

Title: Dynamically Tailoring Interventions for Problem-Solving in Diabetes Self-Management Using Self-Monitoring Data - a Randomized Controlled Trial (RCT)

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**COLUMBIA UNIVERSITY
CLINICAL DIRECTORS NETWORK**

Dynamically Tailoring Interventions for Problem-Solving in Diabetes Self-Management Using Self-Monitoring Data

Project Protocol

A. STUDY PURPOSE AND RATIONALE

In this project, we will evaluate the efficacy of a novel approach to personalizing behavioral interventions for self-management of type 2 diabetes (T2DM) to individuals' behavioral and glycemic profiles discovered using computational learning and self-monitoring data. Growing evidence highlights significant differences in glycemic function (1) and cultural, social, and economical circumstances of individuals with type 2 diabetes (T2DM) that impact their self-management (2). Precision medicine strives to personalize medical treatment to an individual's genetic makeup (3), computationally discovered clinical phenotypes (4), (5),(6) and lifestyle (7). Studies showed the benefits of tailoring not only medical treatment, but also behavioral interventions (8),(9),(10). Yet, currently, personalization of self-management in T2DM requires each individual to engage in discovery, reflection, and problem-solving—critical but cognitively demanding activities (11),(12)—or to rely on their healthcare providers. Both of these may present considerable barriers to individuals from medically underserved low income communities (13),(14). mHealth solutions in T2DM bring promise of reaching wider populations in need of self-management; however, few such solutions provide assistance with personalizing self-management behaviors. Ongoing efforts on personalizing behavioral interventions outside of T2DM focus on tailoring behavior modification techniques to individuals' psycho-social characteristics, such as self-efficacy (15), and tailoring delivery of intervention to individuals' context (16) rather than on personalizing self-management strategies.

The ongoing focus of this research is on developing informatics interventions for diabetes self-management, with a specific focus on discovery with self-monitoring data (11) and on problem-solving for improving glycemic control (17). In our previous research (R01DK090372), we developed and evaluated an informatics intervention, Mobile Diabetes Detective (MoDD) that helped individuals with T2DM identify personal problems related to glycemic control and select appropriate self-management strategies (17),(18). However, MoDD required that individuals select self-management strategies from a generic list developed by diabetes educators (18); many trial participants found this step to be both tedious and overwhelming. In the proposed research we introduce T2 Coach, an mHealth intervention that uses computational analysis of self-monitoring data to identify behavioral patterns associated with poor glycemic control and formulate personalized behavioral goals for changing problematic behaviors. *In our preliminary work (R56DK113189) we have completed the development of T2 Coach and demonstrated that 1) computational phenotyping methods can accurately identify systematic associations between individuals' activities and changes in blood glucose (BG) levels; 2) these patterns can be automatically translated into behavioral goals formulated in natural language consistent with that used by diabetes experts, and 3) individuals with T2DM can understand and follow these automatically generated*

behavioral goals. A pilot study of T2 Coach with 20 individuals with T2DM from medically underserved communities showed that it was feasible, acceptable, and led to sustained user engagement over 4 weeks.

The proposed research will evaluate T2 Coach's efficacy in a two-arm RCT with stratified randomization conducted with Clinical Directors Network (CDN), a well-recognized primary care practice-based research network (PBRN) of Federally Qualified Health Centers (FQHCs), and AHRQ-designated Center of Excellence (P30) for Practice-based Research and Learning.

The specific aims of this proposal are:

AIM 1: To further enhance the design of T2 Coach with multi-media educational modules. To address findings of T2 Coach pilot study, we will create a set of multi-media educational modules on diabetes self-management and nutrition and make them available from T2 Coach app and website.

AIM 2: Using a two-arm RCT with 1:1 randomization at participant level, with stratified randomization to balance by clinical site, sex, and language, evaluate the efficacy of the T2 Coach intervention. We hypothesize that the intervention group (T2 Coach with usual care) will show the following improvements at 6 months and 12 months compared to the control group (usual care):

- H1. (Primary) Improvement in individuals' glycemic control (reduction in HbA1c) at 6 months.
- H2. (Secondary) Improvement in individuals' self-care behaviors (Diabetes Self-Care Inventory (SCA-I)), self-efficacy (Diabetes Self-Efficacy, DSE), and in emotional aspects of living with diabetes (Problem Areas in Diabetes, PAID).
- H3. (Exploratory) Decrease in individuals' Cardiovascular Risk (Body Mass Index, Blood Pressure and Total, LDL and HDL Cholesterol and triglyceride levels and Framingham Cardiovascular Risk Score).

B. RESEARCH QUESTIONS AND HYPOTHESES

This project is expected to last 5 years and will include two separate phases corresponding to the two aims, each with a new set of objective and research activities.

Aim 1: Enhancing the design of T2 Coach with educational modules and text messaging

The specific research questions of Aim 1 include:

- 1. What nutritional and diabetes education is necessary and sufficient for individuals to be able to understand and follow personalized behavioral goals generated by T2 Coach?
- 2. What approach to the design of educational modules can help to deliver the necessary education in an effective and efficient way?
- 3. What improvements are needed to the design of T2 Coach to ensure its usefulness and usability for the intended user population?

Aim 2: Randomized Controlled Trial

The specific research hypotheses of Aim 2 include:

- H1. (Primary) Improvement in individuals' glycemic control (reduction in HbA1c) at 6 months.
- H2. (Secondary) Improvement in individuals' self-care behaviors (Diabetes Self-Care Inventory (SCA-I)), self-efficacy (Diabetes Self-Efficacy, DSE), and in emotional aspects of living with diabetes (Problem Areas in Diabetes, PAID).
- H3. (Exploratory) Decrease in individuals' Cardiovascular Risk (Body Mass Index, Blood Pressure and Total, LDL and HDL Cholesterol and triglyceride levels and Framingham Cardiovascular Risk

Score).

C. STUDY DESIGN AND PROCEDURES

C1. AIM 1: User-centered design of educational modules and refinement of T2 Coach

The overall goal of Aim 1 is to refine the design of the informatics intervention for self-management of type 2 diabetes T2 Coach, developed in our previous research. Specifically, we plan to enhance its design with a number of educational modules and illustrative materials that can help participants to understand personalized goals and incorporate these goals into their daily behaviors. Below we describe the current design of T2 Coach and the proposed activities for enhancing and improving its design. The proposed user-centered design and feedback activities will be conducted with Certified Diabetes Educators and/or health educators and patients with T2DM recruited from two Federally Qualified Health Centers (FQHCs), members of the Clinical Directors Network (a subcontractor in this research project) in the Metropolitan New York Area; The proposed research will include the following activities. The participants will be asked to participate in any number of the activities 1-4 below. We will recruit a new set of participants for activity 5. Pilot Study 2.

1. *User-Centered Design Workshops*
2. *Controlled Lab Study*
3. *Usability Study*
4. *Pilot study 1 (partially implemented T2 Coach)*
5. *Pilot Study 2 (fully implemented T2 Coach)*

T2 Coach Design

T2 Coach is a smartphone app developed using Ionic framework that allows for cross-platform smartphone development; as a result, T2 Coach is available for both iOS and Android. T2 Coach includes a custom interface for low-burden capture of diet and BG levels. To capture *diet*, T2 Coach's smartphone app allows individuals to take pictures of their meals and provide brief textual descriptions. T2 Coach then utilizes crowdsourcing—an approach to solving complex problems by aggregating the solution across a large number of untrained individuals—to obtain nutritional composition of each meal (inclusion of carbohydrate, fiber, protein, and fat and total calories in the meal). Specifically, T2 Coach uses a crowdsourcing workflow developed by researchers at Harvard University, PlateMate (19) to submit meals and their descriptions to a popular crowdsourcing workplace, Amazon Mechanical Turk. PlateMate validation studies showed that nutritional assessments generated using this workflow are comparable with gold standards generated by professional dietitians (20)(19). To capture *physical activity and sleep* T2 Coach uses a commercial activity tracker FitBit. While there exist valid concerns regarding accuracy of measures captured with FitBit, previous studies of FitBit suggested it is a reasonable alternative to the more accurate, but also considerably more expensive ActiGraph tracker (21),(22). Moreover, our own previous studies using FitBit showed high levels of adherence with wearing the tracker and uploading the data: during a 3-month study with 10 participants, they recorded FitBit step counts data on 82% of the days and sleep data on close to 70% of the nights. Using FitBit data, T2 Coach records activity as a number of steps within the 24h time interval; it uses individuals' meal and BG records to label step intervals in relation to meals and BG levels (e.g. 1-hour before breakfast). For sleep, T2 Coach uses FitBit's record of the number of hours slept, as well as quality of sleep. Relevant biomarkers include *BG levels* captured at different times of day and with varying frequency using commercial BG meters and entered using T2 Coach interface. All captured data are sent to the *computational inference engine* on the T2 Coach HIPAA-protected server that uses machine learning methods to identify individuals' behavioral-glycemic phenotypes that link different behaviors and changes in BG levels. These phenotypes are then sent to the T2 Coach *expert system* to formulate personalized behavioral goals that are displayed to individuals within T2 Coach smartphone app. Examples of behavioral goals include the following: "For high carbohydrate breakfasts, reduce your carbs to be about 1 carb choice. Examples of 1 carb

choice are 1 slice of whole wheat toast, 1 cup of oatmeal, or 1 apple.” Notably, all behavioral goals generated by T2 Coach during this study will be first sent for review to CDEs on our research team to ensure their clinical soundness.

The T2 Coach *smart phone app* helps individuals to keep track and review past history of their behaviors (e.g., meals and blood glucose levels), review personalized goals (Figure 2-a), and choose personalized goals that are consistent with their own preferences. Notably, when showing individuals personalized goals related to nutrition, T2 Coach includes examples of individuals’ own meals that are consistent with their selected goals (see Figure 2-a) as well as tips for incorporating these goals into their daily activities. This helps to ensure that T2 Coach delivers support that is adapted to each individual’s cultural and ethnic orientation; any specific dietary preferences and constraints will be reflected in these examples selected from their own past meals. Once an individual sets goals, T2 Coach reminds them about their goals using in-app notifications and/or text messages. Further, T2 Coach helps them track their progress towards these goals. For example, to track nutritional goals, each time an individual records a meal, T2 Coach asks if their new meal meets their established goals (see Figure 4, b-d), thus providing a subtle encouragement to change meals that do not meet their nutritional goals. For goals related to passively recorded physical activity and sleep, progress is tracked automatically using FitBit. Finally, T2 Coach shows the individual their progress towards their goals using color-coded progress indicators (Figure 2-e).

Because T2 Coach draws from an individual’s own past history to infer behavioral-glycemic phenotypes and formulate personalized goals, it requires that individuals collect an initial set of data before it can generate personalized behavioral goals. Moreover, because of its reliance on macronutrients, it cannot detect certain aspects of individuals’ diets, such as insufficient inclusion of fruits and vegetables. To address these challenges, T2 Coach includes a number of non-personalized, generic goals that target common insufficiencies in health behaviors among individuals with T2DM. An example of such goals includes: “Eat more fruits and/or vegetables: Cover at least half of your plate with colorful fruits and/or vegetables. For example, add a side of steamed broccoli, a side salad, or a cup of fruit to your meal.”

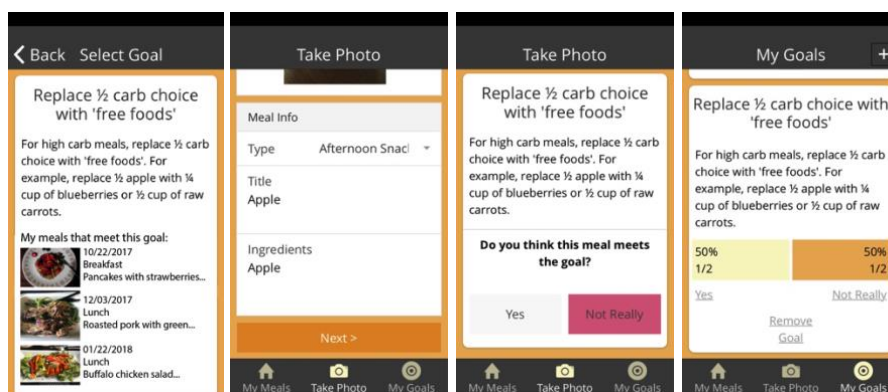


Figure 1: T2 Coach screenshots in a typical mealtime flow: a) choosing a personalized goal with examples, b) recording a meal (an apple), c) assessing a meal on fit with personalized goals (Not Really), d) monitoring progress towards goal achievement.

Our previous research suggested that while individuals recruited from economically underserved populations typically characterized by low literacy could understand personalized goals generated by T2 Coach, they experienced challenges selecting meals that met specific nutritional goals. To address this challenge, in the proposed work for Aim 1 we will rely on user-centered design methods to develop a set of contextual educational modules that help individuals acquire nutritional and other diabetes-related

knowledge necessary to understand the goals.

Companion Text Messaging

In addition to the graphical interface described above, T2 Coach uses interactive text messaging to maintain individuals' engagement with the intervention. All the text messages are automatically generated using a set of specified rules. There are several types of message sequences; each sequence includes several messages exchanged between the user and T2 Coach (we describe each sequence in further detail below). For each of these sequences, the users can set the time when they would like to initiate the sequence. The users can elect to disable text messaging capabilities at any time by texting "STOP":

1. Morning greeting/feedback on progress
2. Goal setting
3. Meal capture/reflection
4. Evening reflection

Morning greeting/feedback on progress

The goal of these messages is to set the mood for daily activities, remind participants of their set goals and action plans, and provide them with a brief motivational message. Below is an example of a morning greeting:

Good morning Mary! Today your plan is to add 2 slices of lean turkey breast to lunch meal. Remember, healthy meals give you the fuel that your body needs to keep you moving throughout the day. Have a great day!

In this message "add 2 slices of lean turkey breast to lunch meal" is an action plan previously selected by the user using the goal setting sequence, and "Remember, healthy meals give you the fuel that your body needs to keep you moving throughout the day. Have a great day!" is a motivational message tailored to the users' level of readiness for behavior change.

Goal setting

Goal setting sequences replicate goal setting capabilities of T2 Coach graphic interface for users who are less familiar with smart phone apps and lower computing literacy. Below is an example of a goal setting sequence. At the beginning of the study, the goals available for selection are generic, non-personalized goals developed by Certified Diabetes Educators, members of our research team. Later in the study, as participants collect more data, these goals are generated by the T2 Coach analytical engine using individuals' self-monitoring records. The sequence below illustrates the initial goal setting session, at the beginning of the study:

App: Hello Mary, welcome to T2 Coach study! Here you can set goals for improving your self-management and work on achieving these goals. What would you like to work on?

1. *Improve my diet*
2. *Increase physical activity*
3. *Improve my sleep*
4. *Improve my blood glucose levels (HbA1c)*

User: 1

App: Ok, you want to improve your diet. Here are a few things you could try to eat healthier and

improve your diabetes self-management. Choose one from the list below:

- 1. Drink more water*
- 2. Eat at least 1 serving of vegetables with every dinner*
- 3. Replace refined carbs with whole-grain carbs*
- 4. See more options*

User: 2

App: Okay, you chose the goal “Eat at least 1 serving of vegetables with every dinner”. Would you like to set this as your goal for the next week?

- 1. Yes, follow this goal*
- 2. No, go back*
- 3. Tell me more about this goal*

User: 1

App: Ok, your new goal is to “Eat at least 1 serving of vegetables with every dinner”. You can see this goal in your app. Here is what you can do today to achieve this goal. Which would you like to try?

- 1. Add a side salad to my dinner*
- 2. Add a serving of steamed broccoli to my dinner*
- 3. Add shredded carrots to my dinner*
- 4. See more options*

User: 2

App: Okay, would you like me to remind you to add a serving of steamed broccoli to dinner?

- 1. Yes, remind me before dinner tomorrow at 6pm*
- 2. Remind me at another time*
- 3. No, I don't want a reminder*

User: Yes

GluCoach: Ok, let me summarize: you chose to “Eat at least 1 serving of vegetables with every dinner”, and today you will try to “Add a serving of steamed broccoli to dinner”. I will remind you about it at 6pm. Have a great day!

Meal capture/reflection

This message sequence is meant to help individuals track their meals and blood glucose levels before and after meals and to remind them about their diet-related goals at the time of meals. Below is an example of the meal capture/reflection sequence after a user has selected a diet-related goal:

At 6:00 pm

App: It's almost dinnertime! Remember your plan to “Add a serving of steamed broccoli to dinner”. And don't forget to check your blood glucose before eating. When you are ready, chose one of the options

below:

1. Log dinner now
2. *Remind me in an hour*
3. *I don't want to log my dinner today, remind me tomorrow*

User: I

App: Use the camera button in the bottom left to record your meal

User: [photo of meal]

App: Can you describe what's in your meal?

User: Rice and beans with chicken

App: What was your blood sugar before dinner?

User: 159

App: Did you follow your plan to add a serving of steamed broccoli? (Y/N)

User: Yes

App: Great job Mary! Enjoy your dinner! I will remind you to check your post-dinner BG in 2 hours.

Capture post-meal BG (2 hours later)

App: Hi Mary, it's time to check your post-dinner BG. Just enter the number when you are ready.

User: 245

App: Ok, I recorded 245 at 8pm. If this is not correct, enter the number and/or the time.

App: This reading is lower than your previous average, great job improving your post-dinner blood glucose!

Evening reflection

App: Hi Mary! Nice job meeting your goal to "eat at least 1 serving of vegetables at every dinner". Do you want to try to "Add a serving of steamed broccoli to dinner" again tomorrow, or try something new?

1. *Keep the same plan for tomorrow*
2. *Try something else*

User: I

App: Okay, what time would you like me to remind you to add a serving of steamed broccoli to my

dinner?

1. Yes, remind me before dinner tomorrow at 6pm
2. Remind me at another time
3. No, I don't want a reminder

User: I

App: OK, I will remind you about it at 6pm. Have a great day!

Handling free-form inquiries and responses

Because T2 Coach is a fully automated system, it will only be able to respond to user messages that follow the predefined scripts and will not have the ability to understand and respond to free-form text. However, we anticipate that the participants may send free-form requests in messages. In case of user entries that are not recognized by the app, it will generate the following message (below). It will also alert the study personnel of an unrecognized message:

"I am sorry, I did not understand that. Please enter your answer again. If you have any questions, please contact your study coordinator. If this is a medical emergency, please contact your healthcare team or call 911."

Handling dangerous blood glucose levels

In case participants record blood glucose levels deemed dangerous by their healthcare providers (the upper and low levels will be established by each of the participating health center), the app will generate the following messages for the participant (below)–A member of the research team will centrally monitor the App and will inform the CDN project director of dangerous values. The CDN project director will subsequently contact the patient's primary care provider regarding the out of range value.

BG below low boundary (to be established by each participating health center):

"This reading is lower than safe levels. Drink a small glass of orange/apple juice and take your blood sugar reading again in 5 minutes. If your reading is still lower than [low boundary], please contact your doctor on call at: [phone number of the center]."

BG above high boundary (to be established by each participating health center):

"This reading is higher than safe levels. Please contact your doctor on call at: [phone number of the center]."

1. User-Centered Design Workshops (2 sessions)

In order to develop initial directions for the educational modules and other planned enhancements to T2 Coach, we will invite 30 individuals recruited from the 2 participating FQHCs to take part in user centered design activities. These will include participatory design sessions and will be conducted either individually or in focus groups, depending on participants' preferences. During the sessions, the participants will work with the researchers to create paper mockups of design features that will be later translated into improvements to T2 Coach interface. The sessions might include such activities as card sorting (when participants are asked to group cards with concepts into groups), labeling (when participants are asked to assign labels to areas of content), role-playing (when participants are asked to enact particular activities and their imagined interaction with the application), among others. The sessions will be audio recorded and transcribed verbatim for analysis.

Based on the user centered design activities described above, the research team will develop initial mockups of the educational modules. We envision these modules to take form of simple info-graphics (potentially combined with voice-over narrative), that can be accessed on demand either independently, or

after individuals reviewed their personalized goals, cover such concepts as macronutrient composition of different foods, portion sizes, etc. Further, we expect that these modules will be contextually adjusted based on the personalized goals; for example, if the goals focus on reducing carbohydrates, the educational modules will focus on carbohydrates and foods that contain them, and on estimating portion sizes for carbohydrates. We will then conduct another set of individual and group-based sessions to obtain feedback on these emerging mockups. During these sessions, the participants will be presented with storyboard and mockups, asked to engage in role-playing to imitate usage of the app in different contexts and scenarios, and then will be asked to provide their feedback. These sessions will also last up to 90 minutes each and will be audio recorded and transcribed verbatim for analysis.

Further we will conduct 1 focus group per FQHC with diabetes educators and dietitians, and other staff that deliver diabetes education and training (n=10).

Data Analysis:

All the materials collected during the described studies, including transcripts of audio recordings of participant interviews and focus groups will be analyzed using the Grounded Theory approach. The transcripts will be coded in open-coding phase for emergent themes using inductive, bottom-up coding approach thus allowing for themes to emerge from the data. In the subsequent axial coding, we will refine and consolidate emergent categories of findings to arrive at themes.

As a result of these activities we will finalize the design of T2 Coach and its educational modules. We will evaluate these final designs using a controlled lab experiment and a pilot study described below.

2. Controlled Lab Study

The goal of this controlled lab experiment is to assess participants' ability to understand personalized nutritional goals generated using T2 Coach, and enhanced with contextual multi-media educational modules, to identify meals that meet these nutritional goals, and to follow these goals in controlled settings.

In this controlled lab experiment, we will invite participants to review personalized behavioral goals generated by T2 Coach, combined with contextual education; the outcomes will focus on individuals' ability to understand goals and educational modules, and to follow specified behavioral goals.

This experiment will use a within-subjects design in which each participant will be exposed to all study conditions (with and without the intervention).

The experiment will include a number of phases, each focusing on a different research question above.

1. Baseline Assessment

- a. Type I Diabetes Nutrition Knowledge Survey (23), included in the attached documents
- b. The Newest Vital Sign (24), included in the attached documents

2. Goal Comprehension Task

The purpose of the goal comprehension task is to assess whether individuals can comprehend goals presented within T2 Coach, after reviewing both goals, and corresponding educational modules, and whether they can identify meals that meet these goals. We expect that of all behavioral goals, nutritional goals will present the most challenges and plan to focus on these goals in this experiment. In this task, the participants will be asked to review a number of nutritional goals (between 5 and 10); for each goal, the task will include a series of binary meal choices, where participants will be asked to choose the meal that best aligns with the goal. To establish a context for the task, the participants will receive the following prompt: "A close friend with diabetes has the following nutritional goal. Can you help them choose the meal that best meets their goal?"

3. Meal Choice Task (baseline)

The purpose of the meal choice task is to establish individuals' nutritional preferences without any

interventions. To achieve that, participants will be given a small collection of cut out and laminated food pictures. Each time the task is given, the images will be related to a particular meal (e.g. breakfast), and the ingredients will be coherently related to each other (e.g. fried eggs and toast). Importantly, there will be multiple images for the same food item with different portion sizes. For example, breakfast might include three images for toast (half a slice, one slice, and two slices), two images for eggs (one egg or two eggs), and two images for bacon. Participants will be asked to: “Put together the meal that you would like to eat for breakfast”

4. Meal Choices with Contextual Education

Finally, the participants will be asked to use a smartphone with T2 Coach enhanced with educational modules to repeat the meal choice task. In this phase, the individuals will first be asked to review and set several nutritional goals, and review corresponding educational modules. Then the participants will be asked again to assemble meals that fit selected goals. After that, the participants will have an option to change their assembled meal by adding, removing, or replacing components, until they arrive at the final version.

Data Analysis

Because the participants will be asked to compose meals by selecting from a specified set of options, it will be possible to unequivocally establish whether each of their selected meals matches its corresponding goal or not. Consequently, for tasks where participants choose the meals that best matches stated goals, we will establish the accuracy of their choices as a binary variable. We will use chi-square to compare this accuracy to the null hypothesis that they are making random guesses and are correct 50% of the time.

3. Usability Study

For these studies, we will recruit individuals with type 2 diabetes (N=30).. The first meeting will last 1 hour and will include brief training on the application and a usability study. During the usability study, the participants will be asked to perform a number of tasks using T2 Coach, including viewing and selecting a goal, recording a meal and assessing it on its fit with selected goals, and reviewing progress towards selected goals. The session will be audio recorded for subsequent analysis. During the session, the observer will note any instances when the participants experience difficulties completing tasks and corresponding usability violations.

4. Pilot study 1 (partially implemented T2 Coach)

In addition to the usability study, we will recruit participants for a pilot study to explore newly developed features of the T2 Coach application. For these studies, we will recruit participants who own and use a smartphone. These participants will receive test strips and data plan in the same way as the RCT participants, but will not be provided with smartphones (see Section O. Compensation to Subjects below). In this study, we assign participants to one of the two groups described below and then compare their experiences between groups.

Group 1: Simulated functionality

In this study, the participants (N=10) will be asked to use an early prototype of T2 Coach application updated based on the findings of the previous user-centered design activities. This version of T2 Coach will include the same smartphone app as described above; however, text messaging will be simulated by a member of our research team (playing a role of a “wizard” in a “Wizard of Oz” study design). Wizard of Oz is a common prototyping technique in user-centered design that allows designers to obtain feedback on partially implemented features before their implementation is completed and while there is still an opportunity to modify the design. In this study, the wizard will follow a predefined script (as described above), responding to user messages in a way that simulates T2 Coach’s planned functionality. The participants will be informed that the app they will use in the study is a prototype with only partially implemented features, and that a member of the research team will be reviewing their requests, and

helping the app to respond appropriately.

After the 2-week study, participants will be invited for a 1-hour meeting to discuss their experiences with the application (see Post-Pilot Interview Guide).

Group 2: Augmenting T2 Coach with a human coach

While T2 Coach aims to facilitate improved diabetes self-management via a set of messaging dialogs that attempt to replicate human coaching, this fully scripted and automated approach may be missing some important aspects that facilitate effective in-person coaching. To this end, we will conduct a study to examine the experience of using the T2 Coach application, augmented with human experts.

In this pilot study, participants (N=10) recruited from the same population as prior phases will be asked to return for a 2-week study. The framing and procedure will be similar to Pilot Study 1, described above, but in this case the “wizards” will be certified diabetes educators who are members of the research team. These expert coaches will follow the same overall dialog structure as the T2 Coach application, but will also have the flexibility to respond to user requests based on their expertise and training as coaches.

After the 2-week study, participants will be invited for a 1-hour meeting to discuss their experiences with the application (see Post-Pilot Interview Guide).

5. Pilot Study 2 (fully implemented T2 Coach)

Finally, after completing the implementation of all the features of T2 Coach, we will conduct another pilot study with n=10 participants who did not participate in any of the previous activities. In this study the participants will be asked to use the fully implemented version T2 Coach for 2 weeks. The study will be followed by a qualitative interview to assess their experiences and identify any remaining design issues and limitations.

Data Analysis

The usability study records will be analyzed by experts in human factors and usability on captured usability violations. These will then be translated into recommendations for changing T2 Coach features.

The results of the post-pilot interview will be analyzed using thematic analysis as described above.

C2. RANDOMIZED CONTROLLED TRIAL of T2 Coach

We will conduct a two arm randomized controlled trial with n=280 participants recruited from the participating FQHCs. The participants will be randomly assigned to the intervention group and the usual care (control) group with 1-1 allocation ratio. Stratified randomization procedures will be used to ensure that the intervention and control groups are balanced by FQHC site and other variables detailed below. Stratified randomization is a two-stage procedure in which patients are first grouped into strata according to some variables that may influence outcomes. With each stratum, patients are randomly assigned to the intervention and the control groups. In this study, we will stratify patients by FQHC site, sex, and language (English and Spanish). We stratify by site because large differences in effect size across sites observed during the MoDD RCT; by sex because previous literature suggests differences in diabetes self-management between sexes (25), and by language to account for possible cultural differences between individuals from different language groups (26). Half of the participants (n=140) will be randomly assigned to a usual care (control) group. Both groups will receive standard diabetes education at their respective FQHC site. In addition, the experimental group will receive instructions to use T2 Coach for a minimum of 6 months (Figure 7). During this 6-month period, we will provide the participants in both the usual care (control) and experimental groups with free test strips for their blood glucose meters. This will help to remove the financial barrier for uninsured study participants. After the 6-month active intervention period, the participants in the experimental arm will be offered an option to continue using T2 Coach until the final 12-month milestone. We will discontinue the glucose test strip supply to assess the feasibility of T2 Coach adoption in ecologically valid settings, and in the context of the current economic healthcare

models.

Study visits and milestones.

This study will include 5 study visits/milestone. In response to COVID-19, study visits will be conducted either in-person at the site or remotely, based on city and state regulations and each FQHC's preference.

The study visits/milestones are as follows: 1) consent/screening visit; 2) baseline assessment visit, 3) intervention training visit (intervention group only), 4) 6-months follow up; 5) 12-months follow-up.

1. Consent/Screening visit. Each participant will be asked to provide consent to participate using one of the strategies delineated below in the Recruitment Section.

2. Baseline assessment visit. During this visit, the Recruitment Coordinator will administer a series of questionnaires and collect other assessment measures (see section F. Study Questionnaires and Measures below). The participants will be able to choose questionnaires in their preferred language. After this visit study personnel will extract relevant assessment measures from the Electronic Health Record of their FQHC (see section F).

3. Intervention training visit (intervention group only). All participants in the intervention group will receive individual training on use of T2 Coach. The intervention training visit will be done either on-site at the FQHC or remotely.

3.1. On-site intervention training visits: The duration of the training is 1 hour. To ensure consistency in training delivery, it will be recorded as a video presentation that would walk the participants through the different features of the app with a voice-over narration. To ensure retention, we will use "teach-back": The participants will be asked to teach study staff how to use the app. In addition, all participants will be provided with a user guide and with a phone number of study coordinators in case they need additional assistance in the use of the app.

3.2 Remote intervention training visit: to ensure high quality of the intervention training, the participants will be asked to download a HIPAA compliant zoom application (or a similar HIPAA compliant application that allows for screen sharing) from the app store (or google play). During this session, they will be provided with a link to a video tutorial and asked to watch the tutorial. After finishing the tutorial, they will be provided with a link to a password-protected zoom call and asked to join a call without using audio and to share their phone screen. A member of the research team will ask the participants to engage with T2 Coach and follow a set of steps for setting goals, while observing the participants' screen; this will enable researchers to provide assistance when necessary.

4. 6-months follow up. During this visit, the participants will complete the questionnaires, and other assessment measures. Specifically, at that time, that participants will be encouraged to capture their HbA1c needed for their regular diabetes care.

5. 12-months follow up. During this visit, the participants will be once again complete the questionnaires, and capture other assessment measures. Similarly to the 6-months follow-up, at this time the participants will be encouraged to capture their Hb1Ac as part of their regular diabetes care.

6. Optional qualitative interviews: we will invite participants in the intervention arm to take part in 1-hour qualitative interviews. Participants who have completed 6-months follow-up will be eligible to participate. Further, we will conduct a similar set of interviews after 12-month follow-up. We expect to

recruit n=30 participants for these interviews.

D. STUDY DRUGS

N/A

E. MEDICAL DEVICES

N/A

F. STUDY QUESTIONNAIRES AND MEASUREMENT

F1. Measures for Aim 1

This study will include the following measures, available in both English and Spanish. The participants will be free to choose the language they are most comfortable with.

1. Type I Diabetes Nutrition Knowledge Survey (23), attached
2. The Newest Vital Sign (24), attached
3. Formative study interview guide, attached
4. Post-pilot study interview guide, attached

F2. Measures for Aim 2

Measures. Study measures for Aim 2 are summarized in Table 2. We selected surveys that were validated in both English and Spanish. Research Associates will administer the study questionnaires in English or Spanish and data will be directly entered in the study database. In response to the COVID-19 pandemic,

assessments will be conducted in-person, on-site at the participating FQHC or remotely.

Data/Variables	Method of Assessment/Measurement	T ⁰	T ⁶	T ¹²
Demographics	Demographics survey (Appendix E)	■		
Mobile Device Proficiency	Mobile Device Proficiency Questionnaire (MDPQ-16) (27): a 12-item 5-point Likert scale. Final score ranges 6-30 with lower scores=lower levels of proficiency.	■		
Current and past medical history, medications (including insulin therapy)	Collected at baseline from patient chart and by study personnel (Research Associate (RA)).	■	■	■
HbA1c	Extracted from EHRs. The RA will make sure that the HbA1c measures are taken at times that align with study visits (and consistently with clinical guidelines).	■	■	■
Fasting blood glucose	Extracted from patient chart	■	■	■
Random blood glucose	Collected from patient glucometer (or self- reported by patients over the phone during remote visits)	■	■	■
Lipid panel	Extracted from patient chart	■		■
BP	Extracted from patient chart	■	■	■
Height	Extracted from patient chart	■		
Weight	Extracted from patient chart	■	■	■
BMI (BMI)	Calculated	■	■	■
Diabetes Self-Efficacy	Diabetes Self-Efficacy Scale, DSES (28): 15-item 10-point Likert scale (1- not at all confident; 4- totally confident) measures the belief that one can self-manage one's own health, adapted to diabetes. Final score 1-4, lower score = poorer self-efficacy.	■	■	■
Emotional Aspects of Living with Diabetes	Problem Areas in Diabetes Scale, PAID, (29): 20-item 5-point Likert scale (0-not a problem; 4-very serious problem) measures the emotional aspect of living with diabetes (alpha = 0.96). Final score 0-80; higher scores = greater emotional discomfort.	■	■	■
Self-care behaviors	Modified Diabetes Self-Care Inventory (30): 15-item 5-point Likert scale (1-never engage; 5-always engage) for measuring different aspects of diabetes self-care. Final score 1-5; higher scores = better self-care.	■	■	■
COVID-19 test, treatment, vaccine, and impact questionnaire	This 16-item questionnaire assesses the impact of COVID-19 pandemic on individuals' health, mental health, and other aspects of life.	■	■	■

Table 1: Study Measures

Surveys. The participants will complete surveys at Time Points T⁰, T⁶, and T¹² at FQHCs supervised by the research staff. The participants will be reimbursed for each visit (\$25 for screening and consenting; \$30 for the baseline visit T⁰, \$40 for the 6-month visit T⁶, and \$55 for the 12-month visit T¹²).

HbA1c. The primary way of obtaining HbA1c readings will be extracting them from patients' records. In cases when participants are unable to obtain an HBA1C test from their Health Center within timeframes consistent with study milestones, they will be offered several alternative options. First, they may choose a home visit by a commercial home visit laboratory service (such as Apex Laboratory, Inc: <https://www.apexlabinc.com/>). During this visit, a lab phlebotomist will collect blood sample required for the test. The sample will be processed and the results will be shared with the participant's healthcare provider; a copy of the results will be shared with the study coordinator and used as an outcome for the study. The costs of the HBA1C home test, including specimen collection and processing, will be paid for by the research study. Second, they may choose to receive a blood sample collection kit via mail, with a set of instructions for collecting blood sample at home (either capillary or dry blood spot), and with a pre-paid envelope to return the collected blood sample to the research lab for processing and analysis (for example, AccuBase HbA1c home testing kit with sample processed at DTI Laboratories: <https://www.dtilaboratories.com/accubase-a1c-test-kit.html>). In case participants select at-home blood sample collection approach, the research team will order the test kit from the service provider, pre-fill all the required participant information (e.g., participant ID, contact email, etc) and then ship the prepared package to the participants. We will ask the participants to schedule time for blood sample collection that will be monitored by study staff, who will provide guidance and answer any questions about the blood sample collection process via Zoom or phone. When the HbA1c report is ready, the study coordinator will print the report, and will mail it to the participant. We will also assess each participant's willingness to share the report with their healthcare providers, and, upon their agreement, will provide appropriate clinical staff at the corresponding FQHC with a printed copy of the report. All costs associate with blood sample collection, shipping, and processing will be covered by the study.

Data Management and Creation of Variables. Data will be captured in paper form (including surveys, anthropometric measurements, BP and laboratory values) or electronically using RedCap (Vanderbilt University). Data that are captured on paper will be transferred into digital form by the research staff using RedCap (Statistical data analyses will be performed using SPSS version 24.0 (SPSS Inc., Chicago, IL).

Sample size calculations. We were guided by published literature to estimate anticipated effect sizes and projected study milestones. The systematic review and meta-analysis of technological interventions for diabetes self-management that focus on medically underserved communities (31) reported effect size of -0.36 at 6 months and diminishing effect of -0.27 at 12 months. As a result, we will use reduction in HbA1c at 6 months as our main outcome with anticipated effect size of -0.36. We will examine the effect of the intervention at 12 months, but as exploratory rather than main outcome. Sample size of 122 per group (total of 244 individuals) will achieve 80% power to reject the null hypothesis of equal means of HbA1c change for the population mean difference of -0.36 with a standard deviation for both groups of 1.0 and with a significance level (alpha) of 0.050 using a two-sided two-sample equal-variance t-test. We anticipate that 12% of the sample will be lost to follow-up at 6 months (average attrition rate in MoDD RCT), thus we need a sample of at least 139 subjects within each group (total n=278 across sites). We propose sample size of 140 participants per group (n=280 total) with 46-47 participants recruited from each of the 6 FHQC.

Qualitative Interviews. We will recruit a purposive sample of participants from the intervention group (n=20) upon completion of the intervention phase of the study for qualitative interviews regarding their experiences with T2 Coach. We will recruit participants to maintain balance between different study sites, and different levels of engagement with T2 Coach. The interviews will be conducted in in-person

meetings at FQHCs or over the phone. Interviews with participants who actively engaged with intervention will focus on their experiences and perceived impact. Interviews with participants who did not engage with GlycoType will focus on barriers to engagement. All interviews will be audio recorded.

G. STUDY SUBJECTS

Participants (N=280, n= 46/47 per site) will be recruited from 6 CDN member Federally Qualified Health Centers (FQHCs) in the New York metropolitan area. These FQHCs serve as the medical and health care home for over 350,000 underserved, low-income patients. Patients served by these sites are predominantly female (57%) and minority (31% are African American and 51% are of Latino). Nearly all patients are low income, with 63% being insured through Medicaid, and 16% are uninsured. To reduce the potential impact of differing clinical practices on the study outcomes, we have targeted sites that meet the following clinical site inclusion criteria: (a) operational for ≥ 2 years, provide primary care to $\geq 5,000$ adult users per year (b) provide diabetes education in groups or individually c) have at least 1 diabetes educator on staff (c) previous participation in other CDN research initiatives. The inclusion criteria for patients will be: (a) a patient of the health center for ≥ 6 months and a diagnosis of T2DM (b) HbA1c ≥ 8.0 in the past month, (c) age 18 to 65 years and (d) owns a smartphone, (e) able to download and use an app from an app store (zoom), (f) able to receive long text messages (over 140 characters), (g) owns a glucometer, (h) proficient in either English or Spanish. The exclusion criteria will be: a) pregnancy; (b) presence of severe cognitive impairment (recorded in patient chart), (c) existence of other serious illnesses (e.g. cancer diagnosis with active treatment, advanced stage heart failure, dialysis, multiple sclerosis, advanced retinopathy, recorded in patient chart) (d) plans for leaving the FQHC in the next 12 months, and e) participation in the previous MoDD trial. To reduce barriers for enrollment in the study, we will provide participants who do not have a smart phone a loaner phone for use during the study. In addition, incentives for adding data to their plan will be provided. To reduce potential bias due to additional incentives (a smartphone), participants in both conditions who do not have a smartphone will be loaned a phone for use during the study.

H. RECRUITMENT OF SUBJECTS

Participants will be recruited from 6 CDN-member FQHCs in the New York Metropolitan area. FQHC clinicians and staff will be convened for information sessions at multiple times to introduce the study and the protocol, including participant selection and recruitment plan. Their feedback will be incorporated into the study protocol.

In response to the COVID-19 pandemic, recruitment will be conducted in-person, on-site at the participating FQHC or remotely.

Remote Recruitment: Recruitment Coordinators, who are credentialed as volunteers by the participating sites, will review the EHR remotely to identify adult patients with type 2 diabetes who have had a HBA1C reading ≥ 8 in the past month and send a recruitment letter by email (if available) and/or mail to these potentially eligible patients. Three to five days after the recruitment letter has been sent, the Recruitment Coordinator will contact the patient to confirm eligibility and obtain informed consent, using one of the following methods:

- 1) Oral consent from a specified script is completed and a copy of the consent document is mailed to the participant.
- 2) Electronic consent (if patient has an email address). The eligible participant is sent a link to a HIPAA certified study database, and is then prompted to review and sign the consent, if they are interested in participating.

In-Person Recruitment: For in-person recruitment, research staff, who are credentialed as volunteers by the participating sites, will work with the clinicians and practice staff to identify adult patients with type 2 diabetes who present for care and have had a HBA1C reading ≥ 8 in the past month. Research staff will then meet with potential patients in a confidential area in the FQHC, provide a verbal explanation of

study purpose and procedures, and confirm eligibility. If the patient is deemed eligible, informed consent will be obtained. Other in-reach recruitment strategies will include referrals of patients from clinicians and practice staff and engagement of patients who attend chronic disease care management groups.

To encourage broader outreach to patients of participating FQHCs, we will use text messaging to advertise the study. All patients identified as eligible to participate in the study will be sent the following text message:

Hi [name of the patient]. My name is [name of the study coordinator assigned to the specific FQHC] and I am a research associate working with Dr. [name of the primary care provider for the patient] at [name of the FQHC] health center. You may be eligible to take part in a study of a text messaging app for health coaching. Participants can receive a free FitBit tracker and up to \$230 for participation. Text back “Y” to receive a call back with more information or “N” if not interested. Thank you!

I. CONFIDENTIALITY OF STUDY DATA

All employees working with the data are required to sign a confidentiality statement and abide by standards of confidentiality outlined in the Clinical Directors Network’s Confidentiality in Research manual. Unique identifiers always replace patient names in any research database. All computer systems are protected from possible external access. A separate master list of names, addresses, and telephone numbers, along with the code numbers will be stored in a secure, password protected electronic file located on CDN’s Local Area Network at CDN’s offices. Only research staff involved with the project will have access to patients’ information shared during the interviews or taken from the medical record during the project. The audio-recordings will be stored on a password-protected computer at CDN and Columbia University and only project staff will have access to the recordings. The audio-recordings will be destroyed within one year of the date of the interview. The master list of names will be destroyed at the end of the project in 2024. All study forms will be kept in a locked file cabinet at CDN’s offices and will then be destroyed seven (7) years after the end of the project in 2031. In case any data needs to be transferred between CDN and Columbia University, the transfer will be done by sending encrypted USB drives via certified mail with tracking number or in person by study personnel. De-identified version of the dataset collected during the study, including participants’ self-monitoring data will be kept indefinitely for secondary analysis and to assist in the development of new computational data analysis methods.

In this study, patients will have a chance to receive messages from T2 Coach that will be sent over cellular network and stored in their message history. We will do everything we can to protect the privacy and security of the data patients send to us. However, since we will be using commercial providers for text messaging, there is a small chance that the data could be accessed by other individuals, if someone breaks into the cell phone company’s data network. Also, patients may accidentally send their data to a wrong number and make it available to individuals not involved with the study. Finally, if the patient’s cell phone keeps a history of text messages and is not password protected, or if the patient loses the cell phone, other individuals may be able to view their messages.

In order to reduce these risks, we recommend that the patients take the following steps:

1. Add the T2 Coach phone number to their address book (and potentially to the list of their favorite numbers) using T2 Coach as a name. This way, when the participant receives messages from the number, it will be easier to see that they are coming from the right number.
2. Put a password on the smart phone so that no one can access the phone.
3. Never send to the project any private information, including social security number or your credit

card numbers.

J. POTENTIAL CONFLICT OF INTEREST

None noted.

K. LOCATION OF THE STUDY

The participating centers all share a common commitment to providing primary care to patients in their neighborhoods and receive funding from a variety of Federal, State and local sources as well as reimbursement from managed care organizations and other insurers. Six Community Health Centers from New York and New Jersey will be selected to participate in the RCT. The six centers will meet participation criteria developed during our Preliminary Work. These criteria include: established for ≥ 2 years; provide primary care to $\geq 5,000$ adult users per year; have at least one staff on-site providing diabetes education in group or individually; and assurance that the center will be able to begin intervention implementation within two months of the time proposed. We have identified the following sites to be included in this research:

- 1) Bedford Stuyvesant Family Health Center
- 2) Family Health Centers at NYU Langone – Family Physician Health Center (Brooklyn, NY),
- 3) Metropolitan Family Health Center (Jersey City NJ),
- 4) Morris Heights Health Center (Bronx NY), and
- 5) Open Door Family Health Center at Ossining (Ossining /Westchester, NY)
- 6) Open Door Family Health Center at Portchester (Portchester/Westchester, NY)

L. POTENTIAL RISKS

The physical risks of the studies are minimal. There are no invasive procedures or study medications involved. Some participants may experience discomfort with using finger prick to capture blood glucose; however, this procedure is a standard care for individuals with type 2 diabetes regardless of their participation in the study.

A project emergency protocol will be developed to address issues that arise during the course of the study, including: blood glucose levels in the emergency range (hyperglycemia: 300 to 400; hypoglycemia: <70)

As part of the process involved in obtaining written informed consent, all participants will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation, and further, that such an action will in no way affect their future interactions with their health care provider. To ensure confidentiality, data will be associated with an individual participant only by an assigned identification number, the code for which will be kept in a locked cabinet at CDN's offices. All data entered into the research database will be protected by confidential entry codes. Names will not be collected on any surveys. In no case will statements or any results about particular centers be traceable to specific center names. Participating clinical centers will not be identified by name in any publications or presentations. For purposes of record keeping, data on centers will be identified by letter with a coding document that allows identification kept in a separate file protected by a separate password.

M. POTENTIAL BENEFITS

The intervention is expected to benefit the patients, by increasing their blood glucose control, reducing risk of diabetes related complications, and increasing their role as active participants in the management

of their diabetes..

N. ALTERNATIVE THERAPIES

N/A

O. COMPENSATION TO SUBJECTS

Aim 1: User-Centered Design

Participants recruited among patients of FQHCs will receive \$20 for each activity they take part in, with the possible total of 5 different activities with the total of \$100 (user-centered design sessions, controlled experiment, usability testing, pilot studies 1 and 2).

Patients who participate in testing T2 Coach at home will receive free glucose strips consistent with their blood glucose meter for glucose testing during the 2-week testing period (1 box of strips).

In addition, they will receive \$10 to cover the cost of text messaging during the pilot test.

The total possible compensation for participating in Aim 1 study activities is \$110.

FQHC staff will receive \$50 for participation in the focus group.

Aim 2: Randomized Controlled Trial

Participants will receive the following incentives for completing the surveys:

- \$25 for screening and consenting
- \$30 for the baseline visit T⁰
- \$40 for the 6-month visit T⁶
- \$55 for the 12-month visit T¹².
- \$20 for participating in a post-study qualitative interview (optional)

A loaner FitBit device (approximately \$30) will be provided to participants for the duration of the study. Participants who opt for conducting study visits on-site at the health center will receive the FitBit when they present for the intervention study visit, while those who select remote study activities will be mailed the smartphone and FitBit device via certified mail with tracking.

Participants will also receive \$10 to cover the cost of text messaging during the 6-month intervention period.

Participants of the RCT may receive up to a total of \$230 (\$170 for the assessment and \$60 for data usage and texting).

Participants of the RCT will be provided with either cash or an electronic gift card for completing the surveys and for their data usage, based on their preference.

Finally, participants will also receive free glucose strips consistent with their blood glucose meter for glucose testing during the intervention period (2 boxes of 50 strips, given one at baseline and one at 3 months). Participants will either be provided with a voucher for a local, site-affiliated pharmacy to obtain the strips or will be mailed the strips via regular USPS.

P. COSTS TO SUBJECTS

The cost for taking part in the study is minimal. It includes the time spent with the Research Staff answering the questionnaires and using the T2 Coach application, for example recording meals and reviewing goals. Further, it may include discomfort due to additional blood glucose testing, which may be

more frequent than is typical for some participants.

Q. PROVISIONS FOR CARRYING OUT STUDY ACTIVITIES REMOTELY DURING THE COVID-19 PANDEMIC

To address the social distancing measures during the ongoing COVID-19 pandemic, all the study procedures will be made available in a virtual form. If social distancing measures are rescinded and it is deemed safe to conduct study procedures in-person, the participants will be offered a choice to either participate in the study remotely, or to participate in-person. The remote version will be available to all individuals recruited for the study beginning in July 2020.

Remote screening and recruitment: Recruitment Coordinators, who are credentialed as volunteers by the participating sites, will review the EHR remotely to identify adult patients with type 2 diabetes who have had a HBA1C reading ≥ 8 in the past month and send a recruitment letter by email (if available) and/or mail to these potentially eligible participants. Three to five days after the recruitment letter has been sent, the Recruitment Coordinator will contact the patient to confirm eligibility and obtain informed consent, using one of the following methods, based on the patient's preference:

1) Oral consent from a specified script is complete. In this version, study personnel will call participants over the phone and read them the consent form following the verbal consent script (attached). The participants will be encouraged to ask questions and asked to provide their oral consent, which will be recorded by the study personnel. The participants will be mailed the printed verbal consent form signed by the study coordinator.

2) Electronic consent (if patient has an email address). The eligible participant is sent a link to a HIPAA certified study database, and is then prompted to review and sign the consent, if they are interested in participating.

In-Person Recruitment: For in-person recruitment, research staff, who are credentialed as volunteers by the participating sites, will work with the clinicians and practice staff to identify adult patients with type 2 diabetes who present for care and have had a HBA1C reading ≥ 8 in the past month. Research staff will then meet with potential patients in a confidential area in the FHQC, provide a verbal explanation of study purpose and procedures, and confirm eligibility. If the patient is deemed eligible, informed consent will be obtained. Other in-reach recruitment strategies will include referrals of patients from clinicians and practice staff and engagement of patients who attend chronic disease care management groups.

Study visits/milestones

All study visits/milestones will be available in the virtual form in the following way.

1) Consent/screening visit. We will use several different approaches for remote consent/screening as noted above.

2) Baseline assessment visit, 6-months follow-up, and 12-months follow-up. For all three study visits, the participants will be offered the following options:

1. Assisted over RedCap: in this option, the participants will receive a text message with a link to a set of surveys on RedCap. The participants will be able to use the link to access the surveys and complete them on their own. A member of the research team will call the participants at the agreed-upon time and provide them with assistance, should it be required.

2. Assisted verbal: in this option, a member of the research team will call participants on their phone at the agreed-upon time, will read them the survey questions and capture their oral answers either directly in Redcap (the project's database) or on paper. These calls will be audio recorded and transcribed to ensure

data quality.

3) Intervention training visit (intervention group only): to ensure high quality of the intervention training, the participants will be asked to download a HIPAA compliant zoom application from the app store (or google play). During this session, they will be provided with a link to a video tutorial on youtube and asked to watch the tutorial. After finishing the tutorial, they will be provided with a link to a password-protected zoom call and asked to join a call without using audio and to share their phone screen. A member of the research team will ask the participants to engage with T2 Coach and follow a set of steps for setting goals, while observing the participants' screen; this will enable researchers to provide assistance when necessary.

Equipment and incentives for patient who request remove study activities will be provided as follows:

- Fitbit and smartphones will be sent over certified mail with delivery tracking.
- Blood glucose test strips will be mailed via USPS.
- Electronic gift cards will be emailed to participants.

R. RADIATION OR RADIOACTIVE SUBSTANCES

N/A