital and physician visits for the province. We will also evaluate the cost effectiveness of the intervention and explore young people's perspectives on its various components. Our study team, in addition to clinicians and researchers, includes a patient and family member with lived experience of using EPI services and key decision-makers to increase the relevance and uptake of the intervention. Specifically, our primary objectives are to:

1. Evaluate the effect of an SMS intervention on attendance at the first consultation appointment within 30 days of study enrolment.
   Hypothesis 1: The SMS intervention will increase rate of attendance at the consultation appointment.
2. Assess indicators of longer-term service engagement 6 months following study enrolment.
   Hypothesis 2: The SMS intervention will lead to improved indicators of longer-term service engagement

(Service Engagement Scale (SES) scores and dropout rates).

3. Determine system-level outcomes, including ED visits and psychiatric hospitalisations, as a function of receiving the SMS intervention, and its cost effectiveness, factoring costs of the intervention and cost offsets of health service utilisation.
   Hypothesis 3: The SMS intervention will lead to decreased use of acute care services (ED visits and psychiatric hospitalisations) and will be cost-effective relative to the control condition, based on improved rate of transition from the ED to EPI services and anticipated reductions in use of costly acute care services.
4. Explore young people's experiences of the intervention and their perspectives on its various components.

This is an exploratory research question that seeks to understand how young people experience the SMS intervention and how they perceive its various components impact their service engagement.

## METHODS AND ANALYSIS

### Study setting

The study setting will be the Gerald Sheff and Shanitha Kachan Emergency Department at CAMH, Ontario's only 24 hours stand-alone psychiatric emergency service. The ED also houses a drop-in 'Bridging Clinic' which provides care to less acute patients who are diverted after ED triage, and rapid follow-up care for patients discharged from the ED and CAMH inpatient units. Together, they serve approximately 1200 patients each month. The EPI programme at CAMH receives over 600 referrals for suspected psychosis annually, approximately 25% of which are from the ED and Bridging Clinic. Reflecting the Ontario EPI Programme Standards, CAMH EPI services are delivered by multidisciplinary teams, employ strategies to promote early entry and ongoing engagement, and provide pharmacotherapy and psychosocial therapies for an average of 3 years.[14] Patients are assigned to the next available and/or most appropriate psychiatrist and case manager (nurse, social worker or occupational therapist) for a joint consultation appointment, typically within 2 weeks, and are contacted by phone by the EPI programme administrator to book and confirm their appointment. After the initial appointment is confirmed, patients receive a phone call reminder the day before their scheduled appointment. As part of routine care, patients who do not attend their scheduled first appointment receive follow-up calls to reschedule an appointment for up to 30 days from the initial referral.

### Eligibility criteria

Study inclusion criteria mirror the intake criteria for the CAMH EPI programme. Participants will be eligible for the study if they: (i) are between 16 and 29 years old and (ii) have been referred by the CAMH ED to CAMH EPI services for suspected psychosis. Our only exclusion criterion is inability to communicate in basic written English. In our pilot SMS study at CAMH, fewer than 5% of potential participants were excluded for lacking a phone; we have budgeted to offer 5% of participants access to a prepaid cellphone for the duration of the study.[27]

### Intervention procedures

Study participants will be recruited at the time of EPI referral for a trial of an SMS intervention designed to engage them during the waiting period for their consultation appointment. They will be randomised to receive either sham or active SMS intervention.

Sham SMS will consist of one message sent just after enrolment indicating that they will be contacted for an appointment. The sham SMS group will not be denied any part of usual clinical care. Thus, the clinic administrator will call patients in both groups to book and remind them of the consultation appointment. Active SMS intervention will include the initial message sent to the control group, plus a series of subsequent messages. These will include the following content: (i) appointment reminders and instructions, (ii) psychoeducational material and (iii) two-way communication check-ins to rate distress (figure 1). Intervention components were developed based on feedback from a survey of youth in the same EPI programme,[30] as well as psychosocial interventions with evidence in early psychosis, including cognitive-behavioural therapy (psychoeducation, behavioural activation) and illness self-management (reminders, distress check-in).[31 32] See online supplemental file 1 for a comprehensive description of the intervention. Messages sent back by participants will be monitored by the research team, and the case manager assigned to their consultation appointment will be notified and will respond accordingly if there are indicators of elevated distress. The intervention will continue until the patient attends the first consultation appointment, or for up to 30 days if the patient does not attend, which reflects the programme's practice of closing referrals for non-attending patients.

Messages will be sent through CAMH's in-house Research Electronic Data Capture (REDCap) platform via a third-party plug-in, Twilio, which supports routing of SMS messages to participant devices.[33–35]All data are stored securely on CAMH's REDCap servers or in a locked office and password-protected database on CAMH's secure network. The purpose of the sham intervention is to separate out the content of the intervention (ie, reminders, psychoeducation, two-way check-ins) from the effect of simply receiving SMS messages, decreasing participant bias.

### Assignment of intervention

Immediately after informed consent, participants will be randomised by REDCap to the active or sham intervention. Generation of the randomisation sequence will be managed by the study biostatistician who is not involved in enrolling participants or assigning intervention arms. Randomisation will be stratified by sex (male or female) and referral source (ED or Bridging Clinic), using a

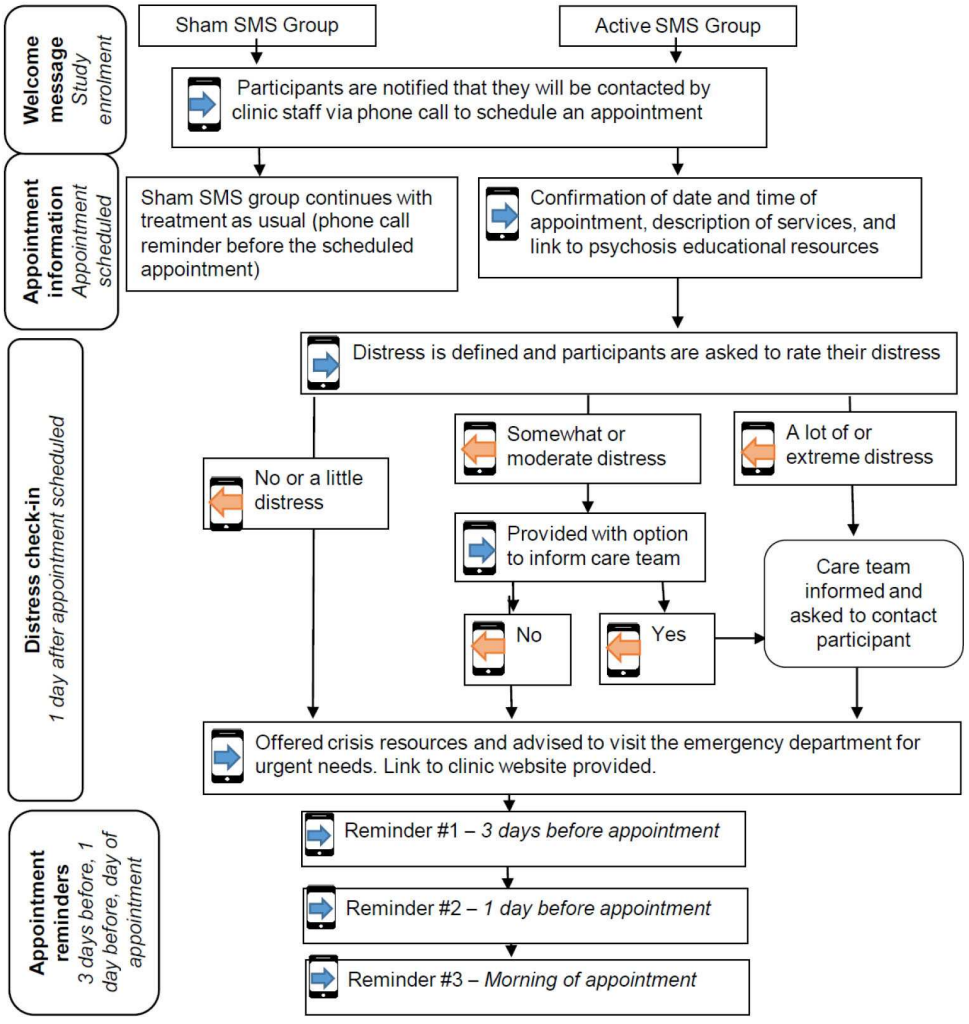


**Figure 1** Study intervention schedule. This figure represents a summary of the intervention schedule and is not exhaustive of text message content. Left arrow, outgoing text messages sent by participants; right arrow, incoming text messages received by participants; SMS, short message service.

computer algorithm to determine a randomised, blocked allocation of participants into intervention groups within strata. Once randomised, treatment assignment will be known only by the study personnel involved in managing the SMS intervention and the case manager monitoring text message responses; the principal investigator and study personnel involved in the chart review and the ICES analysis will remain blind to treatment assignment. Study personnel involved in the qualitative interviews and analysis will also be aware of treatment assignment since only individuals receiving the active intervention will participate in this component of the project.

## Sample size

Our sample size calculations are based on the primary outcome of rate of attendance at the EPI programme consultation appointment. The current rate of attendance at the first consultation appointment for patients referred from the ED and Bridging Clinic is 50%; we have powered our study to detect the treatment effect with an anticipated rate of attendance of 70%, which is the average for all referral sources other than the ED and Bridging Clinic. A total of 186 participants (93 per group) will provide >80% power to detect a change in attendance from 50% to 70% at alpha <0.05. Non-compliance and loss to follow-up are not a concern for our primary outcome since these are counted in the outcome as non-attendance at the consultation. Adjusting analyses for covariates expected to affect attendance (eg, age, sex) is expected to further increase power.

## Study procedures

We will recruit 186 patients consecutively referred from the CAMH ED and Bridging Clinic to the CAMH EPI programme at the time of discharge. During business hours and into the evening, research staff will be on call to the ED to recruit patients as soon as they are identified for the study. Eligible participants who present after hours may be identified by ED staff and referred to the research team who will send them an e-consent form via SMS or email. See online supplemental file 2 for patient consent form. Additionally, potential participants who are missed in the ED/Bridging Clinic may be identified by the EPI clinic administrator who will approach them

over the phone and send them an e-consent form via SMS or email. We have used the approach of having clinical and administrative staff obtain verbal consent to send e-consent forms in other studies with this population.[19]

As part of informed consent, participants will be asked to consent to a review of their chart, a follow-up web-based survey, and linkage of their information to data held at ICES. They will also be given the option to provide consent to be re-contacted for participation in a qualitative interview. There will be no additional in-person assessments for the quantitative component of this study. CAMH uses an electronic health record, which facilitates data abstraction from multiple clinical programmes (ie, both the ED and Bridging Clinic and EPI programme). Research staff and students will be trained by the clinician principal investigators to abstract data into a structured database.

All study participants will receive a $10 e-giftcard once the baseline e-visit is complete. Participants in the active intervention group who complete a web-based survey will receive another $10 e-giftcard and those who complete a qualitative interview will receive a $50 e-giftcard. It will be clarified through the consent process that honoraria are to compensate participants for their time and will not be tied to clinical appointment attendance. For the majority of participants, their initial recruitment and consent will be their only interaction with the research team, with a small subgroup completing qualitative interviews.

## Outcome measures

### Chart review

Outcome measures are shown in table 1. CAMH uses many standardised assessment forms which increases the completeness of patient data. Demographic variables, clinical diagnoses, substance use, duration of untreated psychosis (measured as the period of time from first onset of psychotic symptoms to initiation of EPI services and initiation of treatment with an antipsychotic or mood-stabilising medication), characteristics of the ED visit from which they were referred (urgent presentation—brought by police, involuntary status; timing of visit), and family involvement in care are routinely recorded in the clinical chart by clinicians and will be abstracted from the chart at the time of consultation. Additional variables will likely be available but only for patients accepted into the EPI programme, and this will be reflected in the data analysis. These include several assessments that are performed routinely in the EPI programme. The SES[36] is a brief validated tool designed to measure engagement with community mental health services. In 14 items, it assesses patients' availability for treatment, collaboration, help-seeking behaviours and treatment adherence on a four-point Likert scale with higher scores indicating difficulties in service engagement. The Brief Psychiatric Rating Scale[37] is a clinician or interviewer-rated measure of psychiatric symptoms commonly used as an outcome measure for psychotic disorders and collected monthly in CAMH's EPI programme. It includes items related to suicidality and hostility. The Clinical Global Impression[38] is a clinician-rated measure of the patient's global severity of illness prior to and after initiating a medication. It includes subscales for severity and improvement. Medication and appointment non-adherence will also be assessed over 6 months of treatment. Finally, after 6 months, current EPI enrolment status will be assessed and categorised as: not offered or enrolled in treatment (eg, because they did not ultimately have psychosis), enrolled but disengaged prematurely, accepted for treatment but transitioned to other services or continued in treatment. Data abstractors will undergo rigourous training and monitoring, use standardised extraction forms, and calculate inter-rater reliability.

### Administrative data

Primary data collected for the study will be linked deterministically to data sources held at ICES via participants' unique health card numbers. The information available for each participant will be de-identified, stored and analysed onsite at ICES following procedures approved by Ontario's Information and Privacy Commissioner. The following ICES data sources will be used: the Ontario Mental Health Reporting System, capturing hospitalisations on adult inpatient mental health units,[39] the Canadian Institute of Health Information Discharge Abstract Database, capturing all hospital admissions including hospitalisations on child and adolescent inpatient mental health units,[40 41] National Ambulatory Care Reporting System which captures all ED visits,[42] Ontario Health Insurance Plan claims database, which captures outpatient physician visits,[40] Registered Persons Database, which contains health card numbers, demographic information, and deaths, and Ontario Drug Benefits claims database, which provides information on all covered prescriptions (based on financial need for those under age 65 and for young people up to age 25 who lack private insurance). These data will also be used for cost effectiveness analysis. Outcomes examined in the linked ICES data are listed in table 1.

## Statistical analysis

### Primary analysis

Descriptive and graphical statistics will be used to summarise the data on all randomised participants and to confirm that there are no group differences in baseline demographics and clinical characteristics. Distributional assumptions will be inspected and appropriate transformations or non-parametric methods will be applied as necessary. In general, generalised linear models[43] will be used throughout. These models account for deviation from normal assumption of the outcome variables and control for covariates.

Our analysis of the primary outcome will be a logistic regression to examine the likelihood of attendance at the EPI consultation with treatment assignment using risk ratios.[44] We will carefully select demographic variables and factors known to influence treatment engagement

Table 1 Summary of outcome measures and covariates

| Type | Variables | Data source | Timing |
|---|---|---|---|
| Demographic characteristics | Age | Chart review for all demographic characteristics (CAMH Health Equity form and notes) | Baseline* |
| | Sex and gender | | |
| | Sexual orientation | | |
| | Race/ethnicity | | |
| | Born in Canada | | |
| | Religious/spiritual affiliation | | |
| | Highest level of education | | |
| | Source of income and family income | | |
| | Number of people supported by income | | |
| | Employment status | | |
| | Legal history | | |
| | Housing status | | |
| | Living situation | | |
| | Experience of homelessness | | |
| | Relationship status | | |
| Clinical characteristics | Clinical diagnoses | Chart review for all clinical characteristics (consultation and progress notes) | Baseline |
| | Substance use | | Baseline |
| | DUP | | Baseline |
| | Family involvement in care | | Baseline |
| | Urgent status at ED visit (brought by police, involuntary) | | |
| | Timing of ED visit | | |
| | BPRS[37] | | Baseline and 6 months |
| | CGI[38] | | Baseline and 6 months |
| Service engagement | Attendance at consultation appointment | Chart review for all service engagement measures | 30 days |
| | SES[36] | | 6 months (completed around 3 months in treatment) |
| | Medication and appointment non-adherence | | 6 months |
| | EPI enrolment status | | 6 months |
| System-level outcomes† | Number of ED visits | NACRS[42] | 6 months and up to 2 years |
| | Number of inpatient mental health hospitalisations | OMHRS,[39] CIHI-DAD[40 41] | |
| | Number of days in inpatient mental health hospitalisations | OMHRS,[39] CIHI-DAD[40 41] | |
| | Number of outpatient mental health visits | OHIP[40] | |
| | Prescription drugs—psychiatric medications, continuously vs non-continuously prescribed | ODB | |
| | Mortality including cause of death | Registered Persons Database | |

*Items may be extracted from the ED note or EPI consultation note.
†Administrative data held at Institute for Clinical Evaluative Sciences.
BPRS, Brief Psychiatric Rating Scale; CAMH, Centre for Addiction and Mental Health; CGI, Clinical Global Impression; CIHI-DAD, Canadian Institute of Health Information Discharge Abstract Database; DUP, duration of untreated psychosis; ED, emergency department; EPI, early psychosis intervention; NACRS, National Ambulatory Care Reporting System; ODB, Ontario Drug Benefits; OHIP, Ontario Health Insurance Plan; OMHRS, Ontario Mental Health Reporting System; SES, Service Engagement Scale.

(eg, substance use, family involvement in care)[45] to be included in the model as covariates. A difference in attendance between groups will be declared at a significance level of 0.05. Similar models will be used to address the secondary hypotheses, with specific types of models appropriate to each outcome, including time-to-event analysis to examine premature disengagement from services. Administrative data outcomes will be examined using generalised linear models with proper distribution assumptions.

### Additional analyses: moderation and generalisability

We plan to conduct two additional exploratory analyses. First, we will run moderation analyses on potential effect modifiers by adding an interaction term between the potential moderator and the treatment assignment indicator in the generalised linear models. We are specifically interested in the moderation effects of health equity factors including gender, race/ethnicity and housing status. A significant interaction will provide evidence that the treatment effects may be different in the subgroups. A second exploratory analysis will be conducted to evaluate the impact of selection bias of the study sample and estimate the population average treatment effects by employing weighted analysis using propensity scores.[46]

### Missing data

The risk of missing data is mitigated through the use of chart review and analysis of administrative data. While the primary outcome will not suffer from attrition, other outcomes will, as some follow-up data will only be available for participants who attended their consultation appointment and those who are enrolled in CAMH EPI services. For these additional outcomes, we plan to use multiple imputation methods developed by Schafer to correct potential bias that could be introduced by missing data.[47]

### Economic evaluation

Full details of the economic evaluation appear in online supplemental file 3. We will undertake a cost-effectiveness analysis, where the outcome of interest is consultation appointment attendance, adopting the perspective of the public third-party payer (ie, the Ontario Ministry of Health). We will collect data on the costs of delivering both arms of the intervention. In addition, using a costing algorithm available at ICES,[48] we will estimate all direct patient-level healthcare costs incurred by the public third-party payer for the intervention and control groups, which will include costs of hospitalisations, ED visits, physician services (ie, primary care, psychiatry and other) and diagnostic tests, outpatient prescription drugs for individuals covered under the provincial public drug insurance plan, and other hospital-based care. We will calculate the incremental cost-effectiveness ratio as the difference in discounted mean costs between the intervention and control groups, divided by the difference in attendance rates. We will use a net benefit regression approach to model probabilities of cost effectiveness for each additional patient referred who attends their consultation appointment in the intervention compared with control group. In addition, we will undertake relevant sensitivity analyses to test the robustness of findings by varying relevant parameters, such as the discount rate. Finally, we will examine the real-world budget impact of implementing the intervention across Ontario, to estimate the cost to the Ministry of Health of implementing this model of care across the province and the potential cost-savings to the system associated with this.

### Understanding patient experiences: survey and qualitative analysis

Participants in the active intervention group will receive a one-time survey sent as a web-link to their phone or email address. Survey topics include user experience, attitudes toward the SMS intervention, its perceived benefits and challenges, acceptability and suggestions for improvements. Those who consent to participate in the qualitative research component will be recontacted by phone or email to participate in semi-structured interviews to gain a more in-depth understanding of survey topics. A subsample of 10–15 participants in the active intervention group will be purposively selected to maximise diversity of age, gender and service attendance. We will use critical realist theory as an underlying framework to guide our interviews, surveys and analysis.[49] Interviews will be completed until thematic saturation is achieved, estimated at 12 participants. Interviews will be digitally audio-recorded and transcribed verbatim. Surveys will be completed and stored in REDCap. Transcriptions and survey responses will be analysed using thematic content analysis in NVivo-11. Research participants will be invited to assist with member checking to confirm that themes reflect their experiences. The analysis can inform future improvements to the intervention and considerations for broader implementation, privileging the experiences of the patients attending these programmes.

## Patient and public involvement

A youth and family member who previously received EPI services have been engaged in helping shape the intervention and study design from project inception. They are active members of the project's Steering Committee that meets monthly to inform study design, implementation, evaluation, and dissemination of results. They will have key roles in the plan to spread the intervention, if successful, to other EPI programmes by working with patients and families to adapt the intervention to local contexts. Additional youth with lived experience of receiving EPI services have been consulted on an ad hoc basis through the CAMH Youth Engagement Initiative to provide detailed feedback on the SMS intervention. Patient and family representatives on the research team are compensated for their time.

## ETHICS AND DISSEMINATION

The study was approved by the Research Ethics Board (REB) at the CAMH. The study protocol was prepared according to Standard Protocol Items: Recommendations for Interventional Trials guidelines[50] and registered with clinicaltrials.gov on 6 March 2020 (https://clinicaltrials.gov/ct2/show/NCT04298450?term=ed+to+epi&draw=2&rank=1). REB-approved protocol amendments will be posted on the site. The principal investigators and study team will meet regularly to review accrued data, data confidentiality, any adverse events, adherence to protocol design, recruitment and implementation. This intervention has been designed to have high likelihood of adoption and readiness for spread and scale-up because it responds to a critical need, has a strong evidentiary basis, has advantages over existing practice and is both low complexity and low cost.[51] The study team is well-positioned to support widespread implementation of the intervention if successful. We have used an integrated knowledge translation approach that leverages input from stakeholders, including patients, clinicians (both from the ED and EPI services), policymakers and relevant organisations throughout the study to champion the spread of the intervention to other EPI programmes and youth mental health services more broadly. This trial focuses on a particularly vulnerable population—young people transitioning from adolescence to adulthood and from the ED to EPI services—but the basic intervention is widely applicable. The software platform used to coordinate this intervention is available at no charge, and the SMS functionality for sending and receiving messages carries a nominal fee, supporting broad uptake.

The results of the trial will be reported in scientific journal articles and shared with key stakeholders as they become available. Our study team includes the co-chair of the Early Psychosis Intervention Ontario Network, a network of over 50 EPI programmes across Ontario, and several members of the Canadian Consortium for Early Intervention in Psychosis, providing a durable and established community of practice for immediate spread. De-identified participant data will be available on reasonable request other than system-level data held at ICES. Requests can be made by contacting the principal investigator Dr Nicole Kozloff at nicole.kozloff@camh.ca and will be managed by the Steering Committee.

This pragmatic randomised-controlled trial of a low-cost, low-complexity SMS intervention aims to improve the transition from the ED to EPI services for young people with psychosis. It targets a brief but critical period: if young people cannot even get in the door to EPI services, there is no way for them to reap the many known benefits of EPI care. Improving the ED to EPI transition has the potential to result in more young people with psychosis getting appropriate treatment earlier. The proposed intervention is also likely to be easily adaptable to other referral pathways to EPI services and youth mental health services more broadly. At potentially lower cost to the health system, applying this SMS intervention to the ED to EPI transition has the potential to lead to improved short-term symptoms and functioning, long-term disease trajectories, decreased burden on patients and families, and fewer deaths among young people with psychosis.

**Author affiliations**
[1]Slaight Family Centre for Youth in Transition, Centre for Addiction and Mental Health, Toronto, Ontario, Canada
[2]Psychiatry, University of Toronto, Toronto, Ontario, Canada
[3]Campbell Family Mental Health Research Institute, Centre for Addiction and Mental Health, Toronto, Ontario, Canada
[4]Centre for Addiction and Mental Health, Toronto, Ontario, Canada
[5]Epidemiology & Biostatistics, Western University, London, Ontario, Canada
[6]Institute of Medical Science, University of Toronto, Toronto, Ontario, Canada
[7]Institute for Mental Health Policy Research, Centre for Addiction and Mental Health, Toronto, Ontario, Canada
[8]Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, Ontario, Canada
[9]Margaret and Wallace McCain Centre for Child, Youth and Family Mental Health, Centre for Addiction and Mental Health, Toronto, Ontario, Canada

**Twitter** Alexia Polillo @alexiapolillo, Kelly K Anderson @anderskk3, Claire de Oliveira @clairede0, Juveria Zaheer @juveriazaheer and Nicole Kozloff @nicole_kozloff

**Contributors** NK is the principal investigator who conceived the original study design and obtained funding, with most of the current authors having contributed to the funding application, and all authors having participated in revisions to the study design for important intellectual content. AP, GF, AHCW, AA, VS, JD, LD, ANV and NK sit on the project's Steering Committee. AP, GF, JD and NK form the Data Management Committee. AP leads the survey and qualitative analysis. GF, AHCW, SB and ANV have administrative roles in the clinical programmes and will support the acquisition and interpretation of data. AA and LD act as patient and public consultants. VS acts as a Health System Decision-Maker on the project. KKA, CdO, PK and NK consult on the ICES analysis. CdO is a health economist who consults on the economic analysis. VS, JH and SK provide knowledge translation expertise. JZ provides consultation on the qualitative interviews and analysis. WW acts as the biostatistical consultant. AP and NK drafted the protocol. All authors read, revised and approved the final version of the manuscript.

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**ORCID iDs**
Joanna Henderson http://orcid.org/0000-0002-9387-5193
Nicole Kozloff http://orcid.org/0000-0003-1389-1351

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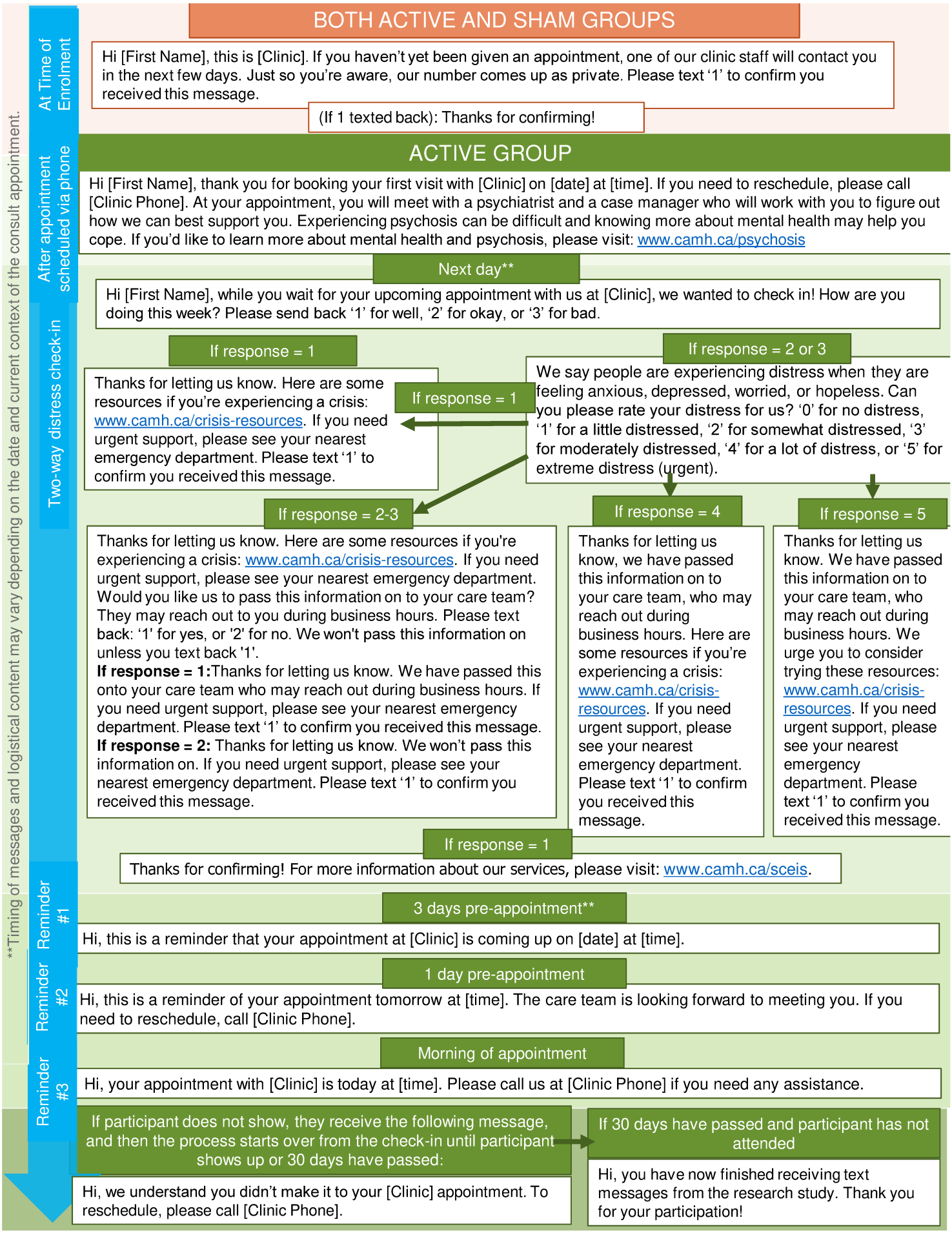
BOTH ACTIVE AND SHAM GROUPS
At Time of Enrolment
Hi [First Name], this is [Clinic]. If you haven't yet been given an appointment, one of our clinic staff will contact you in the next few days. Just so you're aware, our number comes up as private. Please text '1' to confirm you received this message.
(If 1 texted back): Thanks for confirming!
ACTIVE GROUP
After appointment scheduled via phone
Hi [First Name], thank you for booking your first visit with [Clinic] on [date] at [time]. If you need to reschedule, please call [Clinic Phone]. At your appointment, you will meet with a psychiatrist and a case manager who will work with you to figure out how we can best support you. Experiencing psychosis can be difficult and knowing more about mental health may help you cope. If you'd like to learn more about mental health and psychosis, please visit: www.camh.ca/psychosis
Two-way distress check-in
Next day**
Hi [First Name], while you wait for your upcoming appointment with us at [Clinic], we wanted to check in! How are you doing this week? Please send back '1' for well, '2' for okay, or '3' for bad.
If response = 1
Thanks for letting us know. Here are some resources if you're experiencing a crisis: www.camh.ca/crisis-resources. If you need urgent support, please see your nearest emergency department. Please text '1' to confirm you received this message.
If response = 1
If response = 2 or 3
We say people are experiencing distress when they are feeling anxious, depressed, worried, or hopeless. Can you please rate your distress for us? '0' for no distress, '1' for a little distressed, '2' for somewhat distressed, '3' for moderately distressed, '4' for a lot of distress, or '5' for extreme distress (urgent).
If response = 2-3
Thanks for letting us know. Here are some resources if you're experiencing a crisis: www.camh.ca/crisis-resources. If you need urgent support, please see your nearest emergency department. Would you like us to pass this information on to your care team? They may reach out to you during business hours. Please text back: '1' for yes, or '2' for no. We won't pass this information on unless you text back '1'.
**If response = 1:**Thanks for letting us know. We have passed this onto your care team who may reach out during business hours. If you need urgent support, please see your nearest emergency department. Please text '1' to confirm you received this message.
**If response = 2:** Thanks for letting us know. We won't pass this information on. If you need urgent support, please see your nearest emergency department. Please text '1' to confirm you received this message.
If response = 4
Thanks for letting us know, we have passed this information on to your care team, who may reach out during business hours. Here are some resources if you're experiencing a crisis: www.camh.ca/crisis-resources. If you need urgent support, please see your nearest emergency department. Please text '1' to confirm you received this message.
If response = 5
Thanks for letting us know. We have passed this information on to your care team, who may reach out during business hours. We urge you to consider trying these resources: www.camh.ca/crisis-resources. If you need urgent support, please see your nearest emergency department. Please text '1' to confirm you received this message.
If response = 1
Thanks for confirming! For more information about our services, please visit: www.camh.ca/sceis.
Reminder #1
3 days pre-appointment**
Hi, this is a reminder that your appointment at [Clinic] is coming up on [date] at [time].
Reminder #2
1 day pre-appointment
Hi, this is a reminder of your appointment tomorrow at [time]. The care team is looking forward to meeting you. If you need to reschedule, call [Clinic Phone].
Reminder #3
Morning of appointment
Hi, your appointment with [Clinic] is today at [time]. Please call us at [Clinic Phone] if you need any assistance.
If participant does not show, they receive the following message, and then the process starts over from the check-in until participant shows up or 30 days have passed:
Hi, we understand you didn't make it to your [Clinic] appointment. To reschedule, please call [Clinic Phone].
If 30 days have passed and participant has not attended
Hi, you have now finished receiving text messages from the research study. Thank you for your participation!
**Timing of messages and logistical content may vary depending on the date and current context of the consult appointment.

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**ED to EPI: Using SMS (Text) Messaging to Improve the Transition from the Emergency Department to Early Psychosis Intervention for Young People with Psychosis**
**Online Version - Informed Consent Form**

**Principal Investigator:** Dr. Nicole Kozloff
Dr. George Foussias
Dr. Vicky Stergiopoulos
Dr. Aristotle Voineskos

**Co-Investigators:**
Augustina Ampofo
Dr. Kelly Anderson
Sarah Bromley
Jessica D'Arcey
Dr. Jeff Daskalakis
Dr. Claire de Oliveira
Lillian Duda
Dr. Joanna Henderson
Dr. Sean Kidd
Dr. Paul Kurdyak
Dr. Alexia Polillo
Dr. Brittany Poynter
Dr. Wei Wang
Dr. Albert Wong
Dr. Juveria Zaheer

**Sponsor:** Canadian Institutes of Health Research, CAMH Foundation

## Purpose of the Study:

We invite you to participate in this study because you have been referred to the Slaight Centre for Early Intervention Services. The Slaight Centre is an outpatient program for young people experiencing a first episode of psychosis and their families. In this study we will examine if text messaging can improve the transition from the emergency department to early intervention services for youth. We hope that this study will eventually lead to young people getting appropriate treatment earlier and improve their long-term outcomes. Your participation in this study is voluntary. The following information is provided to help you make an informed decision whether or not to participate.

## What will I be asked to do as part of this study?

If you decide to participate in this study, you will be asked to do the following:

1) Intervention: You are being invited to take part in a study. If you consent to participate, you will be randomly assigned to receive one of two types of text messages. Random assignment means that you have an equal chance of being assigned to each text message group. If you are assigned to the text message intervention, you will receive text messages at a time of your choosing (e.g., morning, evening). You will be sent text messages with information about appointment details, education about psychosis, an opportunity to rate your distress, and appointment reminders. These text messages will continue until you attend your first consultation appointment, or for up to 30 days if you did not attend. If you are assigned to the other group, you will receive a one-time text message. If you do not have a phone, one will be offered to you for the duration of the study with the expectation that it is returned at your first consultation appointment.

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Please note that text messages are NOT being monitored constantly and if you are experiencing an urgent issue, this information should not be sent by text message. Instead, please visit your nearest emergency department. Additionally, this is not a direct line of communication with your care team and it is not a secure form of communication. You should not send any personal health information that is not requested by the text messages.

2) Collection of data**:** We will also review your medical chart to obtain additional information about you. Information collected through this study will be transferred to the Institute for Clinical Evaluative Sciences (ICES). ICES is an organization that holds routinely collected data on health care use in Ontario. ICES is committed to protecting the privacy and security of health information. ICES is an approved unit under Ontario's Personal Health Information Protection Act and follows the policies and procedures for privacy protection and data security approved by Ontario's Information and Privacy Commissioner. Linking the data will involve using personal identifiers such as your name, date of birth, and OHIP number to identify your health service use. These identifiers will be removed as soon as the data is connected to ICES. The data will then be replaced by a scrambled code in order to decrease the likelihood of a data breach (when people get access to private information without permission)

3) Follow up survey: You may be asked to complete a brief survey following your participation in the text message intervention. Your participation in the survey is voluntary. If you consent to study participation, you may receive a link to the online survey at the contact information of your choice (text message or email). The survey takes approximately 5 to 10 minutes to complete. If you complete the survey, you will be compensated with a $10 e-gift card sent to you by email or text message from your choice of a list of retailers. The survey contains questions about your experiences with the text message intervention.

## Are there risks involved?

There are no known harms associated with participation in this study. If your text messaging plan does not include unlimited texting, you may incur additional charges on your cell phone bill. The study will not reimburse you for these charges. You may also feel emotional discomfort and fatigue from receiving recurrent text messages with appointment reminders and questions about how you are feeling. If you do feel this way, you may refuse to answer any question, or terminate your participation in this study at any point in time. You may be asked some questions during the survey that might make you feel somewhat uncomfortable. If you do feel uncomfortable, you may indicate this in the comments or skip the question. You can also pause the survey and continue at another time. Please be advised that if the researcher or study personnel sees that there is a risk to your safety or the safety of others, then steps will be taken to ensure your safety and the safety of others. Lastly, the security of information sent by email/text cannot be guaranteed.

## Are there benefits involved?

No direct benefits to your health will likely result from this study. It is possible that the results of this study will increase engagement in early intervention services and may benefit other people now or

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in the future. You will also receive compensation for your time and participation in the study. The investigators responsible for this study or CAMH are not conducting this study to receive commercial benefit. However, if this research produces financial returns from a commercialization of the results in the future, you will not receive any benefit from these returns.

## Can participation in this study end early?

Participation in any research study is voluntary. Your decision whether or not to participate will not interfere with your right to healthcare or other services to which you are otherwise entitled. You can contact the research team through email or phone to withdraw from the study at any time. After data is anonymized your responses cannot be withdrawn, however, no new data will be collected. Throughout your participation in this study, you will continue to receive usual care as agreed upon by you and your treatment team. In the event of research-related harm, you have not waived any legal rights/rights to legal recourse.

## Are study participants paid to participate in this study?

Everyone who participates in the text messaging intervention will receive a $10 e-gift card by email or text message from your choice of a list of retailers. If you decide to withdraw before study end, you will still be paid for your time and participation. Those participants selected to participate in the follow up survey will receive another $10 e-gift card by email or text message from their choice of retailers for completing the survey.

## Will personal information about me be kept confidential?

- The research data will be kept confidential from the inception of the study.
- Any information about you obtained from this research will be kept as confidential (private) as possible unless disclosure is required by law. It is important to note that confidentiality will be protected to the extent permitted by law. However, there are 3 exceptions to our confidentiality policy. In any of the following situations, we are obligated by law to contact authorities: 1) if there is a serious possibility that you may harm yourself or others; 2) if you have been involved in any form of child abuse or neglect; 3) if you have been the victim of abuse by a healthcare worker
- All data obtained from this research will be kept in a locked office and secured password database with limited access only to study personnel and authorized CAMH personnel.
- To protect your identity and confidentiality, all personal identifiers (such as your name, birth date) will be removed (de-identified and replaced with a specific code number; the research records and data will be indicated by a case number rather than your name, and the information linking these case numbers with your identity will be kept separate from the research records. This information will be kept in a separate, secure location and will only be accessible to study personnel.
- Study personnel may also access your health records for research purposes; your medical records will be kept confidential.
- All electronic files will be stored on CAMH's secure hospital or institutional network and will be password protected.
- Other Canadian research centres (other than CAMH) may be involved in analyzing the data,

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and if so this will be confidential, and your name will not be given out.

- Following the completion of the study, the researchers intend to publish the results in scientific journals. You will not be identified in any of these reports. A report of the results of this project will be given to you if you request it.
- The information you provide will not affect the usual care that you receive.
- The investigators on this study will keep the data as long as necessary to fulfill the research purposes and in accordance with the applicable laws and regulations and will use enhanced security measures to store it.
- De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share.
- Your de-identified research data (information about your diagnosis, symptoms, and study evaluations) may be shared with investigators at other Canadian research centres (other than CAMH).

## Will this research study involve the use or disclosure of my identifiable medical information?

- Study personnel will retrieve information about your demographics and clinical care from your medical chart. This will be stored in a secure database with a case number rather than your personal identifiers.

## Who will have access to identifiable information related to my participation in this research study?

Personal Health Information (PHI) is information about your physical or mental health or the health care that you receive that could identify you. In addition to the investigators listed on the first page of this consent form and their research staff, the following individual and/or programs will or may have access to identifiable information (which may include your identifiable medical information):

a. Institute for Clinical Evaluative Sciences (ICES) is a prescribed entity under Ontario's Personal Health Information Protection Act and adheres to policies and procedures for privacy protection and data security approved by Ontario's Information and Privacy Commissioner.

b. *As part of the Research Services Quality Assurance Program, this study may be monitored and/or audited by a member of the Quality Assurance Team. Your research records and CAMH records may be reviewed during which confidentiality will be maintained as per CAMH policies and extent permitted by law.*

c. As a part of continuing review of the research, your study records may be assessed on behalf of the Research Ethics Board. A person from the research ethics team may contact you (if your contact information is available) to ask you questions about the research study and your consent to participate. The person assessing your file or contacting you must maintain their confidentiality to the extent permitted by law.

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## Offer to Answer Questions

We have used some technical terms in this form. Please feel free to ask about anything that you do not understand. Consider this research and the consent form carefully as long as you feel necessary before you make a decision.

Dr. Nicole Kozloff is responsible for this study. If you have any questions, please contact Dr. Nicole Kozloff at 416-535-8501 x 30769.

If you have any questions about your rights as a participant in a research study, you may contact Dr. Robert Levitan, Chair, Research Ethics Board, Centre for Addiction and Mental Health, at 416-535-8501 x 34020.

## Consent to Participate: My signature below indicates that:

- I acknowledge that the research study described above has been explained to me and that any questions that I have asked have been answered to my satisfaction.
- I have been informed of the alternatives to participation in this study, including the right not to participate and the right to withdraw without compromising the quality of medical care for me and for other members of my family.
- I have been informed of the potential risks/harms and discomforts and I also understand the benefits of participating in this study.
- I know that I may ask now, or in the future, any questions that I may have about the study or the research procedures.
- I have been assured that records relating to my research participation and to me will be kept confidential and that no information will be printed that would disclose my identity without my permission, unless required by law.
- I have been given sufficient time to read and understand the above information
- I understand and consent that my records and research data may also be shared with other investigators for analysis and future projects (this would include only de-identified data).

**Please check one:**

☐ **Yes, I consent to participating in this study**

☐ **No, I do not consent to participating in this study**

**Optional – Future Contact:**

Do you agree to be re-contacted by our study team for an in-person interview or other follow up? You will be compensated for your participation.

☐ Yes, I agree to be contacted about study follow-up

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☐ No, I do not wish to be contacted about study follow-up

## Texting Preferences:

**If you agreed to participate in the study:**

At what phone number would you like to receive text messages?

_____

At what phone number or email address would you like to receive other links related to the study (e.g., your e-giftcard, the survey, and future communications)?

_____

What time of day would you prefer to receive text messages?

☐ Morning ☐ Afternoon ☐ Evening

What first name would you like us to call you in your text messages?

_____

## Compensation Preferences:

Which e-giftcard would you like to receive as compensation for participating? It may take up to 10 business days to receive your compensation.

☐ Tim Hortons ☐ Amazon

**Please contact 416-535-8501 x 30677 if you do not receive a text message from us within 24 hours.**

The security of information sent by e-mail/text cannot be guaranteed. Please do not communicate personal sensitive information by e-mail/text. Let the research team know if you do not want to be contacted by e-mail/text. Email/Text is not routinely monitored outside of work hours. Please do not use e-mail/text to communicate emergency or urgent health matters – please contact your clinician or family doctor. If it is a medical emergency, call 911.



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Supplementary File 3

We will undertake a cost-effectiveness analysis, where the outcome of interest is consultation appointment attendance, adopting the perspective of the public third-party payer (i.e., the Ontario Ministry of Health). Using a costing algorithm developed in SAS and available at ICES,[1] we will be able to estimate all direct patient-level healthcare costs incurred by the public third-party payer for both the intervention and control groups. In particular, we will include costs of hospitalizations, ED visits, physician services (i.e. primary care, psychiatry and other) and diagnostic tests, outpatient prescription drugs for individuals covered under the provincial public drug insurance plan, home care, long-term care, and other hospital-based care (which includes rehabilitation and complex continuing care). The costing methodology used in the algorithm includes a bottom-up/micro-costing approach to cost services at the individual level. This makes use of individual episodes of care or utilization in the healthcare system and their associated prices (or costs or amounts paid). A top-down approach, which allocates corporate aggregate (i.e. institutional) costs to individual visits or cases/episodes of care, will be applied in cases where individual unit costs are not available (e.g., for institutional care settings). In addition, we will include all costs associated with delivering both arms of the intervention. Costs will be reported in 2023 using the Consumer Price Index for Health and personal care (Statistics Canada). All costs and outcomes will be discounted at a rate of 1.5% per year, in line with the Canadian Agency for Drugs and Technologies in Health guidelines.[2] The incremental cost-effectiveness ratio (ICER) will be calculated as the difference in discounted mean costs between the intervention and control groups divided by the difference in attendance rates. We will use a net benefit regression approach to model probabilities of cost-effectiveness for each additional patient referred who attends their consultation appointment in the intervention compared with control group. In addition, we will undertake relevant sensitivity analyses to test the robustness of findings by varying relevant parameters, such as the discount rate. Finally, we will examine the real-world budget impact of implementing the intervention across Ontario, to estimate the cost to the Ministry of Health of implementing this model of care across the province and the potential cost-savings to the system associated with this.

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