My Dose Coach Titration and Maintenance in Patients with Type 2 Diabetes Mellitus on Basal Insulin

NCT04678661

Informed Consent Form

8/26/2021

University of Pittsburgh
DIABETES INSTITUTE
in partnership with UPMC

CONSENT TO PARTICIPATE
PATIENT INFORMED CONSENT

MY DOSE COACH PILOT STUDY

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Source of Funding: Sanofi

You are being asked to take part in a research study. Research studies include only those people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

SUMMARY OF RESEARCH

- Evaluate if an online application called My Dose Coach helps individuals with Type 2 diabetes with their insulin dosing and blood glucose control.
- This study may consist of up to 3 study visits over approximately 6 months.
- The risks in participating in this study are minimal.
- My Dose Coach is not intended to replace the care or advice of a health care provider.
- Eligible participants may receive up to $125 for participating in this study.

INTRODUCTION

The purpose of this research study is to evaluate an electronic application (app) designed to help people with type 2 diabetes adjust their insulin doses. The app is called My Dose Coach.

My Dose Coach is designed to help individuals manage their diabetes by following an insulin dose plan as prescribed by their diabetes care team. The diabetes team includes health care providers who are physicians, nurse practitioners, physician assistants, and diabetes educators (now called diabetes care and education specialists). The insulin dosing plan recommended by the diabetes team is entered into the My Dose Coach app by a member of the diabetes team.

This app will allow individuals to log their blood glucose readings and the doses of insulin that their diabetes team recommends for them every day. The app is set up so that individuals and their diabetes team can both see the information and work together to regulate insulin.

This research study will evaluate My Dose Coach in 2 phases. In **Phase 1,** the study is assessing the role of the My Dose Coach app in helping study participants make insulin changes to get their blood glucoses to their target level. People call this the dosing or titration phase when first starting insulin. Insulin doses are planned for with the diabetes team. In this phase, participants will manually enter insulin and blood glucose numbers into the My Dose Coach app. In **Phase 2,** the study is assessing the role of the My Dose Coach app in helping participants keep blood glucoses in their target range. People call this the maintenance phase.

While on the study, participants will be prescribed one of two types of basal insulin to be administered by pen formulation (vs syringe and needle): Lantus U100 or Toujeo U300. Both forms are commonly prescribed to patients who are starting basal insulin and are administered once daily. The type of insulin and dosing instructions will be decided upon between the patient-participant and his/her health care provider following standard clinical guidelines and procedures.

For study purposes, the My Dose Coach app and insulin will be supplied free of charge. The My Dose Coach app has received clearance by the US Food and Drug Administration (FDA) and is commercially available. The insulin being used on this study is an FDA-approved medication and is routinely used in diabetes care.

We are inviting males and females, 18 to 75 years old, who have Type 2 diabetes and are being prescribed basal insulin by their diabetes team at participating UPMC diabetes clinics and are being asked to begin dosing (adjusting) their insulin.

Visit 1 – Baseline – Phase 1

A member of the diabetes care team and the trained research coordinator will help patients, willing to participate in this research study, download and install the My Dose Coach app onto a mobile device and train patient participants on how to use the app. Study participants will receive a text message on their mobile device once the diabetes care team has completed and sent the dose plan. Participants are asked to use the My Dose Coach app for 3 months. During this time, they can enter information into the app about their insulin dosage and blood glucose readings.

If at any time, while using the My Dose Coach app, participants have any questions or technical issues, they should contact one of the study investigators listed on the first page of this consent form or the study coordinator at 412-383-0570.

Participants will manually enter insulin dose (typically once daily) and blood glucose readings (every time blood glucose is checked, typically one to four times per day) into the My Dose

Coach app to determine if they need to make any changes to their insulin dose for the next day based on clinical guidelines set by the participant's health care provider team.

After agreeing to participate, and signing the consent form, participants will be asked to complete a survey during this visit. The survey includes questions about their diabetes, such as how they feel about taking insulin, medicines, and any problems that they may be having. The survey takes about 5-15 minutes to complete.

Visit 2 – at 3 Months - End of Phase 1 / Beginning of Phase 2

When participants return to the clinic for their next visit (~3 months later), a member of the diabetes team will review participants' experiences with starting insulin and determine eligibility for continuing in the study based on their blood glucose readings. All participants that reach their target at 3 months will be invited to continue to Phase 2 of the research study, which will last approximately another 3 months. Participants will be given another 3-month supply of insulin.

Like Phase 1, the My Dose Coach will be used to assist with insulin and medication dosing. The diabetes team will create and send a dose plan by text message to the participant. In Phase 2 the My Dose Coach will be used to help guide and support them in maintaining their glucose control.

Participants will be asked to complete a survey during this visit. The survey includes questions about their diabetes, such as how they feel about taking insulin, taking medicines, and any problems that they may be having. The survey takes about 5-15 minutes to complete. The surveys may be completed in person during a clinic visit for routine clinical care or electronically using their phone, tablet or computer.

Visit 2: Participants who do not reach target after Phase 1 (at 3 months)

The diabetes care team will talk with a participant who does not reach target after the 1st phase of the study to determine the participants ability and interest in continuing to use the My Dose Coach app for another 3 months to help them adjust their insulin dose as in the first 3 months (Phase 1) portion of the study to reach their target glycemic goal. They will have access to the My Dose Coach app to continue help guide and support them in maintaining their glucose control. They will be informed that we will collect medical information for up to 6 months and ask them to complete surveys at 3 and 6 months. The survey takes about 5-15 minutes to complete.

During Phase 2 participants can continue to report any questions or technical issues to one of the study investigators on the first page of this consent form or the study coordinator at 412-383-0570.

Visit 3 – 6 Months – End of Study Participation

Participants will complete another survey at approximately 6 months and will be asked if there

are any issues or concerns that they did not already mention to a member of the diabetes team. The survey takes about 5-15 minutes to complete. The surveys may be completed in person during a clinic visit for routine clinical care or electronically using their phone, tablet or computer.

Data Collection

We are also requesting authorization or permission to review your medical records to gather information about diabetes management from the past year and throughout the study. Information collected from electronic medical records will only be related to the research study. The information is needed to determine whether you meet the conditions for participation in this study and to compare your earlier test results to the findings from this study. The information may include age, gender, race, ethnicity, contact information, location, marital status, employment status, education level, health insurance information, diabetes duration, diabetes-related medication, diabetes-related hospitalizations, hypoglycemic events, co-morbidities, blood pressure, weight, BMI and results from routine blood work. No research data will be placed in your medical record as a result of participating on this study. This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

The My Dose Coach app may also collect the following personal data:

- Identification data: Any information participants or their diabetes team enter during installation, training and use such as name, gender, birth date, email address or phone number.
- Messages sent between the participant and their diabetes team while using the app.
- Health Data: Information about the dose plan sent by the diabetes team, medications, blood glucose readings, weight, hemoglobin A1C or other similar health status information.
- Connection Data: Information on how participants connect to the My Dose Coach app (e.g. type of mobile device used, the mobile device's unique ID, the mobile device's IP address, the mobile device's operating system, and information about the way the My Dose Coach app is used).
- Location Data: The My Dose Coach app does not collect exact location information from the mobile device.

This information is used to allow use and moving around in the app, provide patient support, improve the product and its services, look into any application crashes and errors, protect patient safety and provide updates to the My Dose Coach app. Agreeing to the Privacy Policy when the app is installed on a mobile device gives consent, or allows, the app to collect this information.

STUDY RISKS

The risks of participating in this study are minimal. There is little likelihood of physical risk because of participation in this study. Participants will not undergo any clinical procedures

beyond those used during usual diabetes care. Collection of clinical data will follow usual care procedures and be performed by trained clinical staff. As is usual, patients may experience some physical discomfort during clinical procedures. Participation in this study does involve the potential risk of confusion with clinical treatment and minor psychological distress, but the study team has attempted to minimize the possibility of these risks.

Insulin

Common risks: Low blood sugar (hypoglycemia), which may be serious and life threatening. It may cause harm to your heart or brain. Symptoms of serious low blood sugar may include shaking, sweating, fast heartbeat, and blurred vision.

Infrequent risks: May cause serious side effects that can lead to death, such as severe allergic reactions which may include: a rash over your whole body; trouble breathing; a fast heartbeat; sweating; swelling of your face, tongue, or throat; shortness of breath; extreme drowsiness; dizziness; or confusion. Swelling, weight gain, low potassium levels, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions.

My Dose Coach

There is also potential risk with the My Dose Coach, such as hypoglycemia if an insulin dose was somehow mis-calculated. However, safeguards are built into these products to lessen the likelihood of such risks. In addition, participants may not fully understand the technology process and/or experience frustration.

Text messaging

Text messages are not encrypted or secure during their transmission and could be intercepted.

Surveys

There is a potential for minor psychological distress but the study team has attempted to minimize the possibility of this risk.

Data collection

There is a rare risk of a breach of confidentiality (privacy), but we will do everything possible to protect participants' privacy. To reduce the chances of a breach of confidentiality, all researchers have been trained to protect participants' privacy.

STUDY BENEFITS

There is no guarantee that participants will have any direct benefit from participating in this research.

NEW INFORMATION

Participants will be promptly notified if any new information we learn during this research study may cause them to change their mind about continuing to participate in the study.

PRIVACY (PERSON) AND CONFIDENTIALITY (DATA)

Participants will be assigned a unique study identifier and the linkage code connecting the study identifier with a participant's identity will be stored separately from the research data.

Hard copies of research information are stored behind a double locked environment such as in a locked filing cabinet in a locked office.

Electronic research information is stored on either an UPMC or University of Pittsburgh computer server behind a firewall with limited access using secure computer logins.

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

- University of Pittsburgh Office of Research Protections
- Study Sponsor: Sanofi
- UPMC hospitals or other affiliated health care providers
- Clinicians for patient participants at the Centerville Clinics
- U.S. Food and Drug Administration (FDA)

Study representatives from the University of Pittsburgh will review de-identifiable research information for the purpose of analyzing the study results. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn you or someone with whom you are involved is in serious danger or harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

The investigators may continue to use and disclose, for the purposes detailed above, identifiable information related to your participation in this research study. Per University of Pittsburgh Policy, all research records must be maintained for a minimum of seven years after final reporting or publication of the study findings.

The study sponsor will not have direct access to identifiable personal information in the app. The sponsor contracts with a third party to develop this app and help with the data management. This third party may have access to identifiable personal data and are subject to confidentiality requirements and have committed not to disclose any identifiable information to the sponsor or anyone else unless legally required. The sponsor may have de-identified information of the users of My Dose Coach.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

WITHDRAWAL FROM STUDY PARTICIPATION

You may be removed as a participant on this research study if it is advised by your health care provider to discontinue insulin therapy or if you are no longer able to act independently to follow study procedures due to such reasons as mental/cognitive incapacity or are moved to assisted living.

COSTS

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed only for the purposes of this research study. You will be charged in the usual manner for any procedures performed as part of your routine medical care (care you would receive even if you were not participating in this research study).

PAYMENTS

If you agree to participate in this research study, you may receive up to $125. You will receive $25 for completing the baseline survey and $50 for each completed survey at 3 and 6 months. All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 28% of the payment be sent by the institution to the IRS for "backup withholding"; thus you would only receive 72% of the expected payment.

In addition to monetary compensation, you will be supplied with insulin while you are using the My Dose Coach app in either Phase 1 or both phases of the study, based on your eligibility to move into Phase 2.

COMPENSATION FOR INJURY

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the

costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

VOLUNTARY PARTICIPATION

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future employment at a UPMC Health System facility.

Your physician is involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician.

RIGHT TO WITHDRAW

You understand that you can withdraw from this research study at any time. All data obtained prior to withdrawal from the study will be used in the data analysis.

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CONSENT TO PARTICIPATE

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I will be provided a copy of this consent form for my records.

If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

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Participant's Printed Name Date

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Participant's Signature

INVESTIGATOR'S CERTIFICATION

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of the Person Obtaining Consent Date