Informed Consent Form for Participation in a Research Study

Study Title: Keeping in Touch (KiT) with Youth as they Transition Through Type 1 Diabetes Care: a randomized control trial comparing the effectiveness of an eHealth text message-based intervention in conjunction with usual T1D care compared to usual care alone on diabetes self-efficacy

Lead Researcher: Dr. Rayzel Shulman, Division of Endocrinology, The Hospital for Sick Children. Contact number 416 813 7654 ext 206218

Sponsor/Funder(s): The Hospital for Sick Children; funded by a Canadian Institutes of Health Research (CIHR) Transitions in Care Grant

INTRODUCTION

You are being invited to participate in a clinical trial (a type of study that involves research) because you have type 1 diabetes (T1D) and are preparing for transition from pediatric to adult diabetes care. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

IS THERE A CONFLICT OF INTEREST?

Principal investigators declare no conflicts of interest related to this study or with Memotext.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

The current standard of care (or usual care) for youth with type 1 diabetes (T1D) who are preparing to transition from pediatric diabetes care at SickKids to an adult diabetes care center includes medical appointments with your pediatric diabetes provider, nurses, and diabetes educators. This research study is being done to see whether receiving text message-based diabetes education, support, and resources, in addition to your usual care will improve your efficacy with diabetes self-management and improve your readiness to transition to adult diabetes care. We don't know if receiving the text message-based support is better or worse than the standard of care you're receiving now. We don't know if this text message-based support program will improve your transition process to adult diabetes care. By conducting this research study, we hope to find the answers to these questions.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to investigate the effectiveness of an automated text message-based diabetes education, self-management, and support program (intervention), when it is used in addition to receiving usual diabetes care. This text message-based intervention is called “Keeping in Touch with Youth As They Transition Through Type 1 Diabetes Care” or KiT.

KiT will use participant responses to online surveys (on REDcap) and text message-based questions to send some participants personalized diabetes transition education, support, and resources at various times for 12 months as they prepare to transition to adult diabetes care and after they have transitioned to adult diabetes care. Previous research has shown that digital interventions for supporting type 1 diabetes self-management has improved patient and family engagement with diabetes care. However, these previous digital interventions did not focus on personalized transition support resources or topics of interest expressed by the patient. The KiT program will be personalized according to how prepared a person feels for transition to adult diabetes care and will provide text message education and resources which are of interest or important to them.

KiT was developed by our collaborators: eHealth Innovation at University Health Network and a company called MEMOTEXT, both are based in Toronto. eHealth Innovation is a research facility that is embedded at Toronto General hospital developing technologies to assist patients. MEMOTEXT is a digital patient engagement platform that safely and confidentially uses health data and analytics to optimize digital communications. MEMOTEXT will manage the text messages being sent by the KiT program and the text message responses received from study participants.

**DISCLAIMER:** The study intervention (KiT), does not provide medical advice. The information, including but not limited to, text, graphics, images, videos, links to resources, and other material sent by KiT is for informational purposes only. No material from KiT is intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of your diabetes physician or other qualified health care provider with any questions you may have regarding your diabetes management and treatment, and before undertaking a new health care regimen, and never disregard professional medical advice or delay in seeking it because of something you have read or received from KiT.

**WHAT OTHER CHOICES ARE THERE?**

You can choose not to participate in this study and continue on with your current care (i.e. standard of care).

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

A total of 212 youth/adolescents are expected to be enrolled in the study. This is a multi-center study being done in various centers in Canada, specifically four pediatric diabetes centers in Ontario and two pediatric diabetes centers in Quebec. The Hospital for Sick Children (SickKids) is the lead site for this research study. At SickKids, up to 53 youth/adolescents are expected to participate in this study.

**WHAT WILL HAPPEN DURING THIS STUDY?**
ASSIGNMENT TO A GROUP
If you decide to participate, then you will be “randomized” into one of 2 study groups (Intervention or Control). Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have a 50/50 or 1 in 2 chance of being place in either study group. Neither you nor the study team can choose what group you will be in.

WHAT IS THE STUDY INTERVENTION?

Intervention group: if you are randomized to the intervention group, you will continue to receive your usual diabetes care at SickKids and you will also receive automated text messages from the KiT program that includes but is not limited to: links to REDCap surveys about who you are, your A1c, your current levels of transition readiness, diabetes self-management, perceptions of stigma while living with type 1 diabetes; questions via text message about what diabetes topics interests you the most and what you would like to receive text-message based education, support and resources on; questions via text message about whether or not you have an upcoming diabetes appointment with your pediatric or adult diabetes provider, and if you’d like reminders related to your diabetes care (e.g. for upcoming diabetes appointments). There will also be a question-and-answer feature with the KiT program where you will be able to ask KiT questions related to your diabetes care or resources, and the KiT program will reply with appropriate education or resource materials via text message.

Control group: if you are randomized to the control group, you will continue to receive your usual diabetes care at SickKids and you will also receive automated text messages from the KiT program that only include links to REDcap surveys about who you are, your A1c, your current levels of transition readiness, diabetes self-management, experiences of stigma living with type 1 diabetes.

WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY INTERVENTION?

WHAT ARE THE STUDY PROCEDURES?

There are no study visits, procedures or tasks that will require you to come to the hospital. All study procedures can be completed remotely. These study procedures include:

1. Online study questionnaires (for all participants): at the time of enrollment into the study, the research coordinator will securely collect and store your full name, phone number, date of birth, full postal code and email address; you will be given a Study ID number which is how we will link you to data that we collect from you throughout the study. The research coordinator will only share your phone number, which group you are randomized to and your Study ID with MEMOTEXT. Once MEMOTEXT receives your Study ID and phone number, KiT will send you a link via text-message to online questionnaires. When you click on the link, you will be taken to the secure online survey database called REDCap, where you will complete the following 4 questionnaires. It should take you approximately 15-20 mins to complete all 4 questionnaire at 3 time points (0, 6 and 12 months) for a total of 45-60 minutes during the 12-month study:
   a) questionnaire about you and your diabetes care. It will ask about your planned final pediatric diabetes visit and your planned first adult diabetes visit; how you monitor
your glucose, take your insulin, and questions about your age, sex, gender, and ethnicity

b) The READDY questionnaire which will ask about readiness to transition to adult diabetes care by asking about your confidence in diabetes-specific health knowledge and skills.

c) Self-efficacy with Diabetes Self-Management questionnaire, which will ask you about how confident you feel with managing different elements of your diabetes

d) Barriers to Diabetes Adherence among Adolescents Stigma subscale, which will ask you about your perceived stigma while living with type 1 diabetes

The above online questionnaires will be sent to you at baseline, and then 6 and 12 months. We will also ask you to report your HbA1c at baseline and 12 months, as well as the time between your final pediatric diabetes visit and first adult diabetes visit. When the online questionnaires are sent to you, you will be advised to be connected to a Wi-Fi network when you are ready to complete the questionnaires so that your network service is not interrupted during questionnaire completion and will not incur additional costs to your mobile data plan.

2. **Text messages from the KiT program (for intervention group only):** if you are randomized to the intervention group, your responses to the REDCAP baseline questionnaire and READDY assessment, will be transferred to MEMOTEXT to help personalize your standard education curriculum in the form of text messages from KiT about important things to know or consider when preparing for transition to adult diabetes care. You will receive text messages from KiT program during the 12-month study period.

3. **Process Evaluation (for intervention group only):** if you are randomized to the intervention group, you may be asked to take part in a one-on-one, semi-structured, virtual interview that will be audio-recorded on Zoom, between months 3 and 12 of your study participation; this is part of the process evaluation of this study. All participants in the intervention group have an equal chance of being selected for the process evaluation interview, including high, low and non-users of KiT. The process evaluation is being conducted by our study collaborators at Trillium Health Partners (THP). The goal of the process evaluation is to study how well the intervention (KiT) works and if it is working as intended by analyzing how many study participants are engaging with the KiT messages. If there are participants who show low or no engagement with KiT, the process evaluation will try to uncover reasons as to why this is happening and how to improve the user experience with KiT. This interview will also help our study team understand what changes, if any, you’d recommend for KiT and what would make you continually or more interested and motivated to use KiT. If you are selected for a 45-60 minute virtual interview, this will occur only once, and it will be scheduled to work with your availability. A research staff member from THP will contact you directly using contact information provided by [Site name] if you are selected to be part of the process evaluation.

Information about the text messages exchanged between participants and KiT in the intervention arm will be shared with Trillium Health Partners, our collaborators who will be conducting the process evaluation, to understand how participants are using KiT and to invite those who consented to be contacted for the process evaluation to participate in an interview.

4. **Access to your medical record (for all participants):** The research team will consult your medical record to obtain information relevant to this research.

5. **Access to your healthcare administrative data:** As part of this study, we would like to collect your health card number to link your medical record data and survey responses to
your administrative health care data 12 months prior to the study start and during the 12-month study period. Administrative health care data refers to information which is recorded every time a patient has an encounter with the health care system. This includes visits to a doctor’s office or emergency room, admission to the hospital, anytime a lab test or procedure is done, or a pharmacy receives a prescription. This information is collected by the Ministry of Health for all patients covered by the Ontario Health Insurance Program (OHIP) to keep track of how health services are delivered and how much it costs.

This linkage will allow us to continuously follow your care after your last pediatric visit until the study ends, even after your health care providers change or you move to different clinics/hospitals.

Your health card number (OHIP number) will not be shared with MEMOTEXT or any other members of the research team. MEMOTEXT will never ask you to share your OHIP number. Your OHIP number will be stored separately in a secure file that is encrypted and stored in a locked office at your pediatric diabetes center; no other study data will be on this file. Your OHIP number and responses to the questionnaires will be securely transferred to a private non-profit research institute called the Institute for Clinical Evaluative Sciences (ICES), Toronto.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Complete online questionnaires at baseline, 6 months and 12 months
- If you are randomized to the intervention group, you will receive and reply to text messages sent from KIT
- Ask your study team about anything that worries you.
- Tell the study staff if you change your mind about being in this study.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study intervention including follow-up period will last for 12 months. The overall study should take about 30 months to complete, and the results should be known in about 2.5 years.

Please initial next to your preference for the optional part of this study below:

<table>
<thead>
<tr>
<th>Process Evaluation participation:</th>
<th>Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, I am willing to participate in a one-time, 45-60 minutes, virtual interview that will be audio-recorded as part of the Process Evaluation for this study. If I am selected, you can share my name and phone number with researchers at Trillium Health Partners to contact me for the process evaluation interview.</td>
<td>________</td>
</tr>
<tr>
<td>No, I am not willing to participate in a one-time, 45-60 minutes, virtual interview.</td>
<td>________</td>
</tr>
</tbody>
</table>
CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study staff.

The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from the study will not have any effect on the care you or your family will receive at SickKids. If you decide to leave the study, you can contact a member of the study team to let them know.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the study staff know. However, this would also mean that you withdraw from the study.

CAN PARTICIPATION IN THIS STUDY END EARLY?

If you are removed from this study, the study staff will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

Since you will continue to receive your usual diabetes care and no changes to your medical care will occur during your participation in this study, the risks of participation are low. We do not expect serious risks related to the intervention to occur. If you are uncomfortable or express any distress in answering any of the online survey questions, you can skip questions, take a break or stop answering at any time. We also encourage you to speak to your health care provider or other people that support you if this happens. KiT will provide information and resources by text message that offer suggestions for coping with diabetes stressors. These coping text messages based in behavioral health were created by an expert team consisting of a pediatric psychologist with specialization in diabetes, a diabetes endocrinologist, and a patient partner living with type 1 diabetes. Furthermore, if any of the KiT messages create discomfort or cause distress to you, you will have the option to pause the KiT messages by texting ‘PAUSE’. Participants can select to pause the messages 2 times for up to 2 weeks at a time during the course of the study. Messages will automatically begin after the 2 week period.

There is a potential risk of you finding the KiT messages intrusive or bothersome. To minimize this risk, you will have the option to customize the frequency and time of delivery of texts. In addition, there is a potential risk of personal data being revealed due to the nature of how this intervention is delivered – via text-messaging. However, MEMOTEXT will never ask you to share any personal identifying information, nor will MEMOTEXT receive any personal identifying information about you from the study team, apart from your phone number and Study ID number; both needed to onboard and activate you into the KiT program.

You should ensure that your mobile device is your own personal device and is not shared with anyone else (friend or family), and you should not text KiT any personal identifying information so as to minimize the risk of loss of confidentiality and privacy. Furthermore, KiT will be hosted on a secure server at MEMOTEXT offices in Toronto; these servers will be encrypted and will not be accessed by any members outside of the MEMOTEXT research team.
There is an inconvenience of time. It will take approximately 15-20 minutes to complete all 4 surveys. We will ask you to complete the surveys 3 times during the study (at baseline, 6 and 12 months). This will be a total of 45-60 minutes during the 12 month study.

Risk with audio recordings in the process evaluation: if you consent to participate in the process evaluation portion of this study, with your permission, the study team will record the audio conversation through an external voice recorder and convert it for text for analysis. Once the audio is written up (transcribed) and the analysis is complete, the audio files will be destroyed but the transcripts will be kept for 10 years as per SickKids policy. With audio recording, there is a potential risk of loss of your confidentiality because even though your name will not be part of the audio recording or the transcription, your voice may still be identifiable as your voice. The researchers will take every precaution to maintain confidentiality of the data in an effort to secure confidentiality.

Confidentiality risk: despite protections being in place, there is a risk of unintentional release of information. There is a risk associated with using the digital platforms such as Microsoft Teams and REDCap but both applications will be housed on secure servers at The Hospital for Sick Children, and Trillium Health Partners (THP), if you consent to participate in the process evaluation.

Virtual Communication: If you agree, the study staff may use e-mail or telephone to communicate with you about your participation in this study. The study staff will discuss this with you. Please note that if you consent to using email for communication about this study, the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use e-mail to discuss information you think is sensitive. Do not use e-mail in an emergency since e-mail may be delayed.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not benefit from being in this study. However, the information we learn from this study may be used to help further develop digital and mobile health interventions to help youth as they transition from pediatric to adult diabetes care.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study staff will only collect the information they need for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- Representatives of SickKids Research Ethics Board and other SickKids staff who oversee the conduct of research at SickKids
- The research ethics board overseeing the ethical conduct of this study in Ontario
• This institution and affiliated sites, to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, age, date of birth, email, phone number or other information that may directly identify you will not be used.

The following organizations may also receive study data:
• MEMOTEXT, for the purposes of managing the KiT program and ensuring the correct text-messages are sent to participants in both the intervention and control group. MEMOTEXT will receive your mobile phone number, Study ID number and data from the READDY questionnaire to personalize program content.
• ICES for the purposes of linking your study data to administrative healthcare data sets; enabling the research team to analyze your healthcare utilization and healthcare costs for the duration of the study. The following information will be securely transferred to ICES: your full name, your 6-digit postal code, sex, your OHIP number, your date of birth and your responses to the survey questionnaires. Trillium Health Partners (THP) for the purposes of understanding how participants are using KiT and for contacting you for the Process Evaluation portion of this study. Your name, phone number and email will only be shared with THP if you consent to being contacted about participating in an interview for the Process Evaluation.

Study staff will need to communicate with you via phone and/or email. Email communication is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

In addition to the data that will be collected for this clinical trial, the researchers will also be collecting the following personal health information:
• The study team will only collect the information they need for this study.
• Some of the data collected for this study includes identifiable information about you, including:
  o your full name is needed for the research coordinator to be able to identify you by name,
  o your telephone number is needed to activate you to the KiT program,
  o your email address will be needed as another form of contact
  o your address is needed to determine whether or not you are an Ontario or Quebec resident, which is aggregate information we present in our study results,
  o your date of birth (month and year) is needed to confirm your age of eligibility,
  o your OHIP/RAMQ number is needed to access your health care administrative data for analysis on healthcare utilization and health care costs while you participate in this study.

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary.

If the results of this study are published, your identity will remain confidential. It is expected that
the information collected during this study will be shared through journal publications, academic conferences, and meetings. When the results of this study are shared, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

If you would like to be informed of the results of this study, please let the study team know.

You will only be provided with overall study results (aggregate results from all participants). This means you will not know the results as they relate to you specifically.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

Data collected using the KiT program resides on the MEMOTEXT servers which are encrypted and located in secure and locked offices in Toronto, Ontario, Canada; only MEMOTEXT team members working on KiT will have access to these servers and no study members outside of MEMOTEXT will have access to MEMOTEXT servers; this increases security and privacy of study data. However, no assurance can be made about its confidentiality or that it will only be used for research purposes.

Survey data is collected via REDCap (Research Electronic Data Capture), a secure, web-based application designed exclusively to support data capture for research studies. The application and data are housed on servers provided by The Hospital for Sick Children. These servers are located within SickKids secure data center which is a secure and locked space.

Audio recording of process evaluation: if you consent to participate in the process evaluation portion of this study, with your permission, the process evaluation study team will record the audio conversation through an external voice recorder and convert it to text for analysis. Once the audio recording is written up (transcribed) and the data analysis has been complete, the audio files will be destroyed. The transcripts will be stored for 10 years after the study as per SickKids guidelines; however, the transcripts will be fully de-identified. This means your name and other personal identifying information will not be included with the transcripts. After being stored for 10 years, they will be destroyed as per SickKids guidelines.

**Other future research:**

Your coded study data may be used or shared with other researchers (inside and outside of Canada) for future studies. “Coded” means that directly identifying information (such as your name and date of birth) will be replaced by a study ID, which will be applied to the study data. This may include storing the coded study data in controlled-access databases, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data only for that research. The goal of sharing is to make more research possible. However, the code matching your study data with your name and other directly identifying study data will not be shared.

You will not be asked if you agree to take part in future research studies using your study data. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your study data.
WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

A description of this clinical trial will be available on http://www.clinicaltrials.gov (NCT05434754). This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT IS THE COST TO PARTICIPANTS?

The KiT program will be supplied at no charge while you take part in this study. You will have to have the ability to send and receive text messages on your own personal mobile device. The study does not provide mobile devices to participants.

Participation in this study will not involve any additional costs to you or your private health insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

In recognition of your participation, every time you complete all 4 online questionnaires at each time point, you will receive a $20.00 electronic Amazon gift card. In total, you can receive Amazon gift cards valued at $60.00 (3 time-points at $20 for completion of all questionnaires at each time-point). If you complete process evaluation interview, you will also be compensated with a $25 gift card.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. The results of this study will be available on the clinical trial registry (see the “Will information about this study be available online” section for more details).

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.
WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, you can talk to your study doctor, or the doctor who is in charge of the study at this institution. That person is:

Dr. Rayzel Shulman

_________________
Name

416 813 7654 ext 206218

_________________
Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

Office of the Research Ethics Board at The Hospital for Sick Children

_________________________
Name

416-813-8279

___________________
Telephone
SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and transfer of data and related personal health information as explained in this consent form, to the institutions/individuals explained in this consent form,
- I do not give up any legal rights by signing this consent form,
- I understand that KIT does not provide medical advice and all information I receive from KIT is for informational purposes only and is not a substitute for professional medical advice regarding my diabetes management and treatment,
- I have been told I will be given a signed and dated copy of this consent form,
- I agree to take part in this study.

I consent to participate in this study.

Signature of Participant ______________________ PRINTED NAME ______________________ Date _______________

Signature of Person Conducting the Consent Discussion ______________________ PRINTED NAME & ROLE ______________________ Date _______________

Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.