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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

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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.

Polillo A, *et al. BMJ Open* 2020; 10:e042751. doi: 10.1136/bmjopen-2020-042751