University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Imagine to Remember: Improving Medication Adherence in Pre- and Type 2 Diabetes

NCT Number: NCT04157673

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Permission to Take Part in a Human Research Study

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Adult Consent to Participate in a Research Study

Title of research study: Imagine to Remember: Improving Medication Adherence in Pre- and Type 2 Diabetes

Version Date: 4/19/2020

Investigator: Leonard H. Epstein, Ph.D.

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are at least 18 years old, have either pre- or type 2 diabetes, and are on a medication for it or other conditions that are common in those with pre- and type 2 diabetes.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not 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.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to assess the effectiveness of a new intervention for improving medication adherence in individuals with pre- and type 2 diabetes, as well as, those who may be at risk for developing these diseases. We are interested in improving adherence for either oral glucose-regulating medications (like metformin), or medications for conditions that commonly co-occur with pre- and type 2 diabetes, like high blood pressure or high cholesterol.

How long will the research last and what will I need to do?

We expect that you will be in this research study for about 15 weeks from the first to last appointment. Participation includes completing assessment sessions (lasting 1.75-2.75 hours each) and intervention sessions (up to 45 mins each).

For the study, you will be asked to provide information about your demographics, medical history, prescription use, and to use a special study device to track your medication use. You may also complete memory and decision-making tasks at some appointments. For the intervention, you will be asked to attend weekly sessions that involve interacting with an interventionist, and practicing intervention content on your own, with the assistance of study resources such as the website. These

sessions will be completed either in-person or virtually online.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

You may feel uncomfortable answering certain questions about your health and health history, but you can choose not to respond to those questions. There is the possibility of a breach of confidentiality (i.e., that your private information may be seen by someone outside of the research group) but we will take steps to minimize this possibility.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include an improvement in your medical conditions that you have been prescribed medication for, as well as possible improvements in memory. These improvements may or may not last beyond your enrollment in the study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study.

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (716) 829 – 5140, or by imagine2remember@gmail.com . You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 50 people will be in this research study. Some people who are studied may only complete certain parts of the study—not the whole study.

Permission to Take Part in a Human Research Study

What happens if I say yes, I want to be in this research?

We expect that you will be in this research study for about 15 weeks from the first to last appointment. During this study, you will be asked to attend up to 10 sessions either at our laboratory or online. One of these will be a check-in at 6 weeks during baseline (15 minutes), two to four of these sessions will be intervention sessions (lasting 30 to 45 minutes) each that will occur bi-weekly during treatment, and three of these will be assessment sessions (ranging from 1.75-2.75 hours). Baseline and intervention will last a total of 15 weeks maximally. If you are unable to attend a scheduled session, we will try to reschedule you for another day; rescheduling may make the total duration you are in the study longer.

If you decide to take part, you will first complete a consent and screening/baseline assessment appointment. In this appointment, you will be provided an orientation about the study requirements and procedures. After signing this consent form, we may ask you to sign a release of medical records to be sent to your primary care physician and may ask your physician to send us information confirming your diagnosis of prediabetes or type 2 diabetes, as well as other information pertaining to your eligibility for this study (e.g., diagnosis of high blood pressure or high cholesterol; or when you were first prescribed medications for these or other conditions). We may ask you to sign a release of pharmacy records to be sent to your pharmacy and may ask your pharmacist to send us information pertaining to your current prescription drug use and continued prescription drug use while participating in the study (e.g. medications that are related to the treatment of pre-diabetes/ type 2-diabates or other comorbid disorders such has hyperlipidemia and hypertension)

In this initial screening/baseline appointment, you will also complete measures of demographics, health information, medication use, availability over the course of the study period, as well as memory and thinking tasks. If, based on some of these measures in the initial screening/baseline appointment, you no longer appear to be eligible we may stop the appointment early. If you are eligible, you will be given a special study medication bottle and cap, and be trained how to use them for the study.

During the baseline sessions, we will assess your medication adherence in addition to having you complete some questionnaires. These questionnaires may include thinking and memory tasks.

During each intervention meeting, we will assess your medication adherence in addition to meeting with your interventionist. The intervention sessions will consist of interview-style and/or interactive activities administered by an interventionist. You may also be trained to use self-generated cues about the intervention content, which may be audio-recorded and available in a computer-based program that our research group has developed. This program can be accessed by smartphone, tablet or computer. Intervention sessions may be recorded to ensure treatment is provided as planned.

The length of baseline and intervention periods you get will be chosen by chance, like flipping a coin. Meaning though the intervention and baseline period will last 12 weeks the length of each portion within that time frame will vary depending on your group. Neither you nor the study team will choose what group you get. You will have an equal chance of being given each group.

At the end of the intervention, you will be asked to attend one more session in which you will complete additional questionnaires, thinking and memory tasks.

Upon completion of the study, you will be debriefed.

You may be assigned to a small group of pilot participants to help with quality assurance and validity of data collection procedures. In this case, you may complete fewer sessions and/or fewer procedures than those described above. If you are assigned to this pilot group of participants, you will be notified at the time of consent.

Permission to Take Part in a Human Research Study

Throughout the study, we may stop your participation if you do not, or are unable to, complete any of the study procedures. We may also stop an ongoing session, or end your participation in the study, because we have collected all the information we need.

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

If you take part in this research, you will be responsible for adhering to study procedures and attending study sessions. Specifically, you will be responsible to:

- Bring requested medications and other related materials as instructed to study sessions
- Meet consistently with an interventionist for the 6-week intervention period
- Participate in weekly check-in phone calls
- Return equipment provided to you at the end of the study

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you decide to leave the research, no further data will be collected, but any information that had been provided may be retained by the researcher and analyzed.

Is there any way being in this study could be bad for me? (Detailed Risks)

You may feel uncomfortable answering some of the sensitive questions in this study about your health and decisions. You may refuse to answer any questions you feel discomfort answering and may choose to withdraw from the study for any reason, at any time. You may experience side effects from your medication if your adherence to it increases. Additionally, several of the research center personnel who will conduct study sessions are certified in CPR, first aid, and AED. All personnel who conduct study sessions are trained to contact appropriate medical personnel in the event of an emergency.

Due to the public nature of the internet, any data collection completed online does create potential breach of confidentiality issues. This occurs when your private information is accessed without yours and the research team's permission and then disclosed to a third party. However, all data collected during your sessions will be de-identified and your responses will be linked to a unique participant ID. Additionally, there are security features in place that makes a breach of confidentiality very unlikely to occur.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. All questionnaires will be coded with a numeric code. The numeric code will be linked to your identity through a master list retained by delegated team members. The only written connection between your participation in this study and the study itself will be this signed consent form but your identity will not be made a part of any published findings resulting from this study.

The study team must release certain information to the appropriate authorities if at any time during the study there is concern that child or elder abuse has possibly occurred or you disclose a desire to harm yourself or others. We may contact your physician if at any point during the study you appear in great distress.

Permission to Take Part in a Human Research Study

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. Any such de-identified information will remain on a secure server hosted by the School of Medicine and Biomedical Sciences of the University at Buffalo and/or in locked storage in the offices of the Division of Behavioral Medicine.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical and pharmacy records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Federal law provides additional protections of your medical/ pharmacy records and related health information. These are described in the HIPAA section of this document.

Due to the COVID-19 pandemic any information related to risk of participant/ staff safety in regards to symptoms of the virus may be reported to the Health Department if necessary. This information may include personal information such as name and other relevant demographic information.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to attend scheduled appointments, failure to follow directions, changes in prescription of medications or discontinuation of medications, or nonsystematic responding on questionnaires. If this occurs, you will be debriefed about the nature of the study and be compensated for the amount of time spent in the study. We may also stop an ongoing session, or end participation in the study because we have collected all the information we need.

What else do I need to know?

Who is paying for this research?

This research is being funded by the National Institute of Diabetes and Digestive and Kidney Diseases.

Will I get paid for my participation in this research?

If you agree to take part in this research study, we will pay you up to $150 for your time and effort. You will receive $35 for completion of each of the three assessment sessions ($35 x 3 = $105), and will receive bonuses in the following amounts if you (a) complete all three assessment sessions ($25), (b) return the electronic medication cap and study bottle to the research staff at the end of the study ($20)

Payments that you receive for your participation in this research are considered taxable income. If the amount of payment that you receive reaches or exceeds $600.00 in a calendar year, you will be issued a form 1099.

What will happen to my information and samples?

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Permission to Take Part in a Human Research Study

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

_√__ Information from your full medical records: We may collect information confirming your diagnosis of prediabetes, type 2 diabetes, and other information pertaining to your eligibility for this study (e.g., diagnosis of high blood pressure, high cholesterol; prescription history, pharmacy records)

_√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

__√_ Principal Investigator or designee

C. Who is authorized to receive the information from the information providers identified in (B)?

__√_ Principal Investigator or designee
_____ Other(s) (identify):

D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√_ The sponsor of this research study: the National Institutes of Health.
__√_ The organization(s) responsible for administering this research such as the UB Institutional Review Board and research protection groups that provides ongoing review of the research project.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain

government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?

___√__a. This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall
Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	