STUDY PROTOCOL

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

Study Nickname: KiT

Principal Investigator: Dr. Rayzel Shulman

Sponsor: Dr. Rayzel Shulman and The Hospital for Sick Children.

Funded by: CIHR

Version Date: 10 MARCH 2022

STATEMENT OF COMPLIANCE

The trial will be conducted in accordance with this protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP) and applicable regulatory requirements. The Principal Investigator (PI) will assure that no deviation from, or changes to the protocol will take place without prior agreement from the Sponsor and documented approval from the Research Ethics Board (REB), except where necessary to eliminate (an) immediate hazard(s) to the trial participants.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the REB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the REB before the changes are implemented to the study. All changes to the consent form will be REB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

Name of Principal Investigator (Print): _____

Signature of Principal Investigator: _____
Date: _____
<DD Month YYYY>

Site Address
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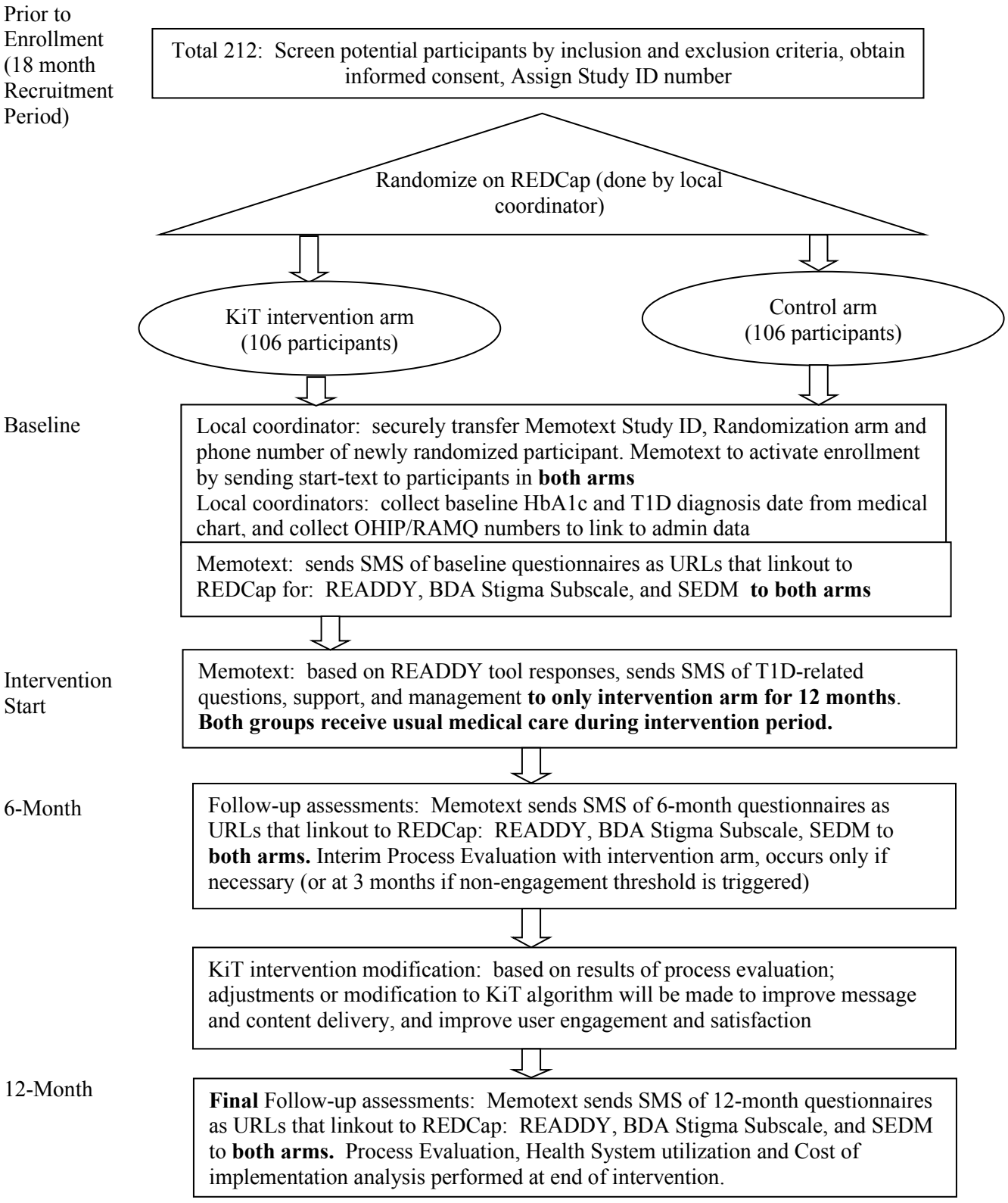
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Keeping in Touch 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
Study Description:	A multi-center, 1:1 randomized control trial with 6 sites (4 in Ontario and 2 in Quebec)
Objectives:	Primary Objective: Diabetes self-efficacy (SEDM) Secondary Objectives: Transition readiness (READDY), Barriers to Diabetes Adherence (BDA) Stigma subscale, HbA1c, healthcare utilization and cost of implementation Exploratory Objectives: embedded process evaluation
Endpoints:	Primary Endpoint: SEDM at 12 months Secondary Endpoints: READDY, BDA Stigma subscale, and HbA1c at 12 months Exploratory Endpoints: qualitative and quantitative data from embedded process evaluation
Study Population:	212 (106 in each arm) adolescents with T1D preparing to transition to adult diabetes care and receiving care for T1D at participating pediatric centres in Ontario or Quebec; English or French speaking and possess their own mobile device that can send and receive SMS messages
Description of Study Intervention:	Text-message based algorithm that operates similar to a chatbot and will send SMS messages for T1D personalized support, education, resources and collection of outcome measures.
Study Duration:	18 months of recruitment and 12-month intervention period
Participant Duration:	12 months for each participant to complete the study

1.2 SCHEMA


Prior to Enrollment (18 month Recruitment Period)
Total 212: Screen potential participants by inclusion and exclusion criteria, obtain informed consent, Assign Study ID number
Randomize on REDCap (done by local coordinator)
KiT intervention arm (106 participants)
Control arm (106 participants)
Baseline
Local coordinator: securely transfer Memotext Study ID, Randomization arm and phone number of newly randomized participant. Memotext to activate enrollment by sending start-text to participants in **both arms**
Local coordinators: collect baseline HbA1c and T1D diagnosis date from medical chart, and collect OHIP/RAMQ numbers to link to admin data
Memotext: sends SMS of baseline questionnaires as URLs that linkout to REDCap for: READDY, BDA Stigma Subscale, and SEDM **to both arms**
Intervention Start
Memotext: based on READDY tool responses, sends SMS of T1D-related questions, support, and management **to only intervention arm for 12 months**. **Both groups receive usual medical care during intervention period.**
6-Month
Follow-up assessments: Memotext sends SMS of 6-month questionnaires as URLs that linkout to REDCap: READDY, BDA Stigma Subscale, SEDM to **both arms.** Interim Process Evaluation with intervention arm, occurs only if necessary (or at 3 months if non-engagement threshold is triggered)
KiT intervention modification: based on results of process evaluation; adjustments or modification to KiT algorithm will be made to improve message and content delivery, and improve user engagement and satisfaction
12-Month
Final Follow-up assessments: Memotext sends SMS of 12-month questionnaires as URLs that linkout to REDCap: READDY, BDA Stigma Subscale, and SEDM to **both arms.** Process Evaluation, Health System utilization and Cost of implementation analysis performed at end of intervention.

1.3 SCHEDULE OF ACTIVITIES (SOA)

Time Point	Enrolment/ Randomization (18 month randomization period)	Intervention Period (12 months)				End of intervention
	-1 week	0	3 months	6 months	12 months	12 months
ENROLMENT						
Eligibility screen	X					
Informed consent	X					
Randomization	X					
INTERVENTION*						
Active arm		X	X	X	X	
Control arm						
ASSESSMENTS						
HbA1c (chart or self-report)		X			X	
Baseline questionnaire		X				
READDY		X		X	X	
SEDM		X		X	X	
Barriers to Diabetes Adherence (BDA) in Adolescence Stigma subscale		X		X	X	
T1D-related hospitalization (OHIP/RAMQ)					X	
T1D-related ED visits (OHIP/RAMQ)					X	
diabetes-related physician visits (OHIP/RAMQ)					X	
Diabetes drugs and devices claims (OHIP/RAMQ)					X	
Process Evaluation			X**	X	X	X
KiT modifications***			X	X		
Cost of implementation analysis			X	X		

**only participants in the active arm will receive the KiT intervention during the 12-month intervention period. Both study arms will receive usual medical care during 12-month intervention period.*

***if there are not enough participants enrolled at 3 months, interim process evaluation will occur at 6 months. If threshold for non-engagement is trigged at any point before 3 or 6 month or 12-month time-point, process evaluation will occur at same time*
****will occur in real-time and only if results of process evaluation reveal modifications or adjustments are required to improve user engagement and satisfaction*

Table 1: Schedule of activities for KiT intervention

2 INTRODUCTION

2.1 STUDY RATIONALE

During the transition to adult diabetes care, young adults with type 1 diabetes (T1D) are at risk for deterioration of their diabetes management, having a gap in establishing adult care, and of acute life-threatening complications such as diabetic ketoacidosis. We have shown that there are persistent gaps in transition care services, poor uptake of existing transition resources, and gaps in collaboration and linkages between pediatric and adult diabetes providers. Most digital transition interventions do not offer personalized educational content or resources to support patients based on their stage of transition readiness and they require additional human resources. As a result, existing digital interventions do not adequately engage patients across the transition continuum or demonstrate scalability. *Our study proposes to implement and evaluate a pragmatic digital tool that delivers just-in-time personalized transition education, to improve patient-reported diabetes outcomes and gaps in diabetes care.*

2.2 BACKGROUND

Type 1 diabetes (T1D) is one of the most common chronic diseases of childhood with significant morbidity and mortality(1). A particularly challenging period for people living with type 1 diabetes (T1D) is emerging adulthood (18-30 years) when parental involvement in diabetes care is decreasing and emerging adults are undergoing emotional, physical, financial, occupational, and social changes within a short period of time(2–4). Prevention of T1D-related complications is vital for patient health. Randomized trials have demonstrated the importance of optimizing blood sugar control (glycemic control) in preventing chronic complication(5,6). However, data from a large U.S. type 1 diabetes registry demonstrated that glycemic control deteriorates in adolescence and remains suboptimal throughout the early to mid-20s(7). This is particularly worrisome because glycemic control early in life has a lasting effect on the future risk of developing long-term diabetes complications(5,6). Further, nearly one in three U.S. adolescents and emerging adults with T1D already have diabetes complications (retinopathy, neuropathy, and nephropathy)(8,9). Prevention of acute diabetes-related complications are equally important. Shulman et al. found that emerging adults with diabetes in Ontario have a 4.27 times higher risk of death compared with those without diabetes (95% CI 3.37 to 5.41)(10).

From pediatric to adult diabetes care: The incidence of type 1 diabetes (T1D) in Canada is amongst the highest in the world (1). In 2012, there were 6,676 children under 18 years of age living with T1D in Ontario alone(11). As these children enter emerging adulthood, they face challenges that complicate the transition to adult diabetes care. One single-centre study in the United States found that 34% of T1D patients transitioning to adult programs reported a gap of more than 6 months in establishing adult care(12). Using data from Ontario, we showed that almost half of emerging adults with T1D had a gap exceeding 12 months between their last pediatric appointment and the time they saw their eventual adult diabetes care physician(13). This may be due to a number of recognized barriers for emerging adults, including making a connection with the new adult team, difficulties communicating with the new clinic regarding scheduling appointments, and lack of perceived value in the clinic visit(14). Many emerging adults arrive at adult clinics feeling inadequately prepared for transition and are often not counselled on topics relevant to their specific needs. Feeling unprepared for adult care has been associated with an

increased risk of having a gap of more than 6 months between pediatric and adult care(15). Further, we have shown that the struggles that transitioning T1D patients experience in taking on multiple new responsibilities and adult providers' lack of appreciation of these struggles are key barriers to successful transition. We have also found that upon the transfer to adult care there was often no sharing of a formal medical summary(16). These studies have identified the need for improved transition preparation, care coordination, and communication between pediatric and adult providers(15). We have shown that there is variability in transition practices across Ontario pediatric diabetes centres(13). There is an urgent need to develop a system-level innovative approach to help emerging adults remain engaged in their care during this vulnerable period.

To reduce complications, the medical care of emerging adults with T1D requires regular access to specialized healthcare services. However, during the transfer to adult care emerging adults are at high risk of dropping out of medical care altogether(17–19), only to resurface with life-threatening diabetes-related complications such as diabetic ketoacidosis (DKA)(20–22). The goal of transition care is to provide care that is uninterrupted and developmentally appropriate while developing adolescents' and emerging adults' skills in decision-making and self-care(20). However, we have documented significant variability and deficiencies in transition care services. In Ontario, pediatric diabetes centres reported challenges related to transition preparation, communication with adult teams, adult programs' ability to meet the needs of emerging young adults, and loss to follow-up(13). We have also found a lack of transition care services in pediatric diabetes centres across Quebec. Adult diabetes care providers in Quebec perceive an absence of transition care preparation for adult care as a major barrier to successful transition(16,23). A few studies have addressed this lack of transition care services using digital resources, but they did not offer personalized educational content or resources to support patients based on their stage of readiness to transition and they required additional human resources. They also failed to fully address the range of factors influencing transition, including the complex psychosocial issues that determine ongoing engagement and glycemic control in this age-group. As a result, existing digital interventions do not adequately engage patients across the transition continuum or demonstrate scalability(24).

Interventions: A variety of interventions targeting the transition from pediatric to adult T1D care have been evaluated, including those directed at patients (educational programs, skills training), clinic staff (transition coordinators, joint clinics run by pediatric and adult physicians), and services (separate young adult clinics, out of hours phone support, enhanced follow-up)(25–33). However, these models tended to be institution-specific with limited access (i.e. location within academic hospital-based sub-specialty centres or targeted 'young adult' clinics), particularly for those living away from home attending post-secondary school or those living outside urban centres. Although these interventions show promise, they are limited by their cost, scalability, and generalizability.

Digital Tools for Transitioning Youth: Most digital interventions for supporting T1D self-management do not focus on providing personalized transition support resources, and do not facilitate content delivery that is specific to the individual's stage of transition readiness or on expressed topics of interest, and require additional human resources (24). As a result, existing digital interventions have not demonstrated cost effectiveness, scalability, or the ability to adequately engage patients across the transition continuum(24).

For example, the Maestro Project in Manitoba demonstrated that a system navigator model that connected transitioning patients to adult care improved the drop-out rate of adult medical care(29). However, this program did not see any improvements in short term outcomes or evaluate the scalability and economic impact of the program. Another study testing a system navigator approach found that clinic visits were maintained, diabetes control improved, and DKA rates reduced. This study infers that the navigator had a significant role in improving outcomes, however, it does not address the relationship between the patient and their pediatric and adult providers over the transition period(32). Our digital tool will help youth with

T1D learn more information about the adult diabetes center they've been referred to as we will be providing a link via a text message to KiT, that will take participants to a landing page that is specific to their adult referral site and will have information about the clinic's healthcare providers, clinic address and contact information, and who to contact to schedule or change appointments, and information on any special programs offered to this patient population.

While telemedicine is being explored as a modality for improving communication and accessibility across the transition period, it remains limited by the lack of interoperability with health records, the personalization of technology used, and reimbursement for the services delivered(24). Recognizing these implementation challenges, the use of text messaging or SMS is being explored as an engaging, acceptable, accessible, and cost-effective way of reaching patients(34). Interestingly, all text message studies to date have relied on a health care provider to deliver the content to patients, or they default to simple reminders for self-care(34,35). To our knowledge, our proposed intervention will be the first to explore how to develop a text message-based algorithm designed to assess the patient's diabetes status, and provide personalized resources associated to that status. Recognizing that most adolescents with poor glycemic control turn to technology in a reactive manner, we hypothesize that pushing support content based on quick and simple assessments via SMS, over time, may improve engagement with support content and self-management(24).

While we have strong evidence of the short and long-term benefits of intensive glycemic control, most adolescents and emerging adults living with T1D are unable to achieve glycemic targets. There are many barriers to optimal T1D transition care, involving a range of patient, provider, and health system factors. Patient-related barriers include limited knowledge and skills for diabetes self-management, competing priorities (e.g. family/school/social relationships), and difficulty making a connection with the adult team. There are also a number of provider- and system-related barriers, such as incomplete transfer of patient information between pediatric and adult providers and poor uptake of available structured tools into practice(36).

2.3 RISK/BENEFIT ASSESSMENT

The value of the information to be gained from this study outweighs the risks of participation in the study as we do not expect the KiT intervention to cause any negative effects on participants, and previous research has already demonstrated that personalized support and data collection must result in meaningful feedback or provide support to the patient(37). The KiT intervention can deliver all of these features and will be delivered through a medium that is used by adolescents on a daily basis, mobile phones and text messaging. This makes this intervention non-burdensome and easy to integrate into everyday life. There is a potential risk of users finding the KiT text messages intrusive or bothersome. To minimize this risk, we will be offering user options to customize 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 participants any personal identifying information, nor will Memotext receive any personal identifying information from the study team, apart from the participant phone number and Study ID number; both needed to onboard and activate the participant with the KiT intervention. Participants will also be briefed during the consent and enrollment process to ensure that their mobile device is their own personal device and is not shared with anyone else (friend or family), and that they 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 sever at Memotext offcies in Toronto; these servers will be encrypted and will not be accessed by any members outside of the Memotext research team, increasing protection of privacy and confidentiality. Overall, This intervention has the potential to offer the missing support and resources needed for young adults as they prepare to

transition from pediatric to adult diabetes care, and this support will be offered in a private and confidential manner.

3 OBJECTIVES AND ENDPOINTS

The **primary objectives** of this study is to compare the effectiveness of a text message-based T1D transition intervention that will personalize transition education and support, as an adjunct to usual T1D transition care versus usual transition care alone on a patient-reported outcome measures (PROM) called the Self-Efficacy for Diabetes Management (SEDM) scale, measured at baseline, 6 months, and 12 months after enrollment in the study.
The **secondary objectives** of this study are to evaluate the impact of this text-messaging based intervention on:

- other patient reported experiences and outcomes (PREMs/PROMs) including the READDY tool, a transition readiness assessment for emerging adults with diabetes diagnosed in youth; and the Barriers to Diabetes Adherence in Adolescence (BDA) questionnaire Stigma Subscale for assessing perceived stigma
- self-reported time between final pediatric diabetes visit and first adult diabetes visit
- self-reported and/or lab reported A1c at baseline and at 12 months after enrollment to study (depending on data availability)
- diabetes-related ED visits (measured using health administrative data)
- diabetes-related hospitalizations (measured using health administrative data)
- diabetes-related physician visits (administrative data)
- diabetes drugs and devices claims (administrative data)
- Aggregate and direct medical costs associated with the intervention and its implementation study data and administrative data)

An additional secondary, exploratory objective is to conduct an **embedded process evaluation**. The process evaluation will occur during the delivery of the intervention, real-time engagement metrics will be analyzed to evaluate participant engagement and will allow for intervention modification to increase and improve user engagement and content delivery. The objective of the process evaluation is to evaluate how and why the intervention achieved (or failed to achieve) the desired effects in order to gain an in-depth understanding of whether the intervention was received as intended, the mechanisms of action, and the conditions and factors associated with initial engagement and sustained use of the intervention. Overall, the embedded process evaluation will optimize the engagement with the intervention and assess the feasibility of implementing this intervention in the real-world.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Compare the effectiveness of a digital T1D transition platform that will personalize transition education and support, as an adjunct to usual T1D transition care versus usual	Self-efficacy for diabetes management measured by the Stanford self-efficacy for Diabetes Management scale (SEDM) at baseline, 6 months, and 12 months. The SEDM is an 8-item measure answered on a Likert scale from 1 (not at all confident) to 10 (totally confident), how confident they feel that they can carry out the listed tasks regularly at the present time. The score is calculated using the mean of the eight items with higher scores indicating self-efficacy.	Validated and reliable (α = 0.90); shown to have good internal consistency and test-retest validity; measure used in adolescents with type 1 diabetes(38,39); measure of self-efficacy related to core elements of diabetes self-management in

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
transition care alone on diabetes self-efficacy	Minimal clinically important difference is 10%	adolescents with type 1 diabetes
Secondary		
evaluate the impact of this textmessage-based intervention on the following, compared to the usual transition care alone: • Transition readiness • perceived stigma of living with T1D • self-reported time between final pediatric diabetes visit and first adult diabetes visit • self-reported and/or lab reported A1c at baseline and at 12 months after enrollment to study (depending on data availability) • diabetes related ED visits • diabetes related hospitalization • diabetes-related physician visits • diabetes drug and devices claims • Cost of implementation	• transition readiness measured by the READDY tool at baseline, 6 and 12 months; READDY is a transition readiness assessment for emerging adults with diabetes diagnosed in youth. The READDY tool assesses diabetes-related knowledge or skill items by querying respondents on 42 total items split into 5 domains: knowledge, navigation, health behaviors, and insulin pump skills. Respondents answer on a Likert scale from "yes, I can do this" to "Haven't thought about it"; confidence level is evaluated in each domain • the Barriers to Diabetes Adherence in Adolescence questionnaire (BDA) Stigma Subscale; in our study, stigma will be defined as an affirmative response to at least one of three key items on this subscale • A1c collected at baseline and 12 months after enrollment to study will be self-reported and/or lab-reported (depending on data availability) • Diabetes related ED visits, hospitalizations, and physician visits, and diabetes drug and devices claims will be measured for the 24 months prior to and 12 months during the intervention using health administrative data from ICES • Costs of implementation • Aggregate and direct medical costs associated with the intervention and its implementation will be measured for the 12 months of the intervention duration using study and administrative data	• The READDY tool has been validated during it's development by examining it's correlation with existing validated transition readiness tools such as TRAQ(40); the READDY tool was favored by the KiT subcommittee that included a patient partner. The KiT subcommittee felt that compared to other transition readiness scales specific to diabetes, the READDY tool was specific and relevant to what is being evaluated and it is patient-reported • 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(41) • HbA1c: From long-term follow up of the landmark Diabetes Control and Complications Trial (DCCT) participants, early metabolic control has a lasting legacy.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
		Individuals randomized to intensive therapy experienced a reduced risk of retinopathy up to 10 years after the study ended despite the convergence of mean HbA1c values to similar levels in both groups (~8%)(42). This underscores the importance of good metabolic control in early adulthood to prevent future diabetes complications. Further, HbA1c is at its highest (indicating poorest control) in the 18-24 year age group(7), even stabilizing HbA1c during this time would indicate a clinical improvement from the current state. • Cost of implementation will be collected to ascertain the cost of developing and using this intervention in a hospital setting in Ontario and Quebec; variables that will be collected for this analysis will include: salaries for staff working on the design, development and management of the intervention for the entire intervention duration; salary of research coordinators working to onboard participants to the intervention; cost of digital services and office equipment needed to develop and manage

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
		the intervention (computers, hosting service, servers); cost of REDcap servers and hospital IT support for REDCap integration with MEMOTEXT platform
Exploratory		
Evaluation of participant engagement and intervention fidelity	Embedded process evaluation using real-time engagement metrics (i.e. number of participants who are engaging with intervention messages on and which types of messages are the most and least engaged with)	Concurrent process evaluation allows for real-time intervention modification to increase and improve user engagement and content delivery

4 STUDY DESIGN

4.1 OVERALL DESIGN

First, we **hypothesize** that the intervention will primarily improve diabetes self-efficacy 12 months after enrollment into the KiT intervention's experimental arm compared to the control arm, which will approximate a year following discharge from pediatric diabetes care. We also expect that 12 months after discharge, the experimental group compared to the control group will show improvements in transition readiness, glycemic control. Second, we hypothesize that this intervention will be feasible to implement in two large provinces in a 'real-world' clinical setting.

We will conduct a **multi-site randomized control trial** to evaluate the effectiveness of an eHealth solution for T1D transition care. The study sample size is 212 adolescents withT1D from 6 pediatric diabetes centres (4 in Ontario and 2 in Quebec) and allocate them 1:1 to the intervention or control arm. Participants will be recruited at their pediatric centre within 3-4 months of either their: planned final pediatric visit or 18th birthday. We opted for individual randomization rather than cluster randomization because the target of the intervention is diabetes self-efficacy during the time between pediatric and adult care and relates to the individual rather than provider or clinic-based practices.

Intervention: both intervention and control groups will receive usual diabetes care including all medical visits and tests. In addition, the intervention group will receive the text messages for diabetes support and resources tailored according to their needs and interest. Both intervention and control groups will also complete PREMs and PROMs at baseline, 6 and 12 months.

Process Evaluation: the embedded process evaluation involves a mixed-methods approach using individual semi-structured interviews alongside user engagement metrics and quantitative outcome data to evaluate how and why the intervention achieved (or failed to achieve) the desired effects. Using an embedded single case design with cross case synthesis, the objective of the process evaluation is to gain an in-depth understanding of whether the intervention was received as intended (intervention fidelity), the mechanisms of action, and the conditions and factors associated with initial engagement and sustained use of the intervention.

Health system impact: We will examine health care utilization of patients with T1D using de-identified administrative health data for at least 12 months after the final pediatric visit. We will securely link patients' health card number to provincial administrative databases housed at ICES in Ontario and Med-Echo and Régie de l'assurance maladie du Québec (RAMQ) databases in Quebec.

Aggregate and direct medical costs associated with the intervention and its implementation: will be assessed for at least 12 months following the final pediatric visit. We will measure all relevant costs associated with implementation of the intervention and resource utilization. More specifically, we will: 1} identify the relevant resource categories e.g. costs associated with organizing and delivering the (variable costs and fixed or overhead costs; 2) measure resource use: ED visits, hospitalizations, and physician visits, and diabetes drug and devices claims; and 3) value each resource item. Costs will be collected in five broad categories: staff (e.g. salaries, fee for services), equipment (e.g. equipment/technology platform and depreciation costs, software costs, installation costs, and maintenance costs), communication (e.g. data transmission costs), administration (e.g. administration costs, supplies) and healthcare resource utilization.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

We chose to conduct a multi-site randomized control trial in both Ontario and Quebec in order to ensure representation across the two main sizes of pediatric diabetes centers (tertiary and community); our intervention will also be available in both English and French; participants in both provinces will be able to select their preferred language of intervention delivery at study enrollment. We opted to do 1:1, individual level randomization because the target of the intervention is individual level diabetes self-efficacy during the time between pediatric and adult diabetes care and not pediatric provider or clinic-based transition care. The treatment allocation not being blinded to the research team will not pose any bias or contamination as randomization to control or intervention group will be completed via an automated computer program on REDCap; the randomization sequence will be generated by a biostatistician who is not involved in recruitment or enrollment and has no contact with study participants. The research team does not know the randomization sequence which will be in blocks of 2 or 4, thus making it difficult to pre-determine treatment allocation during the recruitment or consent process. Also, the control group not having access to the tailored support or diabetes resource messages will not pose any potential problems or issues as the control group and intervention group will both be receiving the regular standard of care for diabetes and will not be restricted access to their usual diabetes resources and supports. Additionally, both the control and intervention group will receive the same incentives to complete the outcome measures at baseline, 6 months, and 12 months.

4.3 END OF STUDY DEFINITION

The end of the study is defined as completion of the l2-months in the intervention period and completion of the following outcome measures at 12-months: SEDM, BDA Stigma subscale, and READDY, as well providing a self-reported A1c at 12-months (or most recent). It is estimated that it will take 30 months from when the study opens to enrollment until the end of the study.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

To be eligible to participate in this study, an individual must meet all of the following criteria:

1. Diagnosed with type 1 diabetes, ascertained from patient's medical chart
2. Receiving out-patient care for T1D at a pediatric diabetes center participating in this study
3. Is within 6 months of either planned transfer or 18th birthday so research coordinator can approach patient and inform them about the study, and then can be re-approached for consenting and enrollment only within 3-4 months of either: planned transfer to adult diabetes care OR 18th birthday
4. Proficient in written and spoken English or French
5. Possession of their own personal mobile device that can support SMS with sufficient capacity to send and receive SMS/texts
6. Valid and working mobile phone number
7. Valid email address
8. Willing to engage with intervention if randomized to intervention arm
9. Willing to complete study outcome measures (questionnaires) at all study time-points regardless of which arm they are randomized to: baseline, 6 months, and 12 months
10. Willing to provide informed consent

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Unable to carry out their diabetes care independently due to an intellectual or neurocognitive disability; discerned from medical chart during pre-screening
2. Non-resident of Ontario or Quebec
3. Planning to move out of either province in the next 6-12 months and after moving, will not be receiving diabetes care in either province and/or will not have a valid and working mobile number
4. Currently enrolled in any other clinical research trial with an SMS-based intervention
5. Currently enrolled in another diabetes intervention trial that will continue beyond the final pediatric diabetes visit

5.3 SCREEN FAILURES

Screen fails are defined as participants who consent to participate in the clinical trial but are not subsequently randomly assigned to the study intervention or entered in the study. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants. Minimal information includes demography, screen failure details and eligibility criteria.

5.4 STRATEGIES FOR RECRUITMENT AND RETENTION

Sample size: The total target sample size for this trial is 212 adolescents with T1D, with 106 participants in each arm (intervention and control arm). Participants will be recruited from participating pediatric diabetes centers in Ontario and Quebec: four pediatric diabetes clinics in Ontario and two in Quebec. Recruitment will occur for 18 months while the intervention will occur for a 12-month period.

- Ontario (4 sites total): Two sites will be tertiary hospitals - The Hospital for Sick Children and the Children's Hospital of Eastern Ontario (CHEO), and the other two sites will be community hospitals - Markham Stouffville Oaklands and Trillium Health Partners.
- Quebec (2 sites total): Two tertiary sites: Montreal Children's Hospital and CHU Saint Justine.

Recruitment, consenting and onboarding process: At each participating site in Ontario and Quebec, the following recruitment process will occur:

1) Local coordinator will identify eligible patients by pre-screening daily or weekly diabetes clinic lists and medical charts for inclusion and exclusion criteria. The local coordinator will obtain prior permission to access diabetes clinic lists from REB and site-specific institutional approval.
2) Initial contact with eligible patients:
    a. Where applicable, a study introductory letter from the local diabetes team (circle of care) will be sent (via email or post-mail) to potentially eligible patients after pre-screening. The introductory letter will inform the patient of the research study (study objective and purpose, study tasks and duration of study), and will inform participant that they are eligible to participate. The study information letter will ask the participant to reach out to their local study coordinator via telephone or email if they are interested in participating. The letter will also allow an opt-out feature where patients can opt-out of being contacted about the study by calling, writing or emailing the contact provided to let the research team know. The letter will also indicate that if there is no response to the letter within 2 weeks of receipt, a member of the study team will reach-out to the patient via phone, email or in-person at their next diabetes clinic visit to explain the study and gauge interest in participation. If via telephone or email, the study team will attempt to contact the eligible patient up to a maximum of 3 times with 1-week in between each contact attempt.
    b. If (a) is not feasible or permissible at a local site, the local diabetes team (circle of care) will send an opt-in letter (via email or post-mail) to all potentially eligible patients at their site. The opt-in letter will also provide the same details about the study as the Study Introduction letter in (a) but in (b), patients will be required to respond to the opt-in letter to express their consent to being contacted about this study by the local research coordinator either by phone, email, or in-person at their next diabetes clinic visit.
3) Other methods of advertising for this study: study flyers and digital advertisements will be posted on diabetes clinic waiting areas and waiting areas digital screens, with the contact information for the local research coordinator; we will also distribute study flyers in newsletters, communication boards, websites, and social media feeds.
4) Two weeks after initial contact from the circle of care, eligible patients (who have expressed interest from (2a) or did not respond to the letter from (2a) or opted-in from (2b) will be approached by the local research coordinator at their diabetes clinic visit or via telephone, video visit, or email to introduce the study again, provide a study information either in hard copy or electronically and discuss interest in participating in the study. The local research coordinator will explain study details including purpose, study tasks, duration of study, responsibilities of participating in the study, risks, and benefits of participating in the study, study confidentiality, types of data that will be collected and what data elements will be shared with other members of the research team (and who these team members are), and planed use of participant data and data analysis. Sufficient time will be provided to answer any questions from the potential participant.
5) After reviewing the informed consent form, if a patient expresses interest in participating in the trial, the local research coordinator will email them a link to a site-specific informed consent form on REDCap, or will provide a hard copy version of the consent form. Local coordinators will explain all sections of the informed consent form to the patient and allow time for questions. When the patient is ready to provide consent, they will be instructed on checking off appropriate

sections of the consent form electronically or on hard copy, and on providing their electronic signature on the electronic consent form or wet signature on hard copy of consent form.

6) Once a completed electronic or hard copy consent form is returned, the local coordinator will obtain relevant demographic and PHI information from the participant and confirm this information with participant, including: First and Last Name, DOB, OHIP # or RAMQ #, mobile phone number, mailing address including 6-digit postal code, and email address. This information will be kept on a site-specific enrollment log that is not stored on REDCap and will not be shared with other members of the study team.
7) The local coordinator will assign a site-specific study ID number to consented participant.
8) The local coordinator will randomize the participant using REDcap's automatic randomization feature. Both the local coordinator and participant will be aware of what study arm they were assigned to as local coordinator will need to explain next steps to the participant depending on study arm and participant will be aware of whether they will receive texts from the KiT intervention.
9) Local coordinator will provide KiT onboarding manual to participant that will outline next steps depending on whether they are assigned to intervention or control arm.
10) Upon randomization, the local coordinator will use secure and confidential institutional email to send Memotext the randomized participant study ID number, randomization arm and mobile phone number.
11) KiT intervention will send an initial SMS to the participant's mobile phone number, letting them know they are now enrolled in the KiT intervention and will be receiving text-messages related to their T1D care and management (for participants in the intervention arm), and periodic URLs that will link-out to surveys on REDcap (for both arms). The message will end by asking the participant to confirm that they are aware they have enrolled in the KiT study by replying with "Yes" or "No".
    a. If "Yes" is returned, the KiT intervention will begin.
        i. First URL linkout to be provided to participant will be to a REDCap survey que that first prompts to participant to complete a short demographic questionnaire. When this questionnaire is completed and submitted, the survey que will automatically produce the next surveys for participant completion, one at a time: READDY tool questionnaire, SEDM, and BDA Stigma subscale
            1. Some of the content and sequence of the messages and resources sent to the participant will be personalized, based on confidence ratings as measured by the "Readiness of Emerging Adults with Diabetes Diagnosed in Youth" (READDY) tool. If participants do not complete READDY tool questionnaire within 1 week of receipt, KiT intervention will send a follow-up reminder SMS asking them to complete the questionnaire. This reminder will be sent a maximum of two times (1 week apart). After the second reminder, the local research coordinator will follow-up with the participant via telephone asking them to complete the READDY tool questionnaire that was texted to them via the KiT intervention.
    b. If "No" is returned, the KiT intervention will reply with "Thank you for letting us know, we will reach out to the research team for more information". Memotext research team will reach out to local coordinator to inquire about participant enrollment and confirm mobile number.
12) KiT intervention will continue to send SMS messages throughout the duration of the study (12-month intervention period) to individuals in the intervention arm. In addition to personalized SMS about T1D care and management that will be sent to intervention group, both study groups will receive SMS messages of URLs that will link to REDCap for the PREMs and PROMs at 6 months and 12 months from the date the baseline survey is completed.

6 STUDY INTERVENTION

6.1 STUDY INTERVENTION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION DESCRIPTION

The KiT intervention is a text messaging algorithm that will operate like a chatbot, querying adolescents with T1D about their confidence with different aspects of T1D self-management as they are preparing to transition to adult diabetes care. The KiT intervention has fivecomponents of messaging (see below); if enrolled in the intervention group, participants will receive all four types of messages while the control group will only receive messages pertaining to the fourth category:

1) Personalized Educational Content (referred to as "push content"): KiT will send some personalized educational content to participants based on self-reported confidence ratings as measured by the "Readiness of Emerging Adults with Diabetes Diagnosed in Youth" (READDY) tool and participants self-reported interest in particular topics. The KiT intervention will send a combination of young-adult friendly educational text messages and links to existing trusted online resources about topics such as driving and diabetes, alcohol and diabetes, managing diabetes-related stressors; and diabetes and sexual health and function.
    a. With respect to managing stressors related to living with type 1 diabetes, KiT will initiate a series of support-based text-messages offering suggestions to improve behavioral health using suggested coping strategies. These behavioral health text messages will be created by an expert group that includes: a pediatric psychologist (JK) who specializes in working with chronically medically ill children and youth and is a certified diabetes educator (CDE); a pediatric endocrinologist who specializes in diabetes (RS); and our study's patient partner (MG)
2) Standard Educational Curriculum: deliver messages and reminders related to transition to adult diabetes care that are relevant to all adolescents with T1D preparing to transition to adult care. These messages will support participants as they navigate adult diabetes care. Messages will cover topics such as preparing for an upcoming clinic appointment, reminders about booking appointments, refilling and paying for diabetes medication and supplies.
3) Provide participant compensation for filling out questionnaires about clinic attendance, recent measures of glycemia including recent lab or sensor estimated HbA1c results, time in range and sensor use in the past 14 days, and patient reported outcome measures (READDY, BDA Stigma subscale, and SEDM; all at baseline, 6 months and 12 months). All participants (in both the control and experimental groups), will be provided the same compensation at the same time-points once all outcome measures at each time-point (baseline, 6 months and 12 months) have been completed: a $20 Amazon gift-card for completion of outcome measures at each time-point for a maximum total value of $60 in Amazon gift-cards per participant. This compensation amount was determined based on the total estimated time to complete all outcome measures (total of 4 outcome measures plus initial survey) at each time-point – approximately 30 minutes. This compensation amount per time-point is further justified as other similar studies in the same population offered $20 for completion of 8-10 outcome

measures that took approximately 45 minutes to complete. When KiT sends messages with links to the REDcap-based outcome measures, all participants will also receive their Study ID number via KiT as they will need to enter this into REDCap when they start their outcome questionnaires; KiT will also send an accompanying text-message reminding participants that they will only receive an automatic e-gift card via KiT text-message once they complete all questionnaires at each time-point.

4) Question and Answer (Q&A) feature: participants in the intervention arm can message the KiT intervention with their T1D related questions and the intervention will send links (where available) via text-message, to relevant resources from the validated resources collected in the environmental scan

Personalized Educational Content: After considering over 20 available transition readiness tools and questionnaires used in the diabetes population, the KiT subcommittee (consisting of our patient partner, and four pediatric diabetes endocrinologists), selected the READDY tool as the preferred diabetes-transition tool to help guide the intervention topics list, content creation and messages. Alongside the KiT subcommittee, an environmental scan was conducted to find what online resources related to T1D transition were provided by organizations, hospitals, institutions and governmental groups across Canada. These resources were categorized based on relevance to T1D transition, availability in French and English, production quality, accessibility, web-site screen resolution adjusting on mobile device, and licensing. Furthermore, these resources were itemized as "topic areas" and mapped to the relevant domain of the READDY tool in an effort to distinguish which items on the READDY tool that the KiT intervention could provide education and resources on. Therefore, the results of the environmental scan that mapped to the READDY tool serves as the knowledge base for the KiT algorithm to deliver educational content and resources. The environmental scan included only Canadian sources, however, we may opt to include non-Canadian educational resources if they are deemed by the research team to be credible.

Also, during Phase 1 of the KiT study, we conducted one-on-one semi-structured interviews and co-design sessions in Ontario and Quebec with pediatric and young adult patients with T1D, as well as pediatric and young adult diabetes providers, asking to help design a digital tool for youth to keep in touch with their diabetes team during transition to adult care. The interviews and co-design sessions revealed what topics, gaps and challenges patients and providers felt were important to address with youth transitioning to adult diabetes care. The most salient topics from these interviews and co-design sessions were then mapped to topic areas within the domains of the READDY tool. Taken together, this revealed the most important topic areas that the KiT intervention would address and provide resources on. The interviews and co-design sessions also revealed additional topics that patients and providers felt were important but did not map to the READDY tool domains or topic areas. **See Appendix, Table 2: KiT Educational Topics and see Appendix, Table 3: KiT Intervention – Feature Category and Sample Dialogue; KiT Sample Messages in Appendix Page 37-40**

Educational Content: We included only topics that were identified to be important to patients based on data from the interviews and co-design sessions and in the literature. We also only included topics for which there are credible resources available. Topics that will be relevant to all participants will be delivered to all participants as part of the "core educational curriculum" and topics that may not be relevant to all, will be delivered only to those who self-report low confidence or interest in those topics. The content of these messages will be developed by the research team and the tone and style of the messages will be developed by the eHealth innovation team with input from patients and providers in the co-design sessions.

Reminders: delivery of messages to help participants navigate diabetes care (e.g. reminders about booking appointments, refilling and paying for medication and supplies). See **Appendix, Table 3: KiT Intervention – Feature Category and Sample Dialogue, under section "Care Coordination"); KiT Sample Messages in Appendix Page 37-40**

Questionnaires and PREMs/PROMs: At baseline, a URL linkout to a REDCap survey que beginning with a short demographic questionnaire will be sent via SMS. The survey que will consist of the short demographic questionnaire, followed by the READDY tool, SEDM, and BDA Stigma subscale, all on REDCap. At 6 and 12-months after baseline, URLs will be sent via SMS to linkouts to REDCap surveys of the READDY tool, and SEDM, as well as self-reported clinic visits attended and measures of glycemia including recent lab or sensor estimated A1c results, time in range and sensor use in the past 14 days.

Other aspects of the KiT intervention messages: Participants in the intervention group will be sent messages at set intervals, however, they will have the option of increasing or decreasing the frequency of messages within a range of options and opt for messages to be sent on their preferred days of the week and time of day. Participants can also pause their messages at any time for a discrete period by texting the word "PAUSE". The tone of the messages sent by the KiT intervention was developed by the eHealth innovation team and reviewed for acceptability with the help of our patient partner and adolescents who are of similar age to those who would be typically transitioning from pediatric to adult diabetes care.

KiT Intervention Technology and Development: the intervention algorithm will be built and managed by our third-party collaborator, Memotext, based in Toronto. Memotext is a digital patient engagement platform that uses health data and analytics to optimize digital communications. Memotext will be designing, developing, deploying and managing our study intervention in partnership with our study collaborators at UHN, the eHealth Innovation team. Memotext will work with SickKids REDCap administrators to ensure that REDCap API (Application Programming Interface) integration is enabled with SickKids REDCap servers in order to deploy chatbot link-outs to REDCap for PREMs and PROMs data collection. Memotext will only be receiving PHI in the form of participant phone number in order to enact registration between participant's personal mobile devise (via SMS) and the chatbot; every participant will have their own Study ID number and Memotext will not be privy to the patients' names or any other personal identifying information. During the consent process, participants will be made aware of all the information collected by the intervention, how this information will be used and who will have access to this information (Memotext and members of the research team); participants will be asked to provide their consent to collect this information within the KiT intervention during the e-consent process. Participants with any type of mobile device that is registered to any mobile network will be able to enroll in this study as text-messaging capabilities are universal for all mobile devices. Participants will be informed that only text-messages via SMS will be sent to their phones and will be advised to be connected to a wifi network when they are accessing links provided by KiT and when completing the outcome measures; this is to ensure that the participant does not incur extra out-o-f pocket costs for data usage while not connected to a wifi network. Memotext's system will maintain logs of all outgoing and incoming messages, and this de-identified data (only linked to Study ID number), will be compiled into a feedback report that will be reviewed and evaluated by the research team on a periodic basis.

Intervention arm: both intervention and control groups will continue with their usual diabetes care. In addition, the intervention group will receive the automated text messages for diabetes support and resources tailored according to their level of confidence and interest in transition topics, for 12 months. At baseline, individuals in the intervention group will receive a link via text-message that will take them to a questionnaire about their demographics and diabetes care, the READDY tool questionnaire, BDA Stigma Subscale, and SEDM on REDCap. Responses to the READDY tool will guide the personalized content of the educational text-messages. During the 12-month intervention period, participants in the intervention group will all receive messages to support participants to navigate diabetes care (e.g.

reminders about upcoming appointments, refilling and paying for medication and supplies.) At 6 and 12 months after enrollment in this study, all participants (intervention and control arms) will receive links via text messages that link-out to REDCap surveys for completion of: a questionnaire about diabetes appointments and care, SEDM, BDA Stigma subscale, and the READDY tool. Financial compensation will be provided for participant time to complete these outcome measures at baseline, 6, and 12 months.

Control arm: Participants randomized to the control arm will also be offered the same incentives to complete questionnaires (outcome measures) but will not receive any other components of the intervention – no personalized/customized support or diabetes resource messages and no reminders. Control arm participants will continue with their usual T1D transition care. They will be sent prompts via SMS asking them to complete the same questionnaire about diabetes appointments and care, PROMs/PREMs as the intervention group, at the same time-points of baseline, 6 months, and 12 months. The same financial incentive will be offered to both intervention and control groups to encourage participants to respond to these prompts.

6.2 RANDOMIZATION AND BLINDING

Eligible participants will be randomised to either intervention or control group in a 1:1 ratio. The randomization sequence will be generated by a computer program using variable block sizes of 2 or 4, and overseen by the biostatistician at The Hospital for Sick Children. The treatment allocation will be concealed until the point of randomization. Randomization will be done by the local coordinator after informed consent has been obtained. The local coordinator will use REDCap's automatic randomization feature that has been enabled for this project. Due to the nature of the intervention, participants and the local coordinator will be aware of their treatment allocation. Research staff (local and Memotext) will not be blinded to the treatment allocation as they will need to be aware of group assignments for the purposes of onboarding participants to the application and querying any technical questions if participants reach out for assistance. Research staff being aware of treatment allocation will not introduce any bias as treatment allocation is done by computer generated sequences and all self-reported primary and secondary outcome measures are completed by participants in both the intervention and control arm, and the remaining outcomes measures are objective in nature: lab or self-reported A1c data, health care utilization and health care costs.

6.3 STUDY INTERVENTION COMPLIANCE

Compliance to the KiT intervention will be defined as responding to questions posed by the intervention messages and completing questionnaires and PREMs and PROMs at study-specific time-points. If a participant does not reply to the first three intervention messages/questions and/or does not complete the PREMs/PROMs sent by the intervention, two reminders to answer the message and/or PREMs/PROMs will be sent by the intervention, one week a part. If there is still no engagement from the participant, the local coordinator will contact the participant via telephone or email. The local coordinator will inquire why the participant has not engaged with the intervention and/or why they have not completed the PREMs/PROMs sent to them and ask if they are still interested in participating in this study. Furthermore, as part of the embedded process evaluation, user engagement will be tracked and analyzed to see who is not engaging with the intervention and possible reasons for why. Also as part of the process evaluation, those who enroll in the study but engage with the intervention only once or not at all or have very sporadic engagement will be invited to participate in a virtual one-on-one interview. These candidates will be contacted by a member of the research team to discuss what could be done to improve their experience. Those who have provided their consent to participate in the process evaluation will be contacted by a member of the research team who will schedule an interview to gather feedback on why they are not engaging with the KiT intervention and what could be improved.

7 DISCONTINUATION AND WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION

Discontinuation from KiT intervention does not mean discontinuation from the study, and remaining study procedures should be completed as indicated by the study protocol.

The data to be collected at the time of study intervention discontinuation will include the following:

- lab reported A1c at baseline and at 12 months after enrollment to study (depending on data availability)
- diabetes related ED visits (measured using health administrative data)
- diabetes related hospitalization (measured using health administrative data)
- healthcare utilization (administrative data)
- Aggregate and direct medical costs associated with the intervention and its implementation study data and administrative data)

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.
An Investigator may discontinue or withdraw a participant from the study for the following reasons:

- Withdrawal of informed consent (participant withdrew for any reason)
- Significant study intervention non-compliance
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

Participants who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study, will be attempted to be replaced if there at least 12 months remaining in the study so new replacements would receive the full intervention. The data from participants who are withdrawn or discontinued from the study will be used in the analysis unless the participant requests otherwise.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if they fail to complete at baseline, 6 or 12 months, the participant questionnaire, READDY tool questionnaire, BDA Stigma subscale, and SEDM, and is unable to be contacted by the study site staff after the maximum number of reminders and contact attempts. Before a participant is deemed lost to follow-up, the Principal Investigator or designee will make every effort to regain contact with the participant (where possible, 2 reminders via KiT intervention and 1 email follow-up or telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts will be documented in the participant's medical record or study file. Should the participant continue to be unreachable, they will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ASSESSMENTS

- **Questionnaires and patient-reported outcomes:** all the following will be sent as a URLs via KiT intervention SMS that will link-out to web-based REDCap surveys:
    - Baseline demographic questionnaire,
    - READDY tool: transition readiness assessment for emerging adults with diabetes diagnosed in youth, administered at baseline, and 6 and 12 months after baseline
    - SEDM: self-efficacy with diabetes self-management, administered at baseline, 6 and 12 months after baseline
    - BDA Stigma subscale: type 1 diabetes stigma assessment subscale, administered at baseline, 6 and 12 months after baseline
    - Self-reported time between final pediatric visit and first adult diabetes visit
    - Self-reported A1c at 12 months after enrollment to study

- **Administrative data via OHIP or RAMQ number collection:** the following data will be collected via linking to administrative datasets via ICES in Ontario and Med-Echo and Régie de l'assurance maladie du Québec (RAMQ) databases in Quebec
    - diabetes related ED visits
    - diabetes related hospitalization
    - diabetes physician visits
    - HbA1c (in Ontario only)
    - claims for diabetes medication and devices
    - costs associated healthcare resource utilization: ED visits, hospitalizations, and physician visits, and diabetes drug and devices claims

- **Cost of implementation:** we will measure all relevant costs associated with the intervention and its implementation using study data. More specifically, costs will be collected in five broad categories: staff (e.g. salaries, fee for services), equipment (e.g. equipment/technology platform and depreciation costs, software costs, installation costs, and maintenance costs), communication (e.g. data transmission costs), administration (e.g. administration costs, supplies)

- **Process Evaluation:** The embedded three-step process evaluation will occur between 3-6 months after the intervention launch, contingent on sufficient participant enrollment and data collection. In Step 1, we will develop a theoretical model depicting the predictors of the initial engagement and sustained use of the KiT intervention (includes personalized educational content, Q & A, and standard educational curriculum) according to extant literature on the e-health interventions. This program theory builds on the tenants of the Health Action Process Approach (HAPA) and the Technology Acceptance Model (TAM) to generate candidate hypotheses, which have been framed using the Context-Mechanism-Outcome (CMO) configurations that are typical of realist evaluation. In Step 2, we will test the hypothesized pathways using semi-structured interviews. We will purposively sample participants across two categories: (1) participants with little to no engagement (bottom 50% of

activity) and (2) participants with high levels of engagement (top 50% of activity) according to the user engagement data (e.g., # of texts that users sent per month, % of external link clicks) at month 3 of the RCT. We will plan to invite all participants with little to no engagement in an interview. Semi-structured interviews will be informed by the HAPA and TAM and will explore how context influences intervention uptake and adherence among participants (please see Interview Guide 1). Specifically, we will explore the technological aspects (perceived usefulness, perceived ease of use), treatment aspects (perceived needs, outcome expectation, self-efficacy, etc.), and social aspects (social support, competing priorities, etc.) of the KiT intervention. For those who have high levels of engagement at three months, we will explicitly explore the interventions' mechanism of action as hypothesized in Step 1 (please see Interview Guide 2). In Step 3, we will identify the potential paths and corresponding combination of factors that are associated with outcome using Coincidence Analysis. We will create case constructions for each participant that will triangulate intervention engagement data, outcome data, and insights from one-on-one semi-structured interviews. Values of each variable will be converted to binary properties according to the definitions and criteria developed by the research team. CNA package in R will be used for data analysis. Participants who complete the process evaluation interview will be compensated with a $25 gift card for their time.

9 STATISTICAL CONSIDERATIONS

8.2 STATISTICAL HYPOTHESES

- **Primary Endpoint(s):** Diabetes self-efficacy measured by SEDM at baseline, 6 and 12 months after baseline. We hypothesize that the intervention, will improve engagement with support content and improve self-management of diabetes among the intervention group compared to control group at 12 months compared to baseline.

- **Secondary Endpoint(s):** transition readiness measured by the READDY tool; perceived stigma measured by the Barriers to Diabetes Adherence (BDA) stigma subscale, and time from final pediatric to first adult diabetes appointment; Baseline adjusted HbA1c; diabetes-related ED visits and hospitalizations at 12 months. We hypothesize that the intervention, may improve transition readiness and improve glycemic management, decrease the time from last pediatric to first adult diabetes appointment, and decrease the frequency of diabetes-related ED visits and hospitalizations in the intervention group compared to the control group at 12 months compared to baseline.

- **Exploratory Endpoint(s):**
    - Within the embedded process evaluation, we will investigate the pragmatic nature of this trial and and study whether making real-time adjustments will improve user interaction and experience will increase user uptake and satisfaction
    - We will measure the cost of implementing this intervention to inform the feasibility of scaling this intervention.
    - We will explore if, any, sociodemographic factors are related to the use, engagement and effectiveness of the KiT intervention on diabetes self-efficacy and/or the readiness to transition to adult diabetes care, and/or barriers to diabetes adherence stigma subscale. We will explore sociodemographic factors using the Ontario Marginalization Index (ON-Marg). The ON-Marg is a data tool that uses the full 6-digit postal code to measure

multiples axes of deprivation in Ontario, including economic, ethno-racial, age-based and social marginalization.

8.3 SAMPLE SIZE DETERMINATION

The total sample size of 212 (106 per arm) was determined based on the number of adolescents with T1D who are annually transferred to adult diabetes care at each participating site:

- Ontario (4 sites total): The Hospital for Sick Children, Children's Hospital of Eastern Ontario (CHEO), Markham Stouffville Oaklands and Trillium Health Partners. The total number of patients annually transferred from these Ontario pediatric diabetes centers to adult diabetes centers is approximately 202. Thus, over an 18-month period, there will be approximately 303 patients transferred to adult diabetes care who are eligible to participate in this trial. We estimate, based on prior experience of the investigators involved in transition research, that we would be able to make contact, recruit, consent and enroll approximately half (152) of the eligible patients (303), and account for 20% (30) being lost to follow-up, we will have approximately 121 participants from Ontario sites enrolled in this trial.

- Quebec (2 sites total): Montreal Children's Hospital and CHU Saint Justine. The total number of patients annually transferred from both pediatric diabetes centers to adult diabetes centers is approximately 152. Thus, over an 18-month period, there will be approximately 228 patients transferred to adult diabetes care who are eligible to participate in this trial. We estimate, based on prior experience of the investigators involved in transition research, that we would be able to make contact, recruit and enroll approximately half (114) of the eligible patients (228), and account for 20% (23) being lost to follow-up, we will have approximately 91 participants from Quebec sites enrolled in this trial.

The required sample size of 212 (106 per arm) will be provide 80% power of detecting a between-group change in mean score for self-efficacy with diabetes management (SEDM) of 1.6, this accounts for 20% loss to follow-up at the 5% significance level (alpha) using a two-sample equal-variance t-test.

8.4 POPULATIONS FOR ANALYSES

An intention-to-treat analysis will be conducted by blinded analysts. We will evaluate the extent of missing data to determine if values are missing at random or not and will consider imputation to account for missing values.

8.5 STATISTICAL ANALYSES

8.5.1 GENERAL APPROACH

Demographics and baseline characteristics will be summarised using descriptive statistics. Continuous data will be reported as means with SDs.

8.5.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

We will compare the mean SEDM score at 12 months between those in the intervention versus control arms. This will be done using linear regression to estimate the effect of the KiT intervention on self-efficacy of diabetes management, controlling for baseline SEDM. The linear model will be estimated using generalized estimating equation (GEE) methods and account for clustering of patients at their pediatric diabetes clinic. We will disaggregate our analysis by sex and gender.

8.5.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

For secondary outcomes, continuous data will be reported as means with SDs and between-arm differences in means will be calculated using Student's t-tests or non-parametric statistics. To account for repeated measures, secondary analysis will be conducted to calculate within (baseline, 6months, 12 months) and between arm-differences to evaluate changes.

We will compare baseline adjusted self-reported mean HbA1c at 12 months between those in the intervention versus control arms. This will be done using linear regression to estimate the effect of the intervention on HbA1c. The linear model will be estimated using generalized estimating equation (GEE) methods to account for the clustering of patients within centres. We will disaggregate our analyses by sex and gender.

From the process evaluation, we will report metrics of user engagement by # of interested topics chosen by the participant, type of specific topics, proactive use of chatbot, response rate (%) to messages that query participants with a question or prompt requiring a SMS response, and proportion (%) of participant clicks on resource and educational links. Furthermore, qualitative observations made during the one-on-one interviews and surveys administered during the process evaluation will be analyzed using thematic analysis strategies guided by HAPA and the TAM, identifying key themes that demonstrate important contextual influences and practices related to the implementation and evaluation of the e-Health technologies in actual contexts of health care delivery. The findings of the qualitative data will be used to develop statements of the relationships between (a) key contextual factors (e.g., perceived needs, outcome expectancies, self-efficacy), (b) the mechanisms by which they affect the implementation of the e-Health interventions, and (c) the impact on the outcomes of the KiT intervention themselves (in Realist Evaluation these statements are referred to as "Context-Mechanism-Outcome Configurations" (43).

The descriptive cost analysis of the aggregate and direct medical costs associated with the KiT intervention will be conducted from the perspective of the Ontario MOHLTC and adopted over a life of the intervention period. We will assume a 1.5% discount rate for costs and consequences going beyond 1 year as per the Canadian Agency for Drugs and Technology in Health (CADTH) guidelines for economic evaluations (44). All costs will be reported in 2023 Canadian dollars using the Bank of Canada Consumer Price Index calculator to adjust for inflation to a given base year (45). We will utilize a bottom-up approach when tallying the healthcare resource utilization costs for individuals over the study duration. Healthcare resource utilization costs will consist of the ED visits, hospitalizations, and physician visits, and diabetes drug and devices claims, as well as other relevant services as decided with the study stakeholders during follow-up. Costs related to hospitalizations and emergency room visits will be estimated using the resource intensity weight (RIW) methodology, whereby the cost is the product of the R1W associated with a particular case and the average cost per weighted case for Ontario and Québec (44). Furthermore, we will simulate the scaling of the program and its impact on the program and health system costs.

8.5.4 BASELINE DESCRIPTIVE STATISTICS

Summary statistics will be used to describe baseline characteristics and other outcomes of interest. Categorical endpoints will be summarized using proportions and frequencies. Continuous endpoints will be summarized using the mean, median, range or standard deviations. Subgroup summarization based on KiT intervention message frequency or other criteria will also be conducted.

8.5.5 PLANNED INTERIM ANALYSES

An interim analysis within the process evaluation is planned to be performed on user engagement and participant satisfaction with the KiT intervention 3 or 6 months after the start of the intervention; timing is contingent on having enough participants enrolled. The interim analysis will be performed by the process evaluation research team, unblinded to the treatment allocation. The results of the interim analysis will be used as feedback information to the research team to make adjustments to the KiT intervention in real-time. These adjustments could be in the form changing the tone of messaging, changing the wording of messages or switching out topics that had the least user engagement, updating or replacing resources or educational content that had the least user engagement or changing the frequency or sequencing of messaging.

8.5.6 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual de-identified participant data will be listed by time point of response to every message and resource sent by the KiT intervention and engagement via clicks on resource and educational links. This individual-level data is required to conduct the process evaluation (interim and full-analysis) to determine on an individual and aggregate scale, what messages and resources participants find the most engaging and useful. This participant data will then enable modifications to the KiT intervention in real-time, improving user uptake and effectiveness. All de-identified participant data will be listed in the data table by study ID number and no PHI information will be listed.

9 PARTICIPANT SAFETY

Due to the nature of the KiT intervention, we do not expect adverse or serious adverse events related to the intervention to occur. If a participant reports any diabetes-related stressors, the KiT intervention will provide text-messaged based resources that offer suggestions for behavioural health in the form of suggested coping strategies, as compiled by our patient partner, pediatric psychologist and pediatric endocrinologist. If a participant texts KiT any messages signalling a crisis situation (see appendix for list of crisis key words that will be recognized by KiT), support messages will be delivered by KiT, encouraging the participant to reach out to medical professionals and will offer key contact information for appropriate assistance. If any of the KiT intervention messages create discomfort or cause distress to study participants we will allow the participant the option to pause the KiT messages until and if they feel ready to resume the messages again. Any elevated harm, discomfort or distress caused by the KiT messages, indicated to us by the participant, will be immediately reported to the Principal Investigator, and the Research Ethics Board and entered the study database as a note to file.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, Investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the PI will promptly inform study participants, and the REB and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study timelines.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the REB.

10.1.2 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating Investigators, their staff, and Collaborators. This confidentiality is extended to cover the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence.

Any research information obtained about the patient in this study will be kept confidential. A patient will not be identified by name, only by unique study ID number. The patient's name or any identifying information will not appear in any reports published as a result of this study. All identifying information will be kept behind 2 security measures or as per equivalent institutional policy, under the supervision of the study/site PI and will not be transferred outside of the hospital.

The representatives of the Research Ethics Board (REB) may inspect all documents and records required to be maintained by the Investigator, including but not limited to, medical records of the participants in this study. The clinical study site will permit access to such records.

Eligible participants will be told about all types of data that will be collected for this study that include PHI, including self-reported characteristics and diabetes care measures, text messages exchanged with the KiT intervention, and OHIP/RAMQ number collection which will be linked to administrative data before they enroll in the study. This information will be presented to them in the informed consent form so they are fully aware of what the study entails and what information the intervention will collect, store and analyze. Participants will also be informed during the consenting process about the collection and use of their cell phone number by the research coordinator and Memotext. Participants will be asked to provide their consent to share their telephone number with Memotext team, which is needed to onboard and activate them into the KiT study. Participants will be provided information on Memotext's secure systems and platforms and ensured that their phone number will not be shared with any members outside of their local coordinator who recruited them for the study and Memotext team working on the KiT intervention, and participants will not be contacted by cell phone (call or text) or email or in any other manner by any members of the research team or Memotext, except for study purposes as outlined by our study objectives. Furthermore, participants will be allowed to provide consent to different aspects of the KiT intervention, should they not be interested in participating in every component of the study. For

example, the informed consent form will ask interested participants to provide their consent individually for each component of the KiT study: main study intervention (receiving KiT intervention text messages and engaging with the text messages if enrolled in the intervention arm), collection and use of OHIP or RAMQ number, and participation in the process evaluation if enrolled in the intervention arm. This way, any participants who do not consent to share their OHIP or RAMQ number for research purposes, can opt-out of that component but still participate in the KiT main intervention study and/or the process evaluation.

De-identification of all study participants: All participants who have provided informed consent and who have been enrolled in the study, will be assigned a site-specific study ID number, which will be recorded in the enrollment log kept at each site. The study ID number will be used to track all participants while they receive the study intervention and during analysis of study results. Separate from the enrollment log, the Master Linking Log containing the Study ID, first and last name, DOB, sex, MRN, phone number, address including and email address of the participant will be kept separately from all other study data and will be stored at each respective site. The Master Linking log will not be shared with any members of the research team outside of the local site and will be secured as an encrypted file on a password protected computer.

Study data from the KiT intervention: User engagement data from the KiT intervention will be stored on the secure severs of our collaborator, Memotext, located in Toronto. Memotext will operate and manage the administration of the KiT intervention. Memotext collects and uses data in accordance with all applicable laws and PPEDA and HIPAA. There will be a data sharing agreement in place between Memotext and all participants sites, to facilitate secure data transfer of de-identified study data from Memotext to SickKids, UHN and Trillium Health Partner for data analysis of the main study outcomes, process evaluation and cost of implementation analysis. The data sharing agreements between all study sites and Memotext will enable secure data transfer of enrolled participant's Study ID numbers and linked mobile numbers. This is necessary to allow Memotext to activate enrolled participants into the KiT intervention to either the intervention or the control arm, depending on the randomization assigned to each enrolled participant. All data transfer will be performed under secure transfer conditions and only accessible by Memotext research team members working on the KiT study. Memotext agrees not to attempt to re-identify de-identified information and not to transfer deidentified information to any party.

OHIP and RAMQ numbers: If a participant provides consent to collect and use their OHIP and/or RAMQ number in accordance with protocol-specified outcomes and analysis, this PHI information will be securely stored in a file separate to the Master Linking Log and separate to the enrollment log of the study. This file will be encrypted and stored on a password-protected computer at each study site. At the time of analysis, this file will be securely transferred from each study site to SickKids via SickKids Secure File Transfer Portal System that requires a password protected account for each sender and receiver of data. All study sites will have a data sharing agreement in place with SickKids to facilitate this data transfer. Once SickKids receives files from all study sites, including Quebec sites using RAMQ, SickKids will initiate a secure file transfer to the ICES, where individual data linkage to administrative datasets for analysis of secondary outcomes will be performed. This file containing OHIP and RAMQ numbers will not be shared with Memotext as their scope of work does not require access to this data.

10.1.3 FUTURE USE OF DATA

Data collected for this study will be analyzed and stored at SickKids for primary and secondary outcome analysis, and at Trillium Health Partners for the analysis of the process evaluation. After the study is completed, the de-identified, archived data will be transmitted to and stored at The Hospital for Sick Children, for use by other researchers including those outside of the study – specifically UHN. Permission

to transmit data to UHN, our other study collaborator, will be included in the informed consent and there will be a data sharing agreement in place between UHN and The Hospital for Sick Children.

10.1.4 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator
Dr. Rayzel Shulman, MD, PhD
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10.1.5 QUALITY ASSURANCE AND QUALITY CONTROL

Each clinical site will perform internal quality management of study conduct, data collection, documentation, and completion.

Data entry for enrollment and randomization, and online questionnaires will be entered through a web browser (on computer or mobile device for participants completing online questionnaires) in real time into a secure central database using REDCap, hosted at SickKids. Data will be systematically checked for completeness and consistency by routine data-pulls of de-identified data from Memotext and SickKids research staff. Queries from these routine checks will be transmitted to the research coordinators at local sites for resolution.

Data entry into the enrollment log, master linking log and OHIP/RAMQ log will be all be done on separate secure files, not entered on REDCap and all stored separately on encrypted files in password-protected computers, at each local site.

10.1.6 DATA HANDLING AND RECORD KEEPING

10.1.6.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site Investigator. The Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

Study data will be entered into REDCap (Research Electronic Data Capture), a secure, web-based application designed exclusively to support data capture for research studies. REDCap is developed and maintained by a team at Vanderbilt University and licensed free of charge by the Research Institute at The Hospital for Sick Children. The application and data are housed on servers provided by The Hospital for Sick Children. These servers are located within SickKids secure data center. Local support for REDcap is provided by SickKids Research IT.

Research coordinators at each study site will have an External REDCap account that requires a secure login and password. Local coordinators will use their individual REDCap accounts to access the KiT Intervention REDCap project and will be able to enroll and randomize participants via REDCap automatic randomization, and enter enrollment data (date of enrollment, study site and Study ID number).

Local coordinators will also be able to track completion of baseline, 6-month and 12-month outcome measures for participants at their site. This is necessary in case the local coordinator needs to make contact with participants who are not engaging with the intervention and/or not completing their outcome measures at the specified time-points.

Data collection on REDCap: Enrollment data, and all outcome measures at baseline, 6 and 12 months will be entered in real-time by local coordinators and participants directly into REDCap. REDcap will house these data on secure servers at SickKids.

Data Collection from medical charts:

1) From Medical Charts: participant birth date (month and year only) to access appropriate age eligibility for study participation; planned final pediatric visit date; baseline HbA1c, first and last name, telephone number and email in order for local research coordinator to establish contact with eligible participants during recruitment phase, either in clinic or virtually via telephone or email. Participant's mailing address including 6-digit postal code will also be obtained from their medical chart. The full mailing address is needed to send study information letters and/or baseline, 6 month or 12 month reminder letters (if preferred by participant versus email communication). Additionally, the full 6-digit postal code is needed for ICES verification during linkage of participant OHIP number to administrative data sets, and for sociodemographic analysis using the Ontario Marginalization Index (On-Marg), which requires the use of 6-digit postal codes instead of first 3 digits of postal code. Only local research coordinators will access information from patient medical charts after obtaining local REB approval and institutional approval for this study. PHI data from participant medical charts will be stored on the enrollment log (encrypted and on password-protected computer). Baseline HbA1c will be entered into REDCap during the time of enrollment.
2) Provincial Health Card Number: we will obtain participant consent to collect OHIP (in Ontario) and RAMQ (in Quebec) numbers in order to perform linkage to provincial administrative data to collect diabetes-related ED visits, hospitalizations, diabetes physician visits, and A1c in Ontario. We will be recording and storing the OHIP and/or RAMQ numbers on a log separate from all other data collection documents and will not enter this information into REDCap or the KiT intervention algorithm, or the enrollment log or Master Linking log. Memotext will not have access to participants' OHIP and/or RAMQ number. Upon study data collection completion, all participating sites will upload their participant OHIP/RAMQ number to a secure file portal in order to enable administrative data linkage via ICES in Ontario and Med-Echo and Régie de l'assurance maladie du Québec (RAMQ) databases in Quebec. To enable ICES verification of OHIP number for linkage to administrative datasets, ICES will receive participant full first and last name, Study ID number, OHIP or RAMQ number, full date of birth and full 6-digit postal code.

Data collection from KiT algorithm: Data collected from the KiT algorithm via text messages will include responses to text queries including but not limited to: the date of upcoming medical visits in order to send reminders in advance of the appointment date, responses about what educational content participants' would like to receive, and the number of times participants' click on links provided to online resources, and any questions texted from the participant to KiT as part of KiT's Q&A feature. Memotext will store all responses and engagement metrics to/with KiT algorithm on their secure severs in Toronto. All data collected by KiT algorithm will be de-identified; no PHI or personal identifying information will be collected by the KiT algorithm via text. Memotext will routinely monitor and check the data output from the KiT algorithm and will also track user engagement.

Memotext protects personal information by security safeguards appropriate to the sensitivity of information. They are committed to keeping personal information secure, and have appropriate technical, administrative, and physical procedures in place to protect personal information against loss or theft, as well as authorized access, disclosure, copying, use, modification, disposal or destruction. In addition, methods of protection and safeguards include, but are not limited to, locked filing cabinets, restricted access to offices, security clearances, need-to-know access and technological measures including the use of passwords, encryption and firewalls.

Data collection for secondary outcomes measured using administrative data: We will securely link patients' health card number to provincial administrative databases housed at ICES in Ontario and Med-Echo and Régie de l'assurance maladie du Québec (RAMQ) databases in Quebec. The study investigators will be permitted to access de-sensitized information only for analysis (i.e., any information that can directly identify a person like health card number or name will be removed or replaced with a code that is not known to the study investigators). We will measure all diabetes-related, hospitalizations, emergency department visits, and physician visits, HbA1c results (Ontario only from the Ontario Lab Information System (OLIS)), and diabetes medications and device claims (if available)in the 24 months prior to enrollment in the study and for 12 months after enrollment. The number of diabetes-related physician visits with during the intervention will be determined from physicians billing claims collected in the Ontario Health Insurance Program (OHIP) database and RAMQ databases in Quebec. In Ontario we will also collect information on hospitalizations for DKA or hypoglycemia from the Canadian Institute of Health Information (CIHI) discharge abstract database (DAD) and emergency department visits for hyper/hypoglycemia will be ascertained using the National Ambulatory Clinic Reporting System (NACRs). In Quebec we will measure hospitalizations from Med-Echo (hospitalizations) and RAMQ databases (physician billings from hospitalizations) and emergency department visits for hypo/hyperglycemia will be identified from the RAMQ databases. Only aggregate data will be provided to the research team.

Data collection for the cost of implementation analysis: In Ontario health care costs will be derived using a study-based data for the cost of the intervention and its implementation and administrative data for the resource utilization. More specifically, we will use validated costing algorithm established at ICES which includes direct health care costs incurred for hospitalizations, outpatient physician services, outpatient laboratory and diagnostic tests, emergency department visits, prescription drugs, same-day procedures, home care services, and complex continuing care(46) In Quebec we will obtain unit costs for hospitalizations from Med-Echo (hospitalizations) and RAMQ databases (physician billings from hospitalizations), and from an index (All Patient Refined Diagnosis Related Groups) that factors in the relative intensity of resources used during the hospitalization, provided by the ministère de la santé et services social (Quebec ministry of health)(47). All data collection for health care costs will be securely stored at ICES and only tables of de-identified data will be securely transferred to the research for health care cost analysis. A data sharing agreement will be in place for this transfer, between ICES and SickKids.

10.1.6.2 STUDY RECORDS RETENTION

To enable evaluations and/or audits from Regulatory Authorities, the Sponsor, the Principal Investigator agrees to keep records, including the identity of all participating patients (sufficient information to link records, CRFs and hospital records), all original signed informed consent forms, copies of all data entry records on REDCap and output data from KiT algorithm, for a minimum of 7 years in accordance with SickKids policy. At the end of the study, all records will continue to be kept in a secure location.

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APPENDIX

Table 2: KiT Educational Topics

		Topic Areas from Environmental Scan	Topics from Interviews and Co-Design Sessions (prominent topics have two x's)
READDY Tool	Knowledge	What is diabetes	
		What is A1C and my target	X
		Hyperglycemic/high blood glucose complications	X
		Hypoglycemic/low blood glucose signs	XX
		Hypoglycemic/low blood glucose treatments (e.g. glucagon)	XX
		Alcohol & glucose	X
		Tobacco & heart health & diabetes	
		Diabetes & sexual health/function	XX
		Glucose control before and during pregnancy	
		Tests done in routine visits to prevent complications	X
	Navigation	What to ask during a clinic appointment	XX
		Contact information of your healthcare team, where to look for advice and help	XX
		Medical insurance	XX
		Emotional, family, peer, and community support	XX
		Refilling prescriptions	XX
		Find a family doctor	
		Disability accommodations	X
		Find trustworthy resources	X
	Insulin	Insulin & syringe, pen, and pump	X

		Insulin dose & blood glucose	
		Insulin dose & food intake	
		Insulin adjustments & glucose patterns	XX
	Health Behaviours	Understanding carbohydrates & carb counting	X
		When to test glucose	
		Taking insulin and checking glucose in public	X
		Weight change	
		Sick day management	XX
		What to do with positive ketones	XX
		Preventing highs and lows during exercise	XX
		Diabetes & driving, treating highs and lows	XX
		Safe sex practices	X
	Insulin Pump	Pump setup	X
		Pump programming (basal and bolus)	XX
		Test basal rate	X
		Pump troubleshooting	X
		Insulin injections	
Non-READDY topics		How to use a glucometer	X
		Diabetes & mental health (eating disorders, navigating stigma, diabetes burnout, managing stress)	XX
		Continuous Glucose Monitoring	X
		Flash glucose monitoring	X
		Travel	X
		Nutrition & healthy eating, fats and protein, eating out	XX
		Diabetes and other health conditions	
		Diabetes and holidays	
		Managing T1D at school and work (not from scan)	XX
		Proper foot care (not from scan)	X

Table 3: KiT Intervention - Feature Category and Sample Dialogue

Feature Category	Intervention Feature	Sample Dialogue
Care Coordination	Asking patient for information about the adult T1D clinic they are going to and providing a clinic welcome package	KiT: Could you tell me the name of the adult clinic that you're going to be attending? User: Women's College Hospital KiT: Wonderful, you can click on this link for more information about the clinic, the providers who work there, and the different services they provide [insert link]
	Asking patient for their scheduled appointments and sending appointment reminders	KiT: Hello! Do you know when your next appointment is? User: It is on Sept 27th 2022 at 2 pm KiT: Perfect, I'll send you a reminder the week before so you don't forget!

	Asking patient for the tests they are required to complete before their appointments and sending reminders	KIT: Were there any tests, like bloodwork, that your healthcare team asked you to complete before your next appointment? User: My doctor wanted me to check my A1C KiT: That's definitely important! I'll send you a reminder 2 weeks before your appointment to get your A1C bloodwork done, so you can be prepared.
	Reminding patients about their medication and device refills	KiT: Just a reminder to check for the number of refills on your diabetes medication and supplies, so you don't run out!
	Reminding patients to upload CGM data	KiT: Did your healthcare team ask you to upload your CGM data before your next appointment? User: Yes KiT: Ok, I'll send you a reminder to do that before your next scheduled appointment
Education and self-advocacy	Sending patient checklists and information on how to prepare for their first adult visit	KiT: Your first appointment with your new adult clinic is coming up soon! I wanted to share some ideas on how to best prepare for it, because I know it can be overwhelming. Click on this link for some helpful tips [insert link]
	Sending patient reflection prompts to support them in self advocating during healthcare visits	KiT: Now that you've had your first visit with your new adult healthcare team, I encourage you to think about how it went. How did your new clinic and team make you feel? What are some things you liked about the visit, and what were some things you wish went differently? Remember that it can take time to build this new relationship, but that there are also other clinics you can try out if this one wasn't a good fit.
	Receiving T1D-related questions from the patient and sending answers from a validated bank of resources	User: How do I talk about T1D with my employer? KiT: Thanks for the question. This is something a lot of people have questions about. [Insert quote and link of validated content resource]
	Prompting patient with T1D information from a validated bank of resources	KiT: Hi, I wanted to send you some information about government assistance programs for people living with T1D. The Assistive Devices Program (or ADP) is a government program that may support you with the costs of your diabetes devices. It is something that needs to be renewed each year with the support from your physician. To learn more go to [link] or ask your physician about it at your next appointment.
	Storing patient's questions and notes that they want to bring up in their clinic visits	User: #NOTE: Remember to ask doctor about controlling my blood sugars when exercising User: #NOTE: How to apply for ADP User: #NOTE: Mental health resources at clinic?? KiT: Your next appointment is coming up soon, and I wanted to send you the notes you made so you can discuss them with your team: "Remember to ask doctor about controlling my blood sugars when exercising, How to apply for ADP, Mental health resources at clinic??"
PREMs/PROMs	Administering baseline and end of study questionnaire to patient	KiT: Please click on this link to complete the baseline and follow-up (6 months and 12 months) questionnaires for the study [insert REDCap link]

KiT – Sample Messages:

Care Navigation

CARE TEAM Your diabetes care team can be made up of a bunch of different healthcare professionals, such as a nurse, endocrinologist, dietician, social worker, and more!

If you're not sure who is a part of your care team, ask your clinic and check out this handy form from Diabetes Canada which lists out all the different healthcare providers who might be: *https://www.diabetes.ca/DiabetesCanadaWebsite/media/Managing-My-Diabetes/Tools%20and%20Resources/know-your-team.pdf?ext=.pdf*

CONTACTS It's important to know how to contact your diabetes care team outside of appointments in case you have questions or need their support. Do you know if your clinic has an on-call or urgent number that you can reach them at?? Try saving your care team as contacts in your phone 📱

PRIMARY CARE A family doctor or nurse practitioner is a really important member of your diabetes care team. They might not be an expert in T1D, but they can support you with all kinds of questions - you can go to them for things like mental health, sexual health, and other physical health concerns (stomach aches, rashes, stuff like that).

If you don't have a family doctor or nurse practitioner, Health Care Connect can help you find one: *https://www.ontario.ca/page/find-family-doctor-or-nurse-practitioner?_ga=2.87075160.154570205.1644426680-1166791615.1644426680*

Ketones and DKA

KETONES I'm sure you've heard the term "ketones" a lot so I wanted to give you a quick refresher on what they are! When your body doesn't have enough insulin to use glucose for energy, it starts using fat as a source of energy - when this happens, your body makes ketones, and high levels of ketones can be harmful.

So, like your car (your body) uses gas (fat) to run, there is a by-product of exhaust (ketones). Too much smoke in the air (ketones in the blood) is toxic! 🚗

DKA Since we're on the topic of ketones, it's important to chat about Diabetic Ketoacidosis (DKA). High levels of ketones in the blood can lead to DKA which is a medical emergency 🚑

In most cases, you can bring your ketone levels back to normal with the proper insulin dose. This link shows you how to calculate the right insulin dose based on your blood ketone levels, and what to do if your ketone levels are too high: *https://type1better.com/wp-content/uploads/2020/07/How-to-Manage-Ketone-Bodies.pdf*

PREVENTING DKA Obviously, no one wants DKA! So to avoid it, make sure to:
- Measure your blood sugar regularly
- Always take your insulin (even when you're sick!)
- Check your blood or urine for ketones if you have any symptoms of DKA so that you can act quickly!

Check out this short video for more info on DKA symptoms and prevention:
https://www.youtube.com/watch?v=NwBzGfKY_gE

Sick Day Management

SICK DAY CARE Getting sick is probably going to happen, and during these times your blood sugars may fluctuate and become unpredictable SO it's really important to keep track of your body when you're not feeling well!

When you're sick, make sure to check your blood sugar and ketones every 2 to 4 hours - set an alarm to wake you up when you're sleeping ⏰ For more info, check out
https://waltzingthedragon.ca/diabetes/illness/home-alone-and-sick/

DEHYDRATION When you're sick with vomiting, diarrhea, or a fever, you're at risk of dehydration, and who wants to be dehydrated (not you, I'm sure)!? So, make sure to drink plenty of sugar-free fluids, avoid caffeine since that can make dehydration worse, and try eating a ½ cup of applesauce, Jell-O, or a popsicle to prevent low blood sugar.

See this Diabetes Canada resource for suggestions of what to drink and eat to prevent dehydration:
https://www.diabetes.ca/diabetescanadawebsite/media/managing-my-diabetes/tools%20and%20resources/stay-safe-when-you-have-diabetes-and-sick-or-at-risk-of-dehydration.pdf?ext=.pdf

TELL A FRIEND If you're not feeling well, make sure to let someone know! That way, you can get rest without worry, knowing you have a friend or family member who can check in on you and help you out if you need it

Hypoglycemia

LOW BLOOD SUGAR Do you know what your symptoms of low blood sugar are? These symptoms can show up in different ways for different people! So when you're feeling like you have low BG, check your sugars and treat your symptoms as quickly as possible!

For a refresher on the signs of low blood sugar, check out this link:
https://www.diabetes.ca/DiabetesCanadaWebsite/media/Managing-My-Diabetes/Tools%20and%20Resources/hypoglycemia-low-blood-sugar-in-adults.pdf?ext=.pdf

FEAR OF HYPO It's totally normal to be afraid of having low blood sugar - especially at night. As with many complex situations, remember that there are things you can do to prevent low blood sugar and manage it when it happens! If you're feeling stressed about your lows and want to make a plan to support you, reach out to your diabetes care team - they're there to help!

Drugs and Alcohol

DRINKING SAFELY Remember not to drink alcohol on an empty stomach! Make sure to eat something with slow-acting carbs before drinking to prevent low blood sugar, and have a snack before bed. *http://www.bcchildrens.ca/endocrinology-diabetes-site/documents/alcohol.pdf*

DRINKING SAFELY When you're drinking, make sure to carry diabetes identification and tell at least 1 person who is drinking with you about your diabetes and how they can help if your blood sugar goes low #teamwork

ALCOHOL LOWS Alcohol induced lows can be different from other lows. Some funky stuff that happens when drinking is that low BG can happen right away, or up to 12 hours after drinking. Your symptoms might be different (it may just feel like you're drunk) and glucagon might not work as well.

SO it's important to check your blood sugar not only while you drink but after you drink, before you go to sleep, and in the morning too! And make sure to have your glucose meter, glucose tabs, and a snack for lows handy.

Travel

TIME ZONES When travelling, stick to your original time zone while in transit, and change your clocks to the time of your destination when you arrive.

If you're travelling through more than 5 time zones, you'll probably have to adjust your insulin (you'll usually need more if travelling west ← and less if travelling east → so it's a good idea to chat with your doctor about making changes to your medication dosage or schedule before you leave for your trip!

TRAVELLING To make sure you can enjoy a stress-free trip, pack lots of extra supplies! It's good to have extra glucose meters, batteries, pumps and infusions sets, insulin and syringes (in case your pump malfunctions), and medications on hand, just in case.

You might even want to split your supplies between two bags, in case one gets lost or stolen!

SECURITY Don't worry - people living with T1D are allowed to carry medical supplies (including emergency juice above the liquid limit) with them when travelling through security! Pumps and CGMs should NOT go through an x-ray machine or body scanner, so you can ask to walk through a regular metal detector or get a pat-down instead.

You can get your doctor to provide you with a letter like this one to make the process of getting through security with your diabetes supplies smoother: *https://www.diabete.qc.ca/wp-content/uploads/2019/04/Voyage-lettreMD-Anglaisdocx-5.pdf*