BMJ Open  Text message-based intervention, Keeping in Touch (KiT), to support youth as they transition to adult type 1 diabetes care: a protocol for a multisite randomised controlled superiority trial

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ABSTRACT

Introduction  Transition from paediatric to adult care can be challenging for youth living with type 1 diabetes (T1D), as many youth feel unprepared to transfer to adult care and are at high risk for deterioration of glycaemic management and acute complications. Existing strategies to improve transition experience and outcomes are limited by cost, scalability, generalisability and youth engagement. Text messaging is an acceptable, accessible and cost-effective way of engaging youth. Together with adolescents and emerging adults and paediatric and adult T1D providers, we co-designed a text message-based intervention, Keeping in Touch (KiT), to deliver tailored transition support. Our primary objective is to test the effectiveness of KiT on diabetes self-efficacy in a randomised controlled trial.

Methods and analysis  We will randomise 183 adolescents with T1D aged 17–18 years within 4 months of their final paediatric diabetes visit to the intervention or usual care. KiT will deliver tailored T1D transition support via text messages over 12 months based on a transition readiness assessment. The primary outcome, self-efficacy for diabetes self-management, will be measured 12 months after enrolment. Secondary outcomes, measured at 6 and 12 months, include transition readiness, perceived T1D-related stigma, time between final paediatric and first adult diabetes visits, haemoglobin A1c, and other glycaemia measures (for continuous glucose monitor users), diabetes-related hospitalisations and emergency department visits and the cost of implementing the intervention. The analysis will be intention-to-treat comparing diabetes self-efficacy at 12 months between groups. A process evaluation will be conducted to identify elements of the intervention and individual-level factors influencing implementation and outcomes.

Ethics and dissemination  The study protocol version 7 July 2022 and accompanying documents were approved by Clinical Trials Ontario (Project ID: 3986) and the McGill University Health Centre (MP-37-2023-8823). Study findings will be presented at scientific conferences and in peer-reviewed publications.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ KiT was co-designed with people living with type 1 diabetes (T1D) and T1D care providers to ensure that it meets their needs and is acceptable. Our embedded process evaluation will inform real-time modifications to Keeping in Touch (KiT) early in the trial to enhance user engagement.
⇒ KiT uses text messages to deliver tailored T1D transition support based on participant-reported confidence about their diabetes-specific knowledge and skills.
⇒ The intervention will be tested in two provinces and offered in English and French.
⇒ KiT has the potential for scalability because most adolescents use mobile phones, and KiT’s text messages are delivered automatically via a computerised algorithm.
⇒ A limitation is that participants and investigators will be unblinded to their randomisation arm, given the nature of the intervention.

Trial registration number  NCT05434754.

INTRODUCTION

Type 1 diabetes (T1D) is one of the most common chronic diseases of childhood, with significant morbidity and mortality. 1,2 Maintaining optimal blood glucose levels prevents and delays long-term diabetes complications; however, in-target glucose management is particularly challenging during adolescence and early adulthood alongside a myriad of emotional, physical, financial, occupational and social changes. 3-6 In Quebec and Ontario, Canada, adolescents transfer to adult healthcare at approximately the age of 18 years.
There is also an increased risk of gaps in routine diabetes care as well as diabetes-related hospitalisations and emergency department visits during this time, which may be due, in part, to deficiencies in transition care preparation. Interventions to improve the transition from paediatric to adult T1D care are reported to improve clinic attendance, diabetes distress and satisfaction with care, however, many interventions are limited by cost, scalability and generalisability.

Two reviews of mobile phone technology, one to support adolescents with T1D and one to support the transition to adult care for all chronic conditions and for liver transplant recipients specifically, suggest that this technology can facilitate the delivery of educational material as well as encourage self-management and independence. However, the outcomes measured in these studies were varied (i.e., haemoglobin A1c (HbA1c), quality of life and self-efficacy) and results were mixed. These promising digital interventions may fail to engage youth across the transition period because they lack a personalised approach which precludes the ability to tailor content specific to an individual’s particular needs, stage of transition readiness or personal interests. To date, most text message studies have described the use of simple reminders for self-care. Text message-based interventions that rely on a healthcare provider to respond to messages are limited in their scalability.

Nevertheless, general transition support delivered via text message is considered an engaging, acceptable, accessible and cost-effective option. To address these limitations, together with youth, including adolescents and emerging adults living with T1D, and paediatric and adult T1D providers, we co-designed an automated text message-based intervention called Keeping in Touch (KiT) to deliver tailored T1D transition support messages in response to participants’ self-reported confidence and interest in transition preparation topics. We hypothesise that compared with usual care, youth who use KiT for 12 months starting within 4 months before their final paediatric visit will have improved diabetes self-efficacy 12 months after enrolment.

Objectives

The primary objective of our study is to test the effectiveness of KiT, a text message-based T1D transition support intervention, on our primary outcome (diabetes self-efficacy) and secondary outcomes, including transition readiness, perceived T1D-related stigma, the time between final paediatric and first adult diabetes clinic visits, HbA1c, and other measures of glycaemia such as time in range (for those using continuous glucose monitors), and diabetes-related hospitalisations and emergency department visits. We will also conduct an embedded process evaluation to identify and understand which, if any, components of the intervention are associated with improved user engagement and individual-level contextual factors that influence the implementation process.

METHODS AND ANALYSIS

Study design

We will conduct a multisite, parallel-group, two-arm, 1:1 allocation ratio, superiority randomised controlled trial (RCT). Our protocol adheres to the Standard Protocol Items for Randomised Trials (SPIRIT) statement. Considering the healthcare payer perspective, we will perform a descriptive cost analysis of the KiT implementation following Canada’s Drug and Health Technology Agency (CADTH) guidelines and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.

Study setting

Our study will be conducted at six paediatric diabetes clinics; four in Ontario (two of which are located in academic tertiary-care hospitals (The Hospital for Sick Children and the Children’s Hospital of Eastern Ontario (CHEO)) and two in community clinics (Trillium Health Partners (THP) and Oak Valley Health (OVH)) and two clinics located in academic tertiary care paediatric hospitals in Quebec, Canada: Montreal Children’s Hospital, McGill University Health Centre (MUHC) and the Centre Hospitalier Universitaire Sainte-Justine (CHUSJ), University of Montréal. Recruitment started in January 2023 and will continue up until the end of June 2024. The intervention will end 12 months after recruitment is complete.

Inclusion criteria

Participants must be adolescents, living with T1D, be receiving care at one of the participating paediatric diabetes clinics, be within 4 months of their planned final paediatric clinic visit before transferring to adult diabetes care, be able to speak, understand and communicate in either English or French, have a mobile device with the capability to receive and send text messages, and a valid email address.

Exclusion criteria

Potential participants are ineligible if they are unable to carry out their diabetes care independently due to an intellectual or neurocognitive disability; are not a resident of Ontario or Quebec, Canada; are planning to change their primary residence out of either province within the upcoming 12 months; are enrolled in another clinical research trial that involves text messaging or any diabetes intervention trial that will continue beyond their planned final paediatric diabetes visit.

Intervention

The KiT algorithm is designed and programmed to send tailored T1D-related text messages at participant-determined frequencies over a 12-month intervention period. In a previous study, we scoped the needs of youth transitioning to adult care. In brief, we conducted interviews and co-design sessions with adolescents and young adults living with T1D and T1D care providers to determine how to optimally deliver transition support via text messages. Interview data analysis was grounded within
the socioecological model and analysed using a thematic content approach.\textsuperscript{24, 25} KiT features, content topics and message formats were selected based on the themes and ideas that emerged in the co-design workshops and are supported in the literature. We validated and refined these through member-checking in co-design workshops.

Research staff consent participants using site-specific version of ethics approved consent form KiT RCT_CTO_ICF_07JULY2022_CLEAN.docx (online supplemental material) virtually or in person. Participants randomised to the intervention arm will receive the KiT text message transition support programme for 12 months, hosted by Memotext, a company that provides a secure platform for digital patient engagement communications. Participants will have the option to use the programme in either English or French, the two official languages in Canada. Participants will have the option to pause the KiT messages at any time during the intervention. KiT has three key functions: (1) personalised T1D educational messages; (2) care coordination; and (3) question and answer (table 1). KiT will only deliver text messages to the participant themselves, however, the participant may share any of the text messages with their support network.

1. **T1D educational messages**: KiT will send text messages about T1D-related transition preparation topics. Core topics will be sent to all participants. Other topics will be delivered based on participants’ self-reported confidence and interest in the topics. This will be based, in part, on responses to a validated transition readiness tool administered at baseline (described in the outcome section below): Readiness Assessment of Emerging Adults with Type 1 Diabetes Diagnosed in Youth (READDY) tool.\textsuperscript{26} Some messages include text only, previously developed during the co-design process, with input from T1D providers and people living with T1D. Some messages include a link to a trusted T1D resource identified in our environmental scan of online educational resources for youth with T1D transitioning to adult care.\textsuperscript{27} A list of education content topics is available in box 1.

2. **Care coordination**: on enrolment and throughout the intervention, KiT will send participants text messages asking if, and when, they have upcoming appointments with their diabetes clinics. KiT will store this information and send participants text message reminders about upcoming visits and information related to transition to adult diabetes care, such as preparing for upcoming clinic appointments. In addition, KiT will send reminders to participants to book appointments and prompt those who have not yet been referred to adult care to follow-up with their paediatric care team for a referral. KiT will remind participants about the importance of having a primary care provider and send links to online services that can help them find one, if needed.

<table>
<thead>
<tr>
<th>Feature category</th>
<th>Intervention feature</th>
<th>Sample dialogue</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personalised T1D educational messages</strong></td>
<td>▶ Participants will receive multiple messages each month about a different T1D transition topic. ▶ Topics will be selected based on the participant’s responses to a transition readiness assessment administered at baseline and topics of their choice.</td>
<td>KiT: When you travel—be sure to pack LOTS of extra supplies for a stress-free trip! You can pack extra: glucose metres, batteries, pumps and infusion sets (some pump companies will give you a travel loaner pump for free!), insulin and syringes (in case your pump malfunctions), test strips and medications. It’s good to have these on hand, just in case. This video is a great example of some things you might want to (over) pack (link to TikTok video)</td>
</tr>
<tr>
<td><strong>Care coordination</strong></td>
<td>▶ Reminders about upcoming appointments. ▶ Reminders to complete lab tests before upcoming appointments (if applicable). ▶ Information about participant’s adult clinic (if available). ▶ Tips about how to prepare for the first adult visit. ▶ Participants can store their own notes, which they can access any time and will be sent back to the participant automatically before an upcoming clinic visit.</td>
<td>KiT: Hello! Do you know when your next appointment is? User: It is on 27 September 2022 at 14:00 hours KiT: Perfect, I’ll send you a reminder the week before so you don’t forget!</td>
</tr>
<tr>
<td><strong>Question and answer</strong></td>
<td>▶ Participant can text KiT T1D-related questions and receive messages in return from a validated bank of resources.</td>
<td>User: How can I adjust my insulin so I don’t go low when I exercise? KiT: Thanks for asking! Hopefully this resource about insulin and exercise from ExCarbs answers your question (link to resource website)</td>
</tr>
</tbody>
</table>

**Table 1** KiT functions and example text messages

**Box 1** T1D related-transition educational content topics

**Topics delivered to all participants in the intervention group**
- Coping with T1D
- Care navigation
- Sick day and ketone management
- Medical insurance

**Topics delivered based on participants’ self-reported confidence and interest**
- Hypoglycaemia
- Pumps and programming
- Insulin adjustments
- Drugs and alcohol
- Travel
- Driving
- T1D accommodations for school and work
- Exercise
- Nutrition and carbohydrates
- Sexual health
3. Question and answer: participants can send text messages asking KIT about topics related to T1D care at any time during the intervention. KIT will match keywords in the question to trusted resources identified in the environmental scan of online educational resources and reply to participants with a text message and a link to a relevant T1D transition resource, if available. Participants randomised to the control arm will receive usual diabetes transition care and text messages from KIT containing links to the outcome surveys over 12 months.

Recruitment
Participants will be recruited over 18 months. We will have poster advertisements in clinic waiting areas. A member of the circle of care will provide a study information letter and introduce a study research coordinator to potential participants. Participants in both arms will receive gift cards as a token of appreciation for their time participating in the study. Recruitment targets are feasible based on six diabetes clinic volumes and experience from recent transition-related studies. Local site coordinators will obtain informed consent.

Randomisation
The allocation sequence will be computer generated using random block sizes by an independent statistician using a 1:1 ratio, stratified by site, at the time of enrolment. Due to the nature of the intervention, participants and investigators cannot be blinded to group allocation. We will conceal random allocation from the independent statistician assigning participants to the interventions and those analysing the data.

Data collection
At the time of enrolment, research coordinators will collect each participant’s postal code to be linked to an area-based validated material and social deprivation index as a measure of socioeconomic status. The coordinator will also collect the most recent HbA1c result (either laboratory or point-of-care) from the health record to measure baseline glycaemic management. There is a standardised method for measuring HbA1c. All participants, in both arms, will receive a text message at the time of enrolment, 6 months and at 12 months containing a link to REDCap surveys for assessment of outcomes. The surveys include a participant information survey, which will collect sociodemographic and diabetes-related healthcare information (online supplemental table 1), and three patient-reported outcome measures.

Text-message records between KIT and participants will be saved on a secure encrypted server at Memotext. We will also collect participants’ provincial health insurance numbers to link to provincial administrative data-sets housed at ICES in Ontario and Régie de l’assurance maladie du Québec (RAMQ) in Quebec. Site coordinators will assign unique study IDs for each participant. Each study ID will be linked to a unique survey code. All survey responses are collected and securely stored in REDCap. Table 2 shows the primary and secondary outcomes and when they are each collected.

Outcomes
Primary outcome
The primary outcome is patient-reported diabetes self-efficacy at 12 months measured using the Self-Efficacy for Diabetes Self-Management (SEDM) scale. Self-efficacy measures a person’s belief that they can carry out a behaviour in a particular situation. Self-efficacy is associated with health-related outcomes. The SEDM scale has been validated in adolescents with T1D and found to be associated with diabetes self-management and glycaemic management in older adolescents.

Secondary outcomes
Secondary outcomes will be measured at baseline, 6 months and 12 months. Table 2 lists all the outcomes, the data source, and when they will be collected.
1. Diabetes self-efficacy
2. Transition readiness
3. Diabetes-related stigma
4. Glycaemic management
5. The time between the final paediatric and first adult diabetes visits (calculated from the self-reported date of the final paediatric and first adult visit)
6. Diabetes-related hospitalisations and emergency department visits
7. Cost of implementation (aggregate cost of implementation and cost per participant)

Patient-reported outcomes
Patient-reported outcomes will be collected in electronic surveys sent to participants via a link in a text message at baseline, 6 months and 12 months. Up to two automatic reminder messages will be sent via text message if a survey is not completed. If a survey still needs to be completed after two text message reminders, the research coordinator will contact the participant to remind them to complete the survey.

We will measure transition readiness using the Readiness Assessment of Emerging Adults with Type 1 Diabetes Diagnosed in Youth (READY) tool. READY is a transition readiness assessment for emerging adults with diabetes that asks about self-reported confidence in five domains: diabetes knowledge, health system navigation, insulin self-management, health behaviours and insulin pump skills (optional). Diabetes-related stigma will be measured using the Barriers to Diabetes Adherence in Adolescence (BDA) questionnaire Stigma subscale. Additional details about the patient-reported outcome measures are presented in table 3.

Glycaemic management
We will collect the most recent HbA1c in the chart at baseline (either lab or point-of-care). We will also collect self-reported HbA1c and other measures of glycaemia (time in range and percent of time in ‘low’ for participants who

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report using a continuous glucose monitor for at least 80% of the time in the preceding 14 days) at baseline, 6 months, and 12 months.

**Diabetes-related hospitalisations and emergency department visits**
We will securely link participants’ provincial health card numbers to provincial administrative databases housed at ICES in Ontario and Med-Echo and Régie de l’assurance maladie du Québec (RAMQ) in Quebec. We will measure all diabetes-related hospitalisations and emergency department visits during the 12 months before enrolment in the study and for 12 months after enrolment. In Ontario, we will ascertain all diabetes-related

**Table 2** Primary and secondary outcomes and time of collection

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Baseline (time of enrolment)</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chart abstraction</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HbA1c (laboratory or point-of-care)</td>
<td>x</td>
<td></td>
<td></td>
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<tr>
<td>Survey</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-Efficacy for Diabetes Self-Management (SEDM)</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Transition Readiness Assessment for Emerging Adults with Diabetes Diagnosed in Youth (READDY)</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Barriers to Diabetes Adherence (BDA) in Adolescence questionnaire Stigma subscale</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Self-reported HbA1c</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Self-reported measures of glycaemia (participants using continuous glucose monitors): time in range and time in ‘low’</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Date of final paediatric visit</td>
<td>x</td>
<td>x (if not provided at baseline)</td>
<td>x (if not provided at baseline)</td>
</tr>
<tr>
<td>Date of first adult visit</td>
<td>x (if final paediatric visit has occurred)</td>
<td>x (if final paediatric visit has occurred and not previously reported)</td>
<td>x (if final paediatric visit has occurred and not previously reported)</td>
</tr>
<tr>
<td>Administrative data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes-related hospitalisations</td>
<td></td>
<td>12 months prior to enrolment and 12 months from the time of enrolment</td>
<td></td>
</tr>
<tr>
<td>Diabetes-related emergency department visits</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HbA1C, haemoglobin A1c; T1D, type 1 diabetes.</td>
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</table>

**Table 3** Description of the patient-reported outcome measures

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Details</th>
<th>Validity/reliability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy (Self-Efficacy for diabetes Self-Management Measure)</td>
<td>Respondents report their certainty in their ability to carry out 10 specific diabetes self-management tasks almost all of the time on a 10-point Likert scale from 1 ‘not at all sure’ to 10 ‘completely sure’.</td>
<td>Validated and reliable in adolescents with T1D ($\alpha=0.90$); shown to have good internal consistency and test-retest validity.33</td>
</tr>
<tr>
<td>READDY (transition readiness assessment for emerging adults with diabetes diagnosed in youth)</td>
<td>Respondents answer on a 5-point Likert scale from ‘yes, I can do this’ to ‘I haven’t thought about it’ for 42 items, split into five domains: diabetes knowledge, health system navigation, insulin self-management, health behaviours and insulin pump skills (optional).</td>
<td>Validated during its development by examining its correlation with existing validated transition readiness tools.26</td>
</tr>
<tr>
<td>BDA (Barriers to Diabetes Adherence) in Adolescence questionnaire Stigma Subscale</td>
<td>Stigma will be defined as an affirmative response to at least one of three key items on this subscale.</td>
<td>The Barriers to Diabetes Adherence in Adolescence questionnaire was developed to measure psychosocial barriers to adherence in adolescents with T1D; the stigma subscale has previously shown to be useful in research and clinical settings.34</td>
</tr>
</tbody>
</table>

T1D, type 1 diabetes.
hospitalisations from the Canadian Institute of Health Information discharge abstract database, and diabetes-related emergency department visits will be ascertained using the National Ambulatory Clinic Reporting System. In Quebec, we will ascertain diabetes-related hospitalisations from Med-Echo (hospitalisations), and diabetes-related emergency department visits will be identified from the RAMQ databases. Diabetes-related emergency department visits will be identified as those with a diagnosis code for hyperglycaemia (ICD-9 code 250) and hypoglycaemia (ICD-9 code 251). Diabetes-related hospitalisations will be identified as those diagnosed with hyperglycaemia (ICD-10 codes E10.0–E14.0 and E10.1–E14.1), including diabetic ketoacidosis and hyperosmolar hyperglycaemic coma and those with a diagnosis of hypoglycaemia (E10.63–E14.63).

Cost of implementation
We will determine the cost of adapting and implementing the intervention in an outpatient paediatric diabetes clinic in Ontario and Quebec. We will consider the costs of adapting the algorithm, salary support for staff to enrol participants, digital services and office equipment to host the intervention (computers, hosting service, servers). Specifically, we will measure the following: (1) labour costs, including staff salaries; (2) infrastructure and equipment costs; and 3) administrative and operating costs. Cost data will come directly from the programme, which will provide detailed information on all costs.

Sample size
Assuming a SD of 1.6 for the self-efficacy score and 6 degrees of freedom for adjustment (1 for HbA1c, 1 for the baseline value of the outcome variable and 4 for the 5 quintiles of deprivation), we require a total sample size of 183 participants to have 80% power with α=0.05, allowing for 20% dropout. This assumes that the covariates used for adjustment explain 10% of the variation in the outcome. Given the absence of published data to inform this quantity, we have opted to be conservative and assume a low $R^2$, which will require a larger sample size rather than assuming a high value of $R^2$.

Statistical analysis
We will conduct an intention-to-treat analysis. We will conduct a secondary as-treated analysis including participants who engaged with KiT (did not have any message delivery failures) stratified by engagement level. Engagement level will be defined according to the intervention usage data during the 12-month intervention period; this approach has been used in prior studies. We will compare the primary outcome, diabetes self-efficacy score at 12 months, between groups. This will be done using analysis of covariance (ANCOVA) to compare the effect of the intervention between arms. We will include the following covariates: intervention arm, baseline diabetes self-efficacy score (to reduce possible residual imbalance between groups), baseline HbA1c (known to be associated with diabetes self-efficacy), and material deprivation quintile (socioeconomic status is known to be associated with T1D care and outcomes).

To compare secondary outcomes between arms at 6 and 12 months, we will use ANCOVA and logistic regression models for continuous and binary outcomes respectively. We will include the following covariates in each of these models: intervention arm, the baseline measure of the outcome of interest (if measured and when the outcome is continuous), baseline HbA1c and material deprivation. We will conduct a secondary analysis to calculate within-arm differences in outcomes at baseline, 6 months and 12 months. For the within-arm analyses, we will use the appropriate paired test (either the paired t-test or McNemar’s test) to account for the repeated measurements on each subject.

For the descriptive cost analysis of the KiT implementation, we will calculate the aggregate cost of implementation and cost per participant. The costs will be reported in 2024 Canadian Dollars, adjusted for inflation using the Bank of Canada inflation calculator. When relevant, we will consider a 1.5% discount rate for cost and health outcomes per the Canadian Guidelines for Economic Evaluations.

Harms
We do not expect adverse or serious adverse events related to the intervention to occur due to the nature of the intervention. Common words associated with high-risk behaviours (eg, suicide) will also be matched, and appropriate support resources will be provided to participants. Participants will have the option to pause the KiT messages at any time during the intervention. Any elevated harm, discomfort or distress experienced by the participants and communicated to the research team will be immediately reported to the principal investigators and the Research Ethics Board.

Patient and public involvement
The KiT intervention was created by a co-design process including people living with T1D and T1D providers. Our research team also includes a patient partner (co-principal investigator) who contributed to the study design and will continue to provide input during the implementation and evaluation phases of the RCT.

Data management
All participants will be assigned a study ID number. Only study team members can access the code linking the participant’s name to the study file. On randomisation, the research coordinator will securely send Memotext the randomised participant study ID, randomisation arm and mobile phone number. KiT will send a text message to the participant’s mobile phone introducing them to the study and send links to complete the study surveys on SickKids REDCap servers to deploy chatbot links for
REDCap surveys. User engagement data will be stored on the secure servers of Memotext, located in Toronto. Memotext collects and uses data in accordance with all applicable laws and PIPEDA and HIPAA.

DISCUSSION
A strength of our study is that the intervention, KiT, was co-designed with people living with TID and T1D providers to ensure that it meets their needs and is acceptable. It also addresses important limitations of previous transition interventions by delivering tailored transition education and support based on participant-reported confidence about diabetes-specific knowledge, skills and topics selected based on interest rather than a one-size-fits-all approach. Further, the intervention will be delivered entirely via text messages, a modality with proven accessibility that is easily scalable since 97.9% of Canadians aged 15–24 years have access to a smartphone.39 Since we are testing KiT in two provinces and two languages, we will be able to evaluate its effectiveness in different contexts. A limitation is that participants and investigators will be unblinded to their randomisation arm, given the nature of the intervention components.

Our findings will inform the field of digital health by testing an intervention delivered entirely by text messages. Further, our findings will add to the literature about the effectiveness of interventions for transition to adult diabetes care without the need for healthcare provider support. Next steps are to assess the cost effectiveness of the intervention and to consider opportunities to scale KiT and to adapt it for other childhood chronic illnesses.

ETHICS AND DISSEMINATION
We have research ethics board approvals at the provincial level from Clinical Trials Ontario (CTO) and centre-level approvals from research ethics boards at all four Ontario sites (The Hospital for Sick Children, the Children’s Hospital of Eastern Ontario (CHEO), Trillium Health Partners (THP) and Oak Valley Health (OVH). We have received research ethics board approval from the McGill University Health Centre (MUHC) REB. In Quebec, there is a central ethics approval process for multisite studies. Protocol amendments (eg, changes to eligibility criteria, outcomes or analyses) will be submitted to the Research Ethics Boards. Important protocol modifications will be communicated to investigators, trial participants, and the ClinicalTrials.gov registry.

We plan to present the findings of this study at scientific conferences and in peer-reviewed publications. We plan to disseminate our findings through diabetes organisations with whom we have engaged since this study’s inception, including Diabetes Action Canada, the Ontario Paediatric Diabetes Network and Foundation Ressources Pour Nos Enfants Diabétiques (FRED). If KiT is effective, we will engage with the Canadian Pediatric Diabetes Consortium (CAPACIt) to explore opportunities to scale and expand its use.

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Contributors RS and MN designed the study. Other authors EM, JAC, LD, A-SB, GLB, MG, JK, VER, PA, EC, MH, AL, IZ and MT contributed to the design of the study. GS prepared the initial draft of the manuscript. All authors provided feedback and approved the final manuscript.

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Competing interests RS and A-SB have received speaking fees from Dexcom. EG is the Site Co-Investigator role for Medtronic study grant to the institution and Chair of Epic® Pediatric Endocrinology Specialty Steering Board. JZ reports receiving personal fees from Abbott Diabetes Care and Novo Nordisk Canada Inc. and research funding support from the University of Toronto, Navigator Limited, the Medical Psychiatry Alliance, Regional Municipality of Peel, Community Foundation of Mississauga, Canadian Institutes of Health Research (CIHR), and Social Sciences and Humanities Research Council of Canada (SSHRC). MH is recipient of the 2019 Canadian Society of Endocrinology and Metabolism’s Young Investigator Award, and a FRGS Senior salary award. Her research has been funded by the Canadian Institutes of Health Research (CIHR), Heart and Stroke Foundation of Canada, Diabète Quebec and Fonds de recherche en Santé du québec (FRGS).

Patient and public involvement Patients and/or the public were involved in the design, conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

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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 messaged-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”; the study nickname is 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 placed 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 questionnaires 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><strong>Yes, I am willing</strong> 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><strong>No, I am not willing</strong> to participate in a one-time, 45-60 minutes, virtual interview.</td>
<td>✉️</td>
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</tbody>
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Version date of this form: ___07-July-2022___
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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:
  - your full name is needed for the research coordinator to be able to identify you by name,
  - your telephone number is needed to activate you to the KiT program,
  - your email address will be needed as another form of contact
  - 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,
  - your date of birth (month and year) is needed to confirm your age of eligibility,
  - 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.
Table 1: Sociodemographic and diabetes-related healthcare information collected on the surveys

<table>
<thead>
<tr>
<th>Data element</th>
<th>Baseline</th>
<th>6 month survey</th>
<th>12 month survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of diabetes</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin regimen (pump or injections)</td>
<td>x</td>
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<td>x</td>
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