INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

eIMPACT-DM Pilot Trial: Depression Treatment to Reduce the Excess Diabetes Risk of People with Depression and Prediabetes

National Institute of Diabetes and Digestive and Kidney Disease, National Institutes of Health (R21DK123582)

ClinicalTrials.gov Identifier: NCT04437485

5.6.21

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with your regular healthcare providers or your relationship with the study team.

WHY IS THIS STUDY BEING DONE?

Diabetes is a common medical condition that can lead to disability, heart disease and other medical conditions, and death. People with depression have a higher chance of developing diabetes than people without depression. The main symptoms of depression are (1) feeling down or depressed and (2) having little interest or pleasure in doing things.

The purpose of this study is to compare standard depression treatment to a new depression treatment to see if the new depression treatment lowers the chance of developing diabetes in the future. You were selected as a possible participant because your medical records show that you are a patient at an Eskenazi Health primary care clinic, are 18 years or older, and have one or more risk factors for diabetes but have not developed diabetes. Your responses to our depression questions also show that you may have a depressive disorder.

The study is being conducted by Dr. Jesse Stewart from the Department of Psychology at Indiana University-Purdue University Indianapolis (IUPUI) and other researchers from the Indiana University School of Medicine. It is supported by a research grant from the National Institutes of Health.

We will use the data from this study to develop new depression treatments that could be easily used in primary care clinics. We hope that these new depression treatments will help prevent diabetes in people with prediabetes.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of 64 people taking part in this research locally.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will be asked to attend a pre-treatment visit and a post-treatment visit six months later. The pre-treatment visit is the start of the study, and the post-treatment visit is the end of the study.

At the pre-treatment visit, you will be randomly assigned to Group A or Group B, as if a coin were flipped to decide. You will be notified of your group assignment. No matter which group you are assigned to, you and your healthcare providers will continue to make your own treatment decisions. Neither you nor your healthcare providers will be able to choose your group assignment.

If you are assigned to Group A (standard depression treatment), you will also be asked to complete five calls with a study assistant over the six months to review depression handouts and to measure your depression. The study assistant will send your depression results to your healthcare providers (primary care provider, counselor, and/or psychiatrist) at your usual primary care clinic at Eskenazi Health and encourage them to treat your depression. You and your usual healthcare providers at Eskenazi Health will decide how to treat your depression during the study.

If you are assigned to Group B (new depression treatment), you will be asked to complete additional calls and visits to receive the new depression treatment called eIMPACT-DM over the six months. A study counselor will work with you and your usual primary care provider at Eskenazi Health to treat your depression during the study. Established depression treatments will be available to you, like antidepressant medicines and talk therapy. You will also have the opportunity to receive newer treatments, like talk therapy on a computer or over the phone. If your depression does not improve, the treatment will be changed to see if another one works better for you.

Each study visit and call is described in more detail below. Please note that we will not audio or video record any of your phone calls or visits in this study.

<u>Pre-Treatment Visit (All Participants)</u>
You will be asked to come to the Clinical Research Center at Indiana University Hospital for the 2½-hour pre-treatment visit. You will need to fast (nothing to eat or drink, except for water) and avoid tobacco products or exercise for at least 8 hours before the visit. You may use water with your medications, but if you need to take medications with food, please bring them with you so you can take them at the end of the visit.

At the pre-treatment visit, the nurse will first obtain a finger-stick blood sample to make sure that you have an A1c below 6.5%, which is required for this study (6.5% and above is the diabetes range). Women able to become pregnant will also complete a urine pregnancy test. If you have an A1c in the diabetes range or a positive pregnancy test, your participation in this study will end, and you will be

paid for your time and effort. Next, the nurse will measure your height, weight, blood pressure, heart rate, respiration rate, and temperature. The nurse will then complete a standard blood draw to collect ½ a tablespoon of blood. This is similar to what your doctor would collect for usual blood tests. This blood will be used to look at your A1c and your insulin resistance. After that, you will be asked to fill out questionnaires on a secure computer in a private room and complete an interview with the study assistant. These questionnaires and the interview will ask you for your basic background, physical and mental health history, and medicines. You will also be asked about your behaviors, mood, and sleep.

Treatment for Group A

If you are assigned to Group A, you will receive standard depression treatment over six months. You and your usual healthcare providers at Eskenazi Health will decide how to treat your depression during the study.

At the end of your pre-treatment visit, you will speak to a study assistant for 20 minutes over IU Zoom Health to review depression materials, including treatment options. IU Zoom Health is a secure form of communication in use at many medical centers. You will also be given a list of mental health services available to Eskenazi patients and will be encouraged to follow-up with your usual primary care provider about your depression. Your primary care provider will also receive a letter from the study team informing them of your depression and assignment to Group A. This letter will also encourage your primary care provider to work with you to address your depression and will provide the same list of available mental health services. Second, you will also be asked to complete five calls with a study assistant over the six months. Each call will be 10 minutes to measure your depression and will occur each month. The study assistant will send your depression results to your healthcare providers (primary care provider, counselor, and/or psychiatrist) at your usual primary care clinic at Eskenazi Health and encourage them to treat your depression if your depression scores remain high. Please note that there are no restrictions on the care you can receive during the study, meaning that you will still have access to and will receive any health services that are part of your usual care.

Treatment for Group B

If you are assigned to Group B, you will receive the new depression treatment called eIMPACT-DM over the six months. A licensed mental health counselor, called a depression clinical specialist (DCS), will work with you and your usual primary care provider at Eskenazi Health to treat your depression.

At the end of your pre-treatment visit, you will speak to the DCS over IU Zoom Health for 20 minutes to review depression materials and schedule your first call. During your first call, the DCS will review additional depression materials and discuss your treatment options and preferences. The DCS will then work with you, the study psychiatrist, and your primary care provider to develop an initial treatment plan that is okay with everyone.

The treatment options are:

- Good Days Ahead: a talk therapy for depression on a computer
- Problem-Solving Treatment for Primary Care (PST-PC): a talk therapy for depression over the phone or IU Zoom or in-person

If Good Days Ahead is selected, you will have the opportunity to complete nine 45-minute sessions on a computer, about one per week. Sessions will take place at Dr. Stewart's research office or a location

selected by you where you can access a computer with internet, like your home, your work, a family member's or friend's home, or a public library. Your preference will determine the location. Good Days Ahead is a computer program, so you will not be meeting face-to-face with a counselor. By completing the sessions on a computer, you will learn techniques that have been shown to improve depression. These techniques include examining unhelpful thoughts, scheduling pleasurable activities, and using effective coping strategies. The topics will be designed for your specific needs, and you can work through the sessions at your own pace. Between these sessions, you will be given projects to help you learn how to use the techniques. This program can be used by people with little computer experience.

If PST-PC is selected, you will have the opportunity to complete eight weekly 30-minute sessions with the DCS over the phone or IU Zoom or in-person at Dr. Stewart's research office. By completing PST-PC sessions, you will learn skills for solving real-life problems contributing to your depression.

No matter which option is selected (Good Days Ahead or PST-PC), you, the study psychiatrist, and your primary care provider will have the ability to decide if antidepressant medicine is a good idea for you to take in addition to participating in the treatment sessions. If an antidepressant medicine is selected, it will be recommended by the study psychiatrist and will be prescribed by your usual primary care provider. The DCS, the study psychiatrist, and your primary care provider will monitor the use of these medicines.

Over the six months, the DCS will have regular contact with you to see how you are responding to the treatments. The DCS will share your progress with your primary care provider. Initially, the DCS will contact you at least every 2 weeks. After your depression improves, the DCS will contact you once a month. If your depression does not improve, the DCS will call you to discuss other treatment options described above. The main idea is that, if your depression does not improve, your treatment will be changed to see if another option works better for you. Please note that there are no restrictions on the care you can receive during the study, meaning that you will still have access to and will receive any health services that are part of your usual care.

Study Newsletter (All Participants)

Three months after you enrolled in this study, the study team will mail a study newsletter to your home address. Each newsletter will be one page and will include an update from the Principal Investigator, a healthy recipe, profiles for the team members, and a reminder to update the study team if your contact information has changed.

Post-Treatment Visit (All Participants)

Six months after the pre-treatment visit, you will be asked to come back to the Clinical Research Center at Indiana University Hospital for the 2½-hour post-treatment visit. This visit will be identical to the pre-treatment visit. If you are still screening positive for depression at the post-treatment visit, the study team will send your primary care provider a letter urging them to follow-up with you about your depression.

Medical Records Review (All Participants)

We are requesting permission to review your medical records from 5 years before the date you enroll in this study to 5 years after your last study visit (the post-treatment visit). To achieve the goals of this study, we need to review your medical history to make sure you are eligible, and we need to track your

health over time. We are examining the short- and long-term effects of depression treatment on physical health, especially diabetes. You do not need to do anything to complete this part of the study.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

Risk of a possible loss of confidentiality
All study personnel are trained in human subjects protection and will make every effort to ensure that your confidential information is kept confidential and secure.

Risk of possibly experiencing emotional discomfort when completing interviews or questionnaires
The study assistants and DCS are experienced and will be sensitive to the nature of the questions. You may terminate the interviews or questionnaires at any time for any reason. You may choose not to answer any question.

Risks of the standard blood draws
Trained and experienced nurses will use standard approaches (finger stick and inserting a needle into a vein) to obtain the needed blood samples. This can be mildly painful, and there is a very low risk of bruising, fainting, or a skin infection. You may terminate a blood draw at any time for any reason.

Suicidal Thoughts
Because this study involves people with depression, some participants may report thoughts of being better off dead or of hurting themselves. This could happen during a call or an in-person visit. *IF* this occurs, our protection plan will be used. You will first be asked follow-up questions. Dr. Stewart (a clinical psychologist) and the study psychiatrist will review the information the same day to determine the right course of action. If we believe that you are in imminent danger of harm, we will have to report it, potentially to authorities including the police, for your own protection. We may contact your primary care provider and the behavioral health clinician in your primary care clinic. We may also consult with the Sandra Eskenazi Mental Health Center and escort you to the Crisis Intervention Unit at Eskenazi Hospital. If you prematurely terminate a call after reporting suicidal thoughts, Dr. Stewart and the study psychiatrist will determine the right course of action and may carry out any of the steps described above. After getting input from your primary care provider, we may decide that is important for your own safety to end your participation in this study.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
By taking part in the study, you will learn about the relationship between depression and diabetes at the post-treatment visit when we review a handout with you. We hope that you will benefit from being in this study by getting treatment for your depression. We also hope that by treating your depression, your risk for diabetes will decrease, although there is no guarantee of that. Your involvement will generate knowledge that may help to treat depression and prevent diabetes in the future.

WHAT ARE THE OTHER TREATMENT OPTIONS?
Instead of being involved in this study, you have the option to not participate. If you decide not to participate, you may choose to seek depression treatment outside of the study. The main treatments for depression are antidepressant medicines and talk therapy, such as cognitive-behavioral therapy. You may want to contact your primary care provider to discuss your treatment options. If you choose not to participate, your decision will not affect your relationship with your regular healthcare providers or your relationship with the study team.

WILL I RECEIVE MY RESULTS?
We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. Specifically, depression results, blood sugar and A1c results, and vital signs (blood pressure, heart rate, respiration rate, and body temperature) will be shared with you and your usual primary care provider if the values fall outside of safety limits. If this occurs, you will be notified during that study visit or call. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

HOW WILL MY INFORMATION BE PROTECTED?
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include the study investigators and their research associates, the Indiana University Institutional Review Board or its designees, the Indiana Clinical Research Center, the study sponsor (the National Institute of Diabetes and Digestive and Kidney Disease/National Institute of Health), and state or federal agencies (for example, the Office for Human Research Protections).

A description of this clinical trial is available on ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT04437485), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. 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.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
Information or specimens collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

We will not use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA.

WILL I BE PAID FOR PARTICIPATION?
You will receive payment for taking part in this study: a $75 Visa gift card (which can be used most places that accept debit cards) for completing the pre-treatment visit and another $75 Visa gift card for completing the post-treatment six months later. If you complete all visits, you will receive a total of $150 in Visa gift cards. You will not be paid for completing any visits or calls related to depression treatment. If you show up for your pre-treatment visit but do not pass the A1c screen (value is 6.5% and above) or pregnancy screen (positive test), you will receive a $15 Visa gift card for your time and effort. If needed, we will arrange for transportation (e.g., a taxi or ride share) to and from all study visits or provide vouchers to cover parking or public transportation costs.

WILL IT COST ME ANYTHING TO PARTICIPATE?
While there are no costs directly associated with participation in this study, you or your insurance company will be responsible for any depression treatments (therapy, medications, etc.) which you would receive if you were not participating in the study. The costs of all study-specific tests and procedures will be provided by the study. However, taking part in this study may lead to added costs to you or your insurance company in the unlikely event of physical or emotional injury resulting from participation in this study. If you have any questions about what costs you will be responsible for, please ask someone on the study team.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?
In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health insurance will be your responsibility. It is also your responsibility to determine the extent of your healthcare coverage. There is no program in place for other monetary compensation for research-related injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
You are encouraged to ask questions any time during the study. For questions about the study or a research-related injury, contact the principal investigator, Dr. Jesse Stewart, at (317) 274-6761. In the event of an emergency, you may call 911 and/or your primary care provider.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, you may do so by notifying any member of the research team (including the principal investigator) at any time by phone, email, or in person. Not taking part in this study will not affect your general healthcare. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

The study investigators may need to take you off the study without your permission if we believe that it is not in your best interest for you to participate.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____