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

NCT04226027

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Columbia University and Clinical Directors Network (CDN)
Patient Informed Consent to Participate in Research

Title:	Dynamically Tailoring Interventions for Problem-Solving in Diabetes Self-Management Using Self-Monitoring Data
Protocol No.:	None IRB Protocol #20182173 AAAS5528
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You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

Someone will explain this research to you. This form sums up that explanation. Taking part in this research is voluntary. Whether you take part is up to you. You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled. You can agree to

take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled. If you don't understand, ask questions. Ask all the questions you want before you decide.

Why is this research being done?

Many people have a hard time managing their diabetes, including maintaining a healthy diet, exercising, and dealing with stress. The purpose of this project is to learn about ways to help people manage their diabetes better. We hope this project will result in better-controlled diabetes by helping people solve diabetes-related problems they face every day. 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.

How long will I be in this research?

We expect that your part in this research will take 1 year from today.

What happens to me if I agree to take part in this research?

If you choose to participate in this study, you will be asked to review and sign the consent form today. We will then ask you to complete 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 put into one of the following two study groups by chance (like a coin toss):

- 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

OR

- The Usual Care Group: in this group, you will continue to receive your regular medical care at the site

You have a 50% chance of being placed in each group. You cannot choose your study group.

Regardless of which study group you are assigned to, you will receive the following:

- A loaner FitBit device that we will ask you to use in the study. We will ask you to return the FitBit after you have completed the study.
- Free test strips for your blood glucose meter (2 boxes of 50 strips).
- You will also be provided with $10 per month for 6 months of the intervention phase to pay for your data plan that you will need to use T2 Coach.

In addition to these, if you are assigned to the intervention group, you will receive the following:

- Access to a smartphone app called T2 Coach. A Research Staff member will provide instructions for how to use T2 Coach and we will ask you to use it for 6 months of the intervention period. We will also provide you with a phone help line where you can receive additional help on using T2 Coach. After these 6 months, you will be able to continue using T2 Coach or stop using it.

If you are assigned to the "usual care" group, you will receive the following:

- During the first 6 months of the study, we will encourage you to use your smartphone to help you manage your diabetes. For example, you can use it to access information about diabetes self-management online, or join diabetes support groups.
- After completing 12 months of the study and your last study assessment, 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.

What are my responsibilities if I take part in this research?

If you agree to take part in this project, we will ask you to do the following:

- Come to the Health Center for 5 study visits over the next year. The first study visit (visit 1 – screening assessment) will take place today. The second study visit, (visit 2-baseline assessment), will take place either today or within one week from today. The third study visit (3) will take place a few days after the second one. The fourth study visit (6-month assessment) will happen in about 6 months, and the fifth and last study visit (12 month-assessment) will happen in one year.
- During study visits 1, 2, 4 and 5, we will ask you questions about your health and about diabetes self-management.
- At visit 3 you will receive training on how to use T2 Coach, if you are in the intervention group. If you are in the usual care group, you will receive training on how to find helpful websites on diabetes self-management.
- During the first 6 months of the study, we will ask you to check your blood glucose levels with a higher frequency that may be typical for you. For example, we will ask you to check your BG before and after every meal for at least the first few weeks of the study. Testing this often has important benefits because it will help T2 Coach learn how your body reacts to nutrition in meals and physical activity. This knowledge will allow T2 Coach to make suggestions for self-management goals tailored to you. We will provide you with additional test strips to offset the costs. You will receive the first box of test strips during the baseline assessment and the second box in 3 months.
- If you are assigned to the intervention group, we will ask you to use T2 Coach to help you set personal self-management goals and keep track of your progress. 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 every day. Finally, we will ask you to wear a fitbit tracker on your wrist throughout the study in order for us to collect your physical activity and sleep data.

- Agree to have your medical records reviewed for the study following visits 2, 4, and 5. 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.

- We plan to audio record study activities. To participate you must agree to be audio recorded during study visits and interviews. The recordings will only be used by members of the study team for analysis and will not be shared outside the study team. Study activities will take no longer than 90 minutes. The audio recording will be stored on a password protected computer for one year after which point it will be destroyed. Each participant will be given a unique identifier so the subject's identity will remain anonymous.
- Check your HbA1c at times prescribed by your primary care provider. In this study, we will record your HbA1c from your medical chart. It is important that you follow your clinician's recommendations for checking your HbA1c. At each of the interviews, we will check with your clinician to make sure you have completed the recommended HbA1C testing. If the HbA1c has not been completed, we will obtain a clinician referral for the test and escort you to the lab at the center to complete the HbA1c test. We will provide the necessary support to ensure that you complete the HbA1c test.
- (optional) After completing the study, you may be asked to take part in a 60-minute interview, which will be conducted either in-person or by phone. This interview will focus on your experience being in this study.

Do I have to attend study sessions in person?
To respond to the ongoing concerns of COVID-19 pandemic, we will give all participants multiple options for participating, consistently with local guidelines. All study sessions will be available online via conferencing applications. You can choose to conduct any study session remotely. If you choose to participate in sessions remotely, you will need access to the Internet and may be asked to download tele-conferencing smartphone app (for example Zoom) on your smartphone. If it is deemed safe to conduct study sessions in person, you will have a choice to attend these sessions at your health center.

Could being in this research hurt me?

There are several risks to participating in this study:

- Some of the questions ask you to share personal information, which may make you feel uncomfortable, stressed, or upset. You may choose not to answer any question or stop participating in the project at any time without giving a reason.
- In this study, we ask you to check your blood glucose more often than your current testing schedule. Checking blood glucose more often may lead to small bruises at the place of the prick. This is not serious and the mark will go away within a few days.
- In this study, you will have a chance to send your blood glucose readings and records of your activities using app-based uploading on your phone or using text messages. You will also use text-messaging and/or telephone voice services to respond to questions from the study team.

- When you use text messaging or telephone voice services, you are using commercial providers, which can lead to some risks to the privacy of your data. Your messages will be sent via your Internet provider that uses commercial data exchange protocols. There is a chance that your data could be accessed by other individuals, if someone breaks into the provider's company's data network. Also, you may accidentally send your data to a wrong number and make it available to individuals not involved with the study. Also, if your smart phone is not password protected or if you lose your phone, other individuals may be able to view your messages and the data in your apps. We will protect your privacy to the extent possible. Later in this form, we will suggest steps you can take to protect your privacy when you are using the Internet and the text messaging technology.
- Finally, some of the features of T2 Coach involve making 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. We will make sure that these goals are safe for all individuals with diabetes. 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.

Will it cost me money to take part in this research?

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 T2 Coach smart phone application.

Will being in this research benefit me?

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.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens if I agree to be in this research, but I change my mind later?

You will not be affected in any way if you decide not to take part in this project. Your choice whether or not to participate will not change health care you receive. Even if you decide to begin the project, you may stop at any time**.** If you decide to stop being part of the project, it will not change your health care.

If you wish to withdraw (revoke your authorization to participate in the research) from the study at any time, you may contact the Principal Investigator, Dr. Lena Mamykina, at: (212) 305-3923

or via email: om2196@cumc.columbia,edu, or Andrea Cassells, MPH, Project Director, at: (212) 382-0699, ext. 227. However, if you revoke this Authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this Authorization, the Researchers and the Sponsor may continue to use and disclose the information they have already collected as permitted by the Informed Consent and HIPAA Authorization form.

Your authorization to use and share your health information does not have an expiration (ending) date.

How will the privacy and the confidentiality of your records be protected?

We will do everything in our power to protect your privacy. Your confidentiality will be protected by assigning a code to your study records. All of your answers from the interviews will be coded and stored in a secure, password protected and encrypted database at Columbia University and CDN. The audio-recordings will be stored on a password- protected computer at Columbia University and CDN and only project staff will have access to the recordings. The audio recording will be stored for one year after which point it will be destroyed. 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. Only research staff involved with the project will have access to information you share or information taken from your medical record during the project. The master list of names will be destroyed seven years after completion of the project in 2031.

The Institutional Review Board that reviewed this protocol, WCG IRB may access your data for monitoring purposes. They will also keep all information private.

The results of this project will be published; however, your name will not appear in any publications or presentations about the results of the project and no one will be able to identify you. At the end of the project, Columbia University and CDN may display the results of the project on its website: www.dbmi.columbia.edu and www.CDNetwork.org.

During the study (or after the first year of the study if you are in the “usual care” group), we will offer you the opportunity to use the T2 Coach smart phone application to keep track of your blood glucose readings and different daily activities. All these records will be stored on the T2 Coach server and displayed to you using the smart phone application. We will do everything we can to protect the privacy and security of the data you send us. However, we cannot guarantee that your privacy will be protected completely because we do not have control over commercial Internet providers and their data transmission protocols. We will protect your privacy to the extent possible. Specifically, all the data you collect will be stored on HIPAA-certified servers at Columbia University and CDN in an encrypted form. All the communication between your phone and the server will be encrypted. We will also suggest ways for you to protect your privacy when you are using your smart phone. As a reminder, when you use smart phone applications and transmit data over the Internet, you are using commercial providers, which can lead to some risks to the privacy of your data. Your messages will be sent via commercial Internet providers. There is a chance that your data could be accessed by other individuals, if

someone breaks into the Internet provider company's data network. Also, if your smart phone is not password protected, if you lose your phone, other individuals may be able to view your messages.

In order to reduce these risks, we suggest that you do the following:

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 address book, 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.

If we believe that you might harm yourself or someone else, as a result of information we obtain from you during your interviews, we are required to inform the appropriate authorities to ensure your safety or the other person's safety. For example, if you tell us that a child is being abused, we are required by law to tell the appropriate authorities about this so that the child is kept out of danger.

What are your privacy rights?

The health-related information that we will receive about you in this study, for example, your daily blood glucose readings, is personal. The research team is required by law to protect the privacy of information called "protected health information" or PHI. We will make every effort to protect the confidentiality of your PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required.

By agreeing with this Informed Consent form and HIPAA Authorization, you give permission for the researchers at Columbia University and CDN to use health information collected during this study. Your information will also be shared with the members of the research team at Columbia University and CDN. However, before sharing your information outside of Columbia University and CDN, we will remove everything that discloses your identity (such as your name or address). Also, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the funder of this project will have access to study information.

The following people and/or agencies will be able to look at, copy, use and share your research information:

- The investigator, Columbia University Medical Center and Clinical Directors Network study staff and other professionals who may be evaluating the study;
- Authorities from Columbia University and Clinical Directors Network, including the Institutional Review Board ('IRB'). An IRB is a committee organized to protect the rights and welfare of people involved in research.

- The Federal Office of Human Research Protections ('OHRP');
- The sponsor of this study, the National Institute of Diabetes and Digestive and Kidney Disease, including persons or organizations working with or owned by the sponsor may review your data for accuracy but may not copy information with your name on it.

Your authorization to use and share your health information does not have an expiration (ending) date. You have a right to refuse to agree with this Informed Consent and HIPAA Authorization form. The care you receive at your Health Center will not be affected if you do not sign this form, however if you do not "agree" to participate at the end of this document, you will not be able to be part of this research study.

Reuse of data collected during this project (optional)

We would like to reuse self-monitoring data you collect during your participation for future research. For example, we may show your captured activities and your blood glucose readings before and after these activities to other individuals and ask them to think about connections between different aspects of the meal and changes in BG levels.

In addition, we may use the images of meals you record for research on nutritional literacy and learning. In this research we may post the images on a public website where many individuals will be able to see them and answer questions about the nutritional composition of meals. In all of these activities, your name or any identifying information about you will not be mentioned. If you choose to make your records available for this future research, please sign your initials next to this part of the consent. If you choose not to make your records available for future research, it will not impact your participation in other research activities described here. If you agree to have your data used for other research projects, check a check box below to indicate that.

Will I be paid to participate in this project?

If you agree to participate in this project, you may receive up to $170 for your time and effort completing the study assessments and for your travel to the center for study visits. You will receive:

- $25 for the screening assessment
- $30 for the baseline assessment
- $40 for the 6-month assessment
- $55 for the 12-month assessment
- $20 for the optional qualitative interview

In addition, we will give you $10 per month for the first 6 months ($60) of the study for the additional data plan and text messaging you may use in this study.

Payments for the assessments and the data plan and text messaging will be provided in the form of cash or in a gift card, based on your preference.

Because testing strips for monitoring your blood glucose levels are expensive, we will give you free test strips (2 boxes of 50 strips). You will receive the first box during the baseline assessment and the second box in 3 months.

In addition, you will be given a loaner FitBit device for tracking of physical activity.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) the organization that is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Who can I call when I have questions about this project?

Please feel free to ask any questions. Think about this project and the consent being asked of you carefully. If you have further questions, concerns, or complaints about this project or if you have a research-related problem, you may contact the Principal Investigator,

Lena Mamykina, Ph.D. at (212) 305-3923 or om2196@cumc.columbia.edu

OR

Andrea Cassells, MPH (212) 382-0699, ext. 227 or acass@CDNetwork.org.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289, researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

If you have any questions concerning your rights as a research participant, you may contact the Columbia University Institutional Review Board by phone at (212)305-5883 or by email at irboffice@columbia.edu, or CDN's IRB at 212-382-0699, ext. 225 or tlin@CDNetwork.org.

Consent to Participate in Dynamically Tailoring Interventions for Problem-Solving in Diabetes Self-Management Using Self-Monitoring Data Study

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 _____

I have read the consent and HIPAA authorization form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent and HIPAA authorization form to keep for my records.

_____

Participant's Name (Print)

_____

Participant's Signature

_____

Date

_____

Person Obtaining Consent/Title

_____

Signature of the Person Obtaining Consent

_____

Date