

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

IRB Approved at the
Western Institutional Review Board
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Dynamically Tailoring Interventions for Problem-Solving in Diabetes Self-Management Using Self-Monitoring Data

Script for Oral Consent for T2 Coach Project

<p>1. Recruiter (study introduction)</p>	<p>Hello - My name is _____. I am calling on behalf of Dr. _____ at [Health Center name] which is doing a research project with Columbia University and Clinical Directors Network. This project is about diabetes self- management using a smartphone app called T2 Coach and we would like to invite you to participate as a research participant.</p> <p>The purpose of this project is to learn about ways to help people manage their diabetes. We are looking to enroll adults 18 to 65 years' old who have a smart phone and can download and use smartphone apps and who have a diagnosis of type 2 diabetes with an HbA1C result of 8 or more in the past month. We plan to recruit a total of 280 persons in this part of the project.</p> <p>We expect that you will be part of this research for 1 year starting today.</p> <p>If you agree to participate, you will be assigned into one of the following two study groups by chance (like a coin toss):</p> <ul style="list-style-type: none"> • The Intervention Group: in this group, you will continue to receive your regular usual care plus a smart phone application, named T2 Coach, that will help you manage your diabetes <p>OR</p> <ul style="list-style-type: none"> • The Usual Care Group: in this group, you will continue to receive your regular medical care at the site <p>You have a 50% chance of being placed in each group. You cannot choose your study group.</p> <p>Regardless of which study group you are assigned to, you will be asked to take part in 5 study sessions, including this one over the course of the year. The first 3 sessions will happen now and in the next few days, the fourth one in 6 months, and the fifth one in 12 months. During three of these sessions, we will ask you survey questions about your health and about diabetes self-management. You will receive a total of \$170 for completing all 3 surveys and an additional \$60 to help pay for your data plan, if you choose to participate. You will also receive a loaner Fitbit tracker that we will ask you to wear on your wrist throughout the study. We will collect</p>
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	<p>your physical activity and sleep patterns from the Fitbit tracker. Finally, you will receive two boxes of 50 glucose test strips for your blood glucose meter.</p> <p>If you agree to participate, your privacy and confidentiality will be fully protected. All information collected will be stored in a password protected, secure server where only the research team involved in this project will have access to it. If you decide not to participate in this study, you will not lose any medical care, health insurance or other services or benefits that you are otherwise entitled.</p> <p>Taking part in this research is voluntary. Whether you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. You may refuse to participate, or withdraw, from this study at any time, for any reason without penalty or loss of benefits for which you are otherwise entitled.</p> <p>Do you have any questions you'd like to ask me so far?</p>
2. Subject	<p>Yes, proceed to statement 3.</p> <p>No, proceed to statement 4.</p>
3. Recruiter	<p>Yes, I would be glad to answer your questions.</p> <p>Note: Answer any question the subject has. Once the subject is satisfied, please continue.</p>
4. Recruiter (study procedures)	<p>If you choose to participate in this study, you will be enrolled by completing a baseline survey, which asks questions about your health and demographic information. This may take between 20 and 40 minutes. After that, you will be assigned to one of the study groups.</p> <p>If you are assigned to the intervention group, during the first 6 months of the study, we will ask you to use T2 Coach to record your meals and daily blood glucose levels. This will mean taking pictures of your meals with your phone and checking your blood glucose before and after these meals for at least some part of the study. We will also ask you to receive and respond to text messages from T2 Coach that will help you set personal self-management goals and keep track of your progress.</p> <p>If you are assigned to the “usual care” group, during the first 6 months of the study, we will encourage you to use your smartphone to help you manage your diabetes. We will provide links to websites to access information about diabetes self-management online. After completing 12 months of the study, you will be given a chance to download the app T2 Coach and use it as often as you like to help you manage your diabetes.</p> <p>In this study, we ask you to check your blood glucose before and after every meal for at least the first few weeks of the study. Testing this often has important benefits because it may help you learn how your body reacts to nutrition in meals and to physical activity. It will also help T2 Coach to make suggestions for self-management goals that are specific to you.</p> <p>We will ask you to check your HbA1c at times prescribed by your primary care provider. It is important that you follow your clinician's recommendations for</p>

	<p>checking your HbA1c. At each of the study sessions, we will check with your Level 1 clinician to make sure you have completed the recommended HbA1c testing, 2021. If the HbA1c has not been completed, we will provide the necessary support to ensure that you complete the HbA1c test.</p> <p>In addition, we will ask for your agreement to review your medical records at baseline (now), in 6 months and in 12 months. We will review information on your health, blood test results, and medicines that have been prescribed by your doctor at the time of each study visit. Finally, we plan to audio record all communications with you, whether in person or over the phone or other media. The recordings will only be used by members of the study team for analysis and will not be shared outside the study team. The audio recording will be stored on a password protected computer for one year after which point it will be destroyed.</p> <p>Do you have any questions or concerns?</p>
5. Subject	<p>Yes, proceed to statement 6.</p> <p>No, proceed to statement 7.</p>
6. Recruiter	<p>Yes, I would be glad to answer your questions.</p> <p>Note: Answer Subject to the fullest extent. Once the Subject is satisfied, please continue.</p>
7. Recruiter (risks, benefits, and costs)	<p>I would like to tell you about risks, costs, and benefits in this study.</p> <p>You may not benefit from being in this project. Your diabetes may or may not be better controlled by participating in the project. You may find the T2 Coach application helpful in managing your diabetes. You may feel good from knowing that what you tell us may help to help more patients manage their diabetes.</p> <p>The only cost to you for taking part in this study is the time you spend answering the questions during the interview, and the time you spend using the T2 Coach smart phone application.</p> <p>There are several risks to participating. Some of the questions we ask during the study may make you feel uncomfortable. You may choose not to answer any question or stop participating in the project at any time without giving a reason. We will ask you to check your blood glucose, which may feel painful. We will also ask you to send and receive text messages with your blood glucose readings. There is a chance that these messages may be accessed by other individuals if someone breaks into the provider's company's data network. Finally, T2 Coach will make recommendations for personal goals regarding your diet, physical activity, and other daily activities. These recommendations will be generated by the app, and not by your healthcare providers. If you are concerned about these goals, please talk to your healthcare team before making any changes to your daily activities. Also, never adjust your medications without consulting your healthcare team.</p> <p>Do you have any questions?</p>
8. Subject	<p>Yes, proceed to statement 9.</p>

	No, proceed to statement 10.	Protocol Level
9. Recruiter	Yes, I would be glad to answer your questions.	Oct 14, 2021
	Note: Answer Subject to the fullest extent. Once the Subject is satisfied, please continue.	
10. Recruiter (confidentiality)	<p>The information that you provide will be kept confidential. Only the T2 Coach research team will have access to your information. The research team will keep all information collected in a password, protected secure server. In order to protect this information, only members of the team have access to this secure server.</p> <p>In order to reduce these risks, we suggest that you do the following:</p> <ol style="list-style-type: none"> 1. Put a password on your cell phone so that no one can access the information on your phone. 2. Record T2 Coach phone number you will use to send text messages in your contacts, to avoid accidentally sending your data to a wrong number. 3. Never send any of your private information via text message or in the app. Do not record your social security number or your credit card numbers in your app. <p>We would like to reuse self-monitoring data you collect during your participation for future research, including pictures of your meals, records captured with FitBit, and your blood glucose levels. We may use these data for future research, which could involve showing it to other researchers and individuals. In all of these activities, your name or any identifying information about you will not be mentioned. At the end of this call, I will ask for your permission to reuse your data.</p> <p>Do you have any questions or concerns?</p>	
11. Subject	<p>Yes, proceed to statement 12.</p> <p>No, proceed to statement 13.</p>	
12. Recruiter	<p>Yes, I would be glad to answer your questions.</p> <p>Note: Answer Subject to the fullest extent. Once the Subject is satisfied, please continue.</p>	
13. Recruiter	Based on the information that you have been provided, are you willing to participate in this study?	
14. Subject	<p>Yes, Proceed to statement 15.</p> <p>No, Proceed to statement 16.</p>	
15. Recruiter	Thank you. I will continue with the data reuse statement and we'll move on to the next part of the project.	
16. Recruiter	Thank you for your time. I can be reached at _____, if you happen to change your mind. Have a good day.	

RESEARCHER'S STATEMENT

I give permission for the de-identified data collected as part of this research can be used for future research

(Please initial the appropriate answer): Yes _____ No _____

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I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Name of subject who gave oral consent to take part of the T2 Coach Research Project:

Subject's Name

Date of Oral Consent.

Person Obtaining Oral Consent: Name (Print)

Signature

Date

If the subject agrees to take part of the study or if at any time during the conversation they ask for a contact, please give the following information:

Questions and Answers

If you have any additional questions, please feel free to call me at:

Name of Research Coordinator: _____ Phone No.: _____

Project Manager: TJ Lin (212)382.0699 ext. 225 Email: Tlin@CDNetwork.org