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

Weight Loss for Prediabetes Using Episodic Future Thinking (MINDD4)

NCT Number: NCT03670602

Document Date: 1/15/2021

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: MINDD 4: Prediabetes, Delay Discounting, and Weight Loss.

Version Date: 6/18/2020

Investigator: Leonard Epstein, Ph.D. (UB)

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 an adult at risk for Type 2 Diabetes and may have hypertension (high blood pressure) and/or hyperlipidemia (high cholesterol).

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 behavioral weight control program to improve weight loss, decision-making, and blood sugar over a 6-month period in adults with prediabetes.

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 six months. You will attend an in-person screening session that will last up to two hours. If you are not eligible to continue, we may end the screening session early. If you are eligible to continue, during the first 2 months, you will attend weekly group meetings and during months 3-6, you will attend group meetings every other week and then once per month. These group meetings will last up to one hour each. You will also have sessions with a case manager before or after group meetings that will last up 30 minutes each. During weeks when you do not come into the lab to meet with your case manager, you will have phone meetings with them. You may also elect to complete a final research visit 6 months after the initial treatment period has ended.

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 some of the sensitive questions in this study about your health and decisions. You may experience hunger from changes in eating patterns and possible discomfort related to changes in physical activity. You may also experience possible discomfort or bruising from blood glucose and/or cholesterol testing.

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 weight loss, improved control of blood sugar levels, and changes in your eating and physical activity behaviors. You may also learn about the experimental research process and your health.

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.

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 716-829-3400. 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 80 people to complete this research study. About 400 people will be enrolled nationally.

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

If you decide to take part, you will first complete a consent and screening 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. We may

ask them to send us information confirming your diagnosis of prediabetes including any information pertaining to your eligibility for this study or comorbid medical conditions (e.g., high blood pressure, high cholesterol). We may also 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 or other disorders such has hyperlipidemia and hypertension). We will then give you a tour of the research center and describe the tasks in detail that you will be completing throughout the study.

You will complete assessments where we will collect demographic and health information and you will have your height, weight, blood glucose, blood pressure, and cholesterol measured. You may also complete tasks to measure your thinking and memory skills. If you are a female, you may be asked to provide a urine sample to test for pregnancy. If throughout the study there is reason to believe you have become pregnant (i.e. you express that there is believe), we will provide pregnancy testing. If the pregnancy results are positive, you will be informed and will be ineligible to continue with the study. Receiving a copy of your results and sending a copy of your results to your physician are optional and you have the right as a research participant to not participate in this portion of the study.

We will also review your responses from the eligibility survey you completed (prescreen survey) and discuss responses or any new discoveries that may affect your adherence to this study. At the end of the screening session you will not know if you are eligible to continue with the study. The research team will review your responses and collected measures and follow up with you within one week to inform you of your eligibility. If you are eligible at that time, we will schedule for the first assessment session. With your permission, if you are deemed ineligible due to blood glucose values near to but below the prediabetic threshold (hemoglobin A1c from 5.4-5.6%), we may elect to contact you at a later date to re-screen you.

I would like to be re-screened at a later date if my blood glucose values are below but near the prediabetic threshold:

___ Yes ___ No

I would like to have a copy of my blood sample and/or blood pressure results:

___ Yes ___ No

I would like to send a copy of my blood sample and/or blood pressure results to my physician:

___ Yes ___ No

If your blood pressure and/or blood sample results are considered critical, we will provide you with a copy of your results, advise you to follow up with your physician, and send the critical results to your primary care physician or our study physician who can provide the appropriate medical referral. After you leave the study session today, if you decide you do not want your results sent to a physician, please contact the primary investigator at (716) 829-3400. Additionally, based on responses to questionnaires in this study, if you may be at risk for depression or an eating disorder, your primary care physician may notified who can provide the appropriate medical referral.

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All participants in this study will receive access to an effective weight loss program. We are also comparing the effectiveness of two possible additions to this program. It is not clear which of these additional treatments is better. Therefore, you will be assigned to one of two groups that experiences one or the other. Which group you are assigned to will be chosen by chance, like flipping a coin. You will not be told which treatment you are getting, however some of the researchers will know.

For both groups, during each treatment meeting, you will be weighed and then have about a 60-minute group session either preceded or followed by a 20-30 minute session with a case manager. The group sessions review information about weight loss and maintenance and engage in-group problem solving for participants who are struggling with behavior change. Intervention sessions may be audio or video recorded to ensure treatment is provided as planned.

Participants in both groups will meet with a case manager to review progress. During the individual meeting with your case manager, you will be taught behavior change techniques and review and address diet and activity self-monitoring and any barriers to adherence with the weight-loss behaviors. Quizzes to assess mastery of educational materials will be given. You will receive feedback and your interventionist will assist with your progress and problem solving and communicate with you to structure solutions. One treatment group will also be trained to use self-generated cues, or positive thinking cues, that they will use daily. These cues 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 and you will be trained on how to use our web-based mobile system.

In response to the coronavirus outbreak, intervention sessions may also be carried out via video conference that may also be recorded. You will also be asked to complete monthly assessments regarding the impact of coronavirus on your life and decision-making.

With your permission, you may also be re-contacted for a longer-term follow up consisting of an assessment session about 6 months after the completion of the initial 6-month study period, meaning about 12 months after your initial baseline session. At the 12-month assessment we would again measure your weight and A1c, and you may also complete tasks to measure your thinking and questionnaires regarding the impact of coronavirus on your life and decision-making. This elective 12-month assessment would be conducted via video conference and would not necessitate your attendance at the lab.

I consent to being re-contacted after the 6-month assessment for an additional assessment session at about 12-months after treatment begins:

___ Yes ___ No

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.

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:

- Be weighed at the beginning of each session.
- Have your height, blood glucose, blood pressure, and cholesterol collected.
- Answer questions about your preferences and you will have your memory tested.
- Wear an activity monitor.
- Participate in weekly, bi-weekly, and monthly group sessions as well as individual case manager sessions.
- Complete assigned readings and quizzes from our Healthy Habits manual.
- Record your dietary intake and physical activity.
- Receive study text and/or email messages and access information on a study website.
- Answer questions regarding the impact of coronavirus on your life and decision-making.

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

You can leave the research at any time and 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 hunger from changes in eating patterns and possible discomfort related to changes in physical activity. You may also experience possible discomfort or bruising from blood glucose and/or cholesterol testing. This bruise should fade over time without treatment. If your blood glucose exceeds the range for prediabetes, you will be informed and directed to your physician or other medical care provider for further evaluation. 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 deidentified 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. In order to monitor this research study, representatives from federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect research records which may reveal your identity.
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 audio recordings of treatment sessions (one on one sessions with your case manager) will contain your voice and may have reference to your first name, however, no other identifying information will be available from this recording. These recordings will be stored as an electronic audio file (e.g. mp3) on a secure and encrypted server that is password protected, which only research staff will have access to. Audio recordings will be used to ensure treatment is being provided as planned and will be listened to be a supervisor to give feedback to your case manager. After the audio is reviewed and feedback is provided to your case manager, the recording will be deleted. In most cases the audio recording will be deleted within two weeks, but may be retained for the duration of the study. Once the study is complete all audio recording will be deleted.

The video recordings of treatment sessions (group sessions) may contain your voice and may have reference to your first name (e.g. when you are participating in discussion points), however we will set up our video camera in such a way that only the group leader and presentation material (e.g. PowerPoint presentation) will be recorded. No other identifying information will be available from this recording. Video files will be stored on a secure and encrypted server that only research staff will have access to. If you miss a group session and would like to view the video of the group session, the video file will be transferred to our lab's Amazon Drive, and you will be given a link to view the video. Only you, others who missed the group session, and the research team will be able to view the video. All videos will be deleted at the end of the study.

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

The study team must release certain information to the appropriate authorities if at any time during the study there is concern that child abuse or elder abuse has possibly occurred or you disclose a desire to harm yourself or others.

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration may 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.

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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 follow directions, nonsystematic responding to questionnaires, or HbA1c (blood sugar) levels that are not in the prediabetes range. 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?

This study will ask you questions about recent depression. If you score high on a depression questionnaire, you will be provided with a list of resources and your physician may be notified.

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 $250 for your time and effort. You will be compensated $10 for completing the screening session and if eligible to continue, you will be compensated $10 for completing the baseline assessment session. You will also be compensated $20 for wearing the activity monitor for 7 days and completing the food recall for 3 days. You will also be compensated $30 at the 3-month assessment session and $20 for wearing the activity monitor for 7 days and completing the food recall for 3 days. You will be compensated $40 at the 6-month assessment session and $20 for wearing the activity monitor for 7 days and completing the food recall for 3 days. You will be compensated $10 for completing monthly assessments regarding stress, social connectedness, life changes, complete decision making tasks, and answer questions about the impact of coronavirus on your life and on people you know (up to 6 monthly assessments at $10 each). Finally, if you elect to participate in the longer-term follow up assessment session at about 12 months, you will be compensated $30 for completing the assessment session and $10 for answering questions regarding the impact of coronavirus on your life and decision-making.

Payments will be made after each completed assessment session. Participants who rely on public transportation or taxi or travel from outside of the city limits may be compensated additional to account for the round trip. Incomplete sessions will be paid on a prorated basis.

If you receive a single gift card or debit card deposit of $100 or greater, you will be asked to complete an IRS Form W-9. This form will be held confidentially by the research team and those responsible for administering research funds.

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 are my alternatives to participating in this research study?

Instead of being in this research study, your choices may include consultation with your physician for any health concerns. The important risks and possible benefits of these alternatives include: meeting with a professional familiar with your health history, which may have a monetary cost associated.

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What will I be told about clinically relevant research results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will let you know what they have found. If your blood pressure and/or blood sample results are considered critical, we will provide you with a copy of your results, advise you to follow up with your physician, and send the critical results to your primary care physician or our study physician who can provide the appropriate medical referral. You may have to pay for those additional services yourself.

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 including any information pertaining to your eligibility for this study and comorbid conditions (e.g., high blood pressure, high cholesterol, HbA1c measures, 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
__√__ Others: Your primary care physician and your pharmacy

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

__√__ Principal Investigator or designee
__√__ Others: Your primary care physician

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 National Institutes of Health or other government agencies that oversee research with humans.

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__√__ The organization(s) responsible for administering this 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 will this information be kept by the Principal Investigator?

___√__ 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.

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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.

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	