

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

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To cite: Sanmugalingham G, Mok E, Cafazzo JA, *et al.* Text message-based intervention, Keeping in Touch (KiT), to support youth as they transition to adult type 1 diabetes care: a protocol for a multisite randomised controlled superiority trial. *BMJ Open* 2023;**13**:e071396. doi:10.1136/bmjopen-2022-071396

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-071396>).

MN and RS are joint senior authors.

Received 28 December 2022
Accepted 18 April 2023



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ABSTRACT

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

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

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

STRENGTHS AND LIMITATIONS OF THIS STUDY

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

Trial registration number NCT05434754.

INTRODUCTION

Type 1 diabetes (T1D) is one of the most common chronic diseases of childhood, with significant morbidity and mortality.^{1 2} Maintaining optimal blood glucose levels prevents and delays long-term diabetes complications³; however, in-target glucose management is particularly challenging during adolescence and early adulthood alongside a myriad of emotional, physical, financial, occupational and social changes.^{4–6} In Quebec and Ontario, Canada, adolescents transfer to adult health-care at approximately the age of 18 years.

There is also an increased risk of gaps in routine diabetes care as well as diabetes-related hospitalisations and emergency department visits during this time,^{7,8} which may be due, in part, to deficiencies in transition care preparation.^{9–12} Interventions to improve the transition from paediatric to adult T1D care are reported to improve clinic attendance, diabetes distress and satisfaction with care,^{13–16} however, many interventions are limited by cost, scalability and generalisability.

Two reviews of mobile phone technology, one to support adolescents with T1D and one to support the transition to adult care for all chronic conditions and for liver transplant recipients specifically, suggest that this technology can facilitate the delivery of educational material as well as encourage self-management and independence. However, the outcomes measured in these studies were varied (ie, haemoglobin A1c (HbA1c), quality of life and self-efficacy) and results were mixed.^{17,18} These promising digital interventions may fail to engage youth across the transition period because they lack a personalised approach which precludes the ability to tailor content specific to an individual's particular needs, stage of transition readiness or personal interests.¹⁹ To date, most text message studies have described the use of simple reminders for self-care.²⁰ Text message-based interventions that rely on a healthcare provider to respond to messages are limited in their scalability.²¹

Nevertheless, general transition support delivered via text message is considered an engaging, acceptable, accessible and cost-effective option.²¹ To address these limitations, together with youth, including adolescents and emerging adults living with T1D, and paediatric and adult T1D providers, we co-designed an automated text message-based intervention called Keeping in Touch (KiT) to deliver tailored T1D transition support messages in response to participants' self-reported confidence and interest in transition preparation topics. We hypothesise that compared with usual care, youth who use KiT for 12 months starting within 4 months before their final paediatric visit will have improved diabetes self-efficacy 12 months after enrolment.

Objectives

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

METHODS AND ANALYSIS

Study design

We will conduct a multisite, parallel-group, two-arm, 1:1 allocation ratio, superiority randomised controlled trial (RCT). Our protocol adheres to the Standard Protocol Items for Randomised Trials (SPIRIT) statement. Considering the healthcare payer perspective, we will perform a descriptive cost analysis of the KiT implementation following Canada's Drug and Health Technology Agency (CADTH) guidelines and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.^{22,23}

Study setting

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

Inclusion criteria

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

Exclusion criteria

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

Intervention

The KiT algorithm is designed and programmed to send tailored T1D-related text messages at participant-determined frequencies over a 12-month intervention period. In a previous study, we scoped the needs of youth transitioning to adult care. In brief, we conducted interviews and co-design sessions with adolescents and young adults living with T1D and T1D care providers to determine how to optimally deliver transition support via text messages. Interview data analysis was grounded within

Table 1 KiT functions and example text messages

Feature category	Intervention feature	Sample dialogue
Personalised T1D educational messages	<ul style="list-style-type: none"> ▶ Participants will receive multiple messages each month about a different T1D transition topic. ▶ Topics will be selected based on the participant's responses to a transition readiness assessment administered at baseline and topics of their choice. 	KiT: When you travel—be sure to pack LOTS of extra supplies for a stress-free trip! You can pack extra: glucose metres, batteries, pumps and infusion sets (some pump companies will give you a travel loaner pump for free!), insulin and syringes (in case your pump malfunctions), test strips and medications. It's good to have these on hand, just in case. This video is a great example of some things you might want to (over) pack (link to TikTok video)
Care coordination	<ul style="list-style-type: none"> ▶ Reminders about upcoming appointments. ▶ Reminders to complete lab tests before upcoming appointments (if applicable). ▶ Information about participant's adult clinic (if available). ▶ Tips about how to prepare for the first adult visit. ▶ Participants can store their own notes, which they can access any time and will be sent back to the participant automatically before an upcoming clinic visit. 	KiT: Hello! Do you know when your next appointment is? User: It is on 27 September 2022 at 14:00 hours KiT: Perfect, I'll send you a reminder the week before so you don't forget!
Question and answer	<ul style="list-style-type: none"> ▶ Participant can text KiT T1D-related questions and receive messages in return from a validated bank of resources. 	User: How can I adjust my insulin so I don't go low when I exercise? KiT: Thanks for asking! Hopefully this resource about insulin and exercise from ExCarbs answers your question (link to resource website)

KiT, Keeping in Touch; T1D, type 1 diabetes.

the socioecological model and analysed using a thematic content approach.^{24 25} KiT features, content topics and message formats were selected based on the themes and ideas that emerged in the co-design workshops and are supported in the literature. We validated and refined these through member-checking in co-design workshops.

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

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

transitioning to adult care.²⁷ A list of education content topics is available in box 1.

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

Box 1 T1D related-transition educational content topics

Topics delivered to all participants in the intervention group

Coping with T1D
 Care navigation
 Sick day and ketone management
 Medical insurance

Topics delivered based on participants' self-reported confidence and interest

Hypoglycaemia
 Pumps and programming
 Insulin adjustments
 Drugs and alcohol
 Travel
 Driving
 T1D accommodations for school and work
 Exercise
 Nutrition and carbohydrates
 Sexual health

3. Question and answer: participants can send text messages asking KiT about topics related to T1D care at any time during the intervention. KiT will match keywords in the question to trusted resources identified in the environmental scan of online educational resources and reply to participants with a text message and a link to a relevant T1D transition resource, if available. Participants randomised to the control arm will receive usual diabetes transition care and text messages from KiT containing links to the outcome surveys over 12 months.

Recruitment

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

Randomisation

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

Data collection

At the time of enrolment, research coordinators will collect each participant's postal code to be linked to an area-based validated material and social deprivation index as a measure of socioeconomic status.^{28 29} The coordinator will also collect the most recent HbA1c result (either laboratory or point-of-care) from the health record to measure baseline glycaemic management. There is a standardised method for measuring HbA1c.³⁰ All participants, in both arms, will receive a text message at the time of enrolment, 6 months and at 12 months containing a link to REDCap surveys for assessment of outcomes. The surveys include a participant information survey, which will collect sociodemographic and diabetes-related healthcare information (online supplemental table 1), and three patient-reported outcome measures.

Text-message records between KiT and participants will be saved on a secure encrypted server at Memotext. We will also collect participants' provincial health insurance numbers to link to provincial administrative datasets housed at ICES in Ontario and Régie de l'assurance maladie du Québec (RAMQ) in Quebec. Site coordinators will assign unique study IDs for each participant. Each study ID will be linked to a unique survey code. All survey

responses are collected and securely stored in REDCap. [Table 2](#) shows the primary and secondary outcomes and when they are each collected.

Outcomes

Primary outcome

The primary outcome is patient-reported diabetes self-efficacy at 12 months measured using the Self-Efficacy for Diabetes Self-Management (SEDM) scale. Self-efficacy measures a person's belief that they can carry out a behaviour in a particular situation.³¹ Self-efficacy is associated with health-related outcomes.³² The SEDM scale has been validated in adolescents with T1D and found to be associated with diabetes self-management and glycaemic management in older adolescents.³³

Secondary outcomes

Secondary outcomes will be measured at baseline, 6 months and 12 months. [Table 2](#) lists all the outcomes, the data source, and when they will be collected.

1. Diabetes self-efficacy
2. Transition readiness
3. Diabetes-related stigma
4. Glycaemic management
5. The time between the final paediatric and first adult diabetes visits (calculated from the self-reported date of the final paediatric and first adult visit)
6. Diabetes-related hospitalisations and emergency department visits
7. Cost of implementation (aggregate cost of implementation and cost per participant)

Patient-reported outcomes

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

We will measure transition readiness using the Readiness Assessment of Emerging Adults with Type 1 Diabetes Diagnosed in Youth (READDY) tool.²⁶ READDY is a transition readiness assessment for emerging adults with diabetes that asks about self-reported confidence in five domains: diabetes knowledge, health system navigation, insulin self-management, health behaviours and insulin pump skills (optional). Diabetes-related stigma will be measured using the Barriers to Diabetes Adherence in Adolescence (BDA) questionnaire Stigma subscale.³⁴ Additional details about the patient-reported outcome measures are presented in [table 3](#).

Glycaemic management

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

Table 2 Primary and secondary outcomes and time of collection

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

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

Diabetes-related hospitalisations and emergency department visits

We will securely link participants' provincial health card numbers to provincial administrative databases housed

at ICES in Ontario and Med-Echo and Régie de l'assurance maladie du Québec (RAMQ) in Quebec. We will measure all diabetes-related hospitalisations and emergency department visits during the 12 months before enrolment in the study and for 12 months after enrolment. In Ontario, we will ascertain all diabetes-related

Table 3 Description of the patient-reported outcome measures

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

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

Cost of implementation

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

Sample size

Assuming a SD of 1.6 for the self-efficacy score³³ and 6 degrees of freedom for adjustment (1 for HbA1c, 1 for the baseline value of the outcome variable and 4 for the 5 quintiles of deprivation), we require a total sample size of 183 participants to have 80% power with $\alpha=0.05$, allowing for 20% dropout. This assumes that the covariates used for adjustment explain 10% of the variation in the outcome. Given the absence of published data to inform this quantity, we have opted to be conservative and assume a low R^2 , which will require a larger sample size rather than assuming a high value of R^2 .

Statistical analysis

We will conduct an intention-to-treat analysis. We will conduct a secondary as-treated analysis including participants who engaged with KiT (did not have any message delivery failures) stratified by engagement level. Engagement level will be defined according to the intervention usage data during the 12-month intervention period; this approach has been used in prior studies.³⁵

We will compare the primary outcome, diabetes self-efficacy score at 12 months, between groups. This will be done using analysis of covariance (ANCOVA) to compare the effect of the intervention between arms. We will include the following covariates: intervention arm, baseline diabetes self-efficacy score (to reduce possible residual imbalance between groups), baseline HbA1c

(known to be associated with diabetes self-efficacy),³³ and material deprivation quintile (socioeconomic status is known to be associated with T1D care and outcomes).³⁶ To compare secondary outcomes between arms at 6 and 12 months, we will use ANCOVA and logistic regression models for continuous and binary outcomes respectively. We will include the following covariates in each of these models: intervention arm, the baseline measure of the outcome of interest (if measured and when the outcome is continuous), baseline HbA1c and material deprivation. We will conduct a secondary analysis to calculate within-arm differences in outcomes at baseline, 6 months and 12 months. For the within-arm analyses, we will use the appropriate paired test (either the paired t-test or McNemar's test) to account for the repeated measurements on each subject.

For the descriptive cost analysis of the KiT implementation, we will calculate the aggregate cost of implementation and cost per participant. The costs will be reported in 2024 Canadian Dollars, adjusted for inflation using the Bank of Canada inflation calculator.³⁷ When relevant, we will consider a 1.5% discount rate for cost and health outcomes per the Canadian Guidelines for Economic Evaluations.

Harms

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

Patient and public involvement

The KiT intervention was created by a co-design process including people living with T1D and T1D providers.³⁸ Our research team also includes a patient partner (co-principal investigator) who contributed to the study design and will continue to provide input during the implementation and evaluation phases of the RCT.

Data management

All participants will be assigned a study ID number. Only study team members can access the code linking the participant's name to the study file. On randomisation, the research coordinator will securely send Memotext the randomised participant study ID, randomisation arm and mobile phone number. KiT will send a text message to the participant's mobile phone introducing them to the study and send links to complete the study surveys on SickKids external REDCap (for both arms). The REDCap Application Programming Interface integration enables SickKids REDCap servers to deploy chatbot links for

REDCap surveys. User engagement data will be stored on the secure servers of Memotext, located in Toronto. Memotext collects and uses data in accordance with all applicable laws and PIPEDA and HIPAA.

DISCUSSION

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

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

ETHICS AND DISSEMINATION

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

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

Consortium (CAPACity) to explore opportunities to scale and expand its use.

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Acknowledgements We would like to acknowledge Noor El-Dassouki, Research Associate, UHN for her contribution to the development of KiT and editing the manuscript.

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

Funding This work was supported by a Canadian Institutes of Health Research (CIHR) Team grant: Transitions in Care. Application number 423967.

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

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

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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