INtegrating DEPrEssioN and Diabetes treatmENT (INDEPENDENT) Study

Informed Consent version date: May 29, 2017

NCT02022111

PARTICIPANT INFORMATION SHEET & CONSENT FORM

(Please give one copy to the participant and keep a copy for the Investigator)

Site Investigator: _____ **Study Site:** _____

Study Title: Integrating Depression and Diabetes Treatment (INDEPENDENT) Study

Coordinating Centre: Madras Diabetes Research Foundation, Chennai, India

Sponsor Names: National Institute of Mental Health, National Institutes of Health, USA

Introduction:

You are invited to participate in a study for individuals with diabetes who are not controlling their blood glucose (sugar), blood pressure, or cholesterol, AND are feeling low, "tension", or depressed. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. To participate or not is entirely your choice. If you decide to participate, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.

Before making your decision:

- Please carefully read this patient information and consent form or have it read to you
- Please ask questions about anything that you do not understand

You can have a copy of this consent form if you would like to review it at home. You are free to discuss this information with members of your family or your doctor. Take as much time as you need to think about whether you would like to participate. By signing the consent form you will not give up any legal rights. If you decide to participate, you will be asked to sign the consent form, along with a study doctor, to indicate that you understand what the research study is about and what is involved in your participation.

Why are we doing this study?

Having poorly controlled blood glucose (sugar), blood pressure, or cholesterol, and feelings of depression increase the risk of serious illnesses like heart attack, heart failure, stroke (brain injury caused by blocked blood flow), blood clots, kidney disease, eye, foot and skin problems, and nerve damage affecting the sense of touch. In this study, we will test whether using a care coordinator to help you and a computerized decision-making system to help your doctors and nurses is better than usual diabetes care for controlling blood sugars, pressure, and cholesterol, as well as lowering feelings of depression. We are doing this study to see if there are better ways to care for people with diabetes and depression. A total of 360 people at 3 clinics in India will be involved in this study for 2 years. About 120 participants will be selected from this clinic to participate in the study.

If you agree to participate, you will be randomly assigned by the computer to one of two groups: either (1) letting your usual doctor know about your diabetes control and feelings of depression and continuation of

your care as usual, or (2) frequent monitoring by an additional staff member (care coordinator), a computerized support program that helps the doctors who are overseeing your diabetes and depression care by updating them about your progress, and review of your diabetes and depression care by a panel of senior doctors. The care coordinator will also remind the patients about appointments and visits, and help patients follow the physician's advice. The treatments given to patients in both the groups will remain the same. However, the people working with the care coordinator and computerized system will receive more active help with managing their health.

There is a 50:50 chance of being assigned to either of the two groups (like the flip of a coin). The group assignment each person receives is decided by chance only ("random allocation").

During the Study:

If you are interested in participating, you will have two appointments at the beginning of the study to determine if you are eligible to participate in the study. The first visit may be conducted over the phone or in person. During the first visit you will be given information about the study and asked for your verbal consent to answer a brief set of questions about your health and feelings. If at any point you disclose thought about killing yourself, the study staff may not be able to keep this information confidential. Depending on how much you feel like hurting yourself, the study staff may involve other study staff members, trusted family members, or mental health professionals.

If you are still eligible to participate after this first appointment, you will be invited to come into the clinic for a second visit. You will be asked to fast overnight before the second visit. For this second study visit, you will be asked to review and sign this consent form at the beginning of the visit. If you are unsure you would like to participate in the study or sign this form you may leave and return with the form at a later date. If you decide to sign the form you will be asked detailed questions about your past and current medical history, medications, and feelings. You will be informed at this visit if you qualify to participate in the study. If you qualify, you can choose if you would like to enroll. If you choose to enroll you will be asked additional questions, undergo a physical exam, and a blood draw. The blood tests may include checking your blood sugar and cholesterol levels, and checking to see if your kidney and liver are functioning normally. The amount of blood taken will be no more than 2 teaspoons (10 ml). A urine test for kidney function and pregnancy test (if applicable) may also be done.

If you are enrolled in the study, you will be called by study staff for check-ups at the clinic every 6 months (all the tests at these 6-monhtly visits will be paid for by the study) and possibly additional visits with the care coordinator.

Subsequent follow-up clinic visits: The expected time that you will be followed-up for this study is 2 years. Those assigned to getting usual care will be seen based on the doctor's recommendations, with a visit every 6 months for study-related tests which include some questionnaires and blood tests. For these 6-monthly tests, a study staff member from the clinic will call you to arrange your visit. Those assigned to the group with the care coordinator and computerized care system may be called back to the clinic more often to meet with the care coordinator.

Risks and Discomforts:

This study will not cause you any harm or discomfort more than your existing care for diabetes. When blood is drawn for lab tests during the study, there is a small possibility of bruising, discomfort from the needle puncture, and infection. At present, there are no other anticipated risks or side effects.

You may not participate if you are a woman of childbearing potential who is not using an approved birth control method, if you are pregnant, or if you are nursing. If you become pregnant during the course of the study, you should notify the study doctor of this fact immediately, since diabetes and depression during pregnancy requires more careful management, different from the standard care planned in this study, which is for non-pregnant adults. You may also not participate in this study if you have had previous severe mental illnesses like bipolar disorder or are currently using medication for mental illness.

Benefits:

The benefits to you for participating in this study are that you may become more aware of your condition and treatments with increased clinic visits. However, we do not know which of the two study groups is better, so you may receive no direct benefit from participating. Information gathered from this study may be helpful to the future management of diabetes and depression for others that are affected by these conditions.

Participation in this study will not cost you anything, as all the tests will be paid for. In addition, you will receive 200 Indian rupees to cover your travel costs for the 6-monthly testing visits.

How this Study is Different from Usual Care:

Some diabetes clinics in India already use additional staff for patient follow-up, which is similar to the care coordinator. Some hospitals make use of electronic health records for collecting patient information, which is similar to the computerized system in this study. However, we do not know whether using a care coordinator and computerized system together helps the doctors caring for you and improves your condition more than usual care. In this study we will be using both methods.

Confidentiality:

During your participation in this study, the research staff will collect information related to your health. Your information will be safely stored locally and sent to the study Coordinating Centre in Chennai. Your information will be kept in a secure location and only authorized personnel can access it. The Coordinating Centre will store and process your information electronically. In the electronic database, your information will be identified only with a code number. At the end of the study, all identifiers that can link you to your information will be destroyed; the remaining information will be stored for 3 years and securely disposed thereafter. Blood samples will only be identified with a code number.

By signing the consent form, you are agreeing to allow the study monitors, government regulatory agencies, and Research Ethics Boards to examine your medical records. Your name will not be shared unless the law requires it. You will not be identified personally in any of the reports, publications, or presentations about this study.

Withdrawal of Participation:

It is entirely your decision to participate or not participate in this research study. You can leave the study at any time for any reason. If you decide to leave the study before it ends, we will ask you for the reasons for withdrawal, but you do not have to provide the reasons. There will be no penalty or loss of benefits if you decide not to participate or decide to withdraw.

Your participation can also be stopped by your study doctor or the study sponsor for the following reasons:

- Any undesirable effect appears
- If you do not comply with the requirements of the study
- If your study doctor or the sponsor has the opinion that it would be in your best interest to withdraw from the study
- If the sponsor stops the study

Inquiries/Questions:

If you have any questions about the research that is being conducted, develop a research-related problem, or note a change in your condition, you should contact the Site Investigator:

[Name of Site Investigator]
[Address of Site Investigator]
[Phone number of Site Investigator]

Should you have any questions regarding your rights as a research participant, you should contact:

[Name of Head or Member Secretary of ethics committee]
[Role on Ethics Committee (e.g., Head, Member Secretary], [Name of ethics committee]
[Address of ethics committee or contact person]
[Phone number of contact person]

CONSENT FORM

(Please give one copy to the participant and keep a copy for the Investigator)

Study Title: Integrating Depression and Diabetes Treatment (INDEPENDENT) Study

Participant: Mr/Mrs/Miss _____ _____ ____ / ____ /_____; _____ years
First Name Last Name Birth Date (dd/mm/yyyy); Age

Please read the following before putting your signature below:	Place [**X**]
(i) I confirm that I have read and understood the information in this consent form and have had the opportunity to ask questions.	[ ]
(ii) I understand that participation in this study is entirely my decision and that I may withdraw at any time without giving any reason and without my medical care or legal rights being affected.	[ ]
(iii) I understand that the information collected in this research study may be reviewed by the ethical oversight, government regulatory agencies, and study team or sponsors to ensure that the research study is being conducted properly and ethically, even if I withdraw. I understand that my identity will not be revealed in any information released to third parties or published.	[ ]
(iv) I agree not to restrict the use of any of my information or results that arise from this study provided that the information is used only for scientific purposes.	[ ]
(v) I have been given a copy of this consent form to keep. By signing this form I have not given up any legal rights.	[ ]

_____ Date: ___ / ___ /_____
Signature/Thumb Impression of Participant

_____
Printed Name of Participant

_____ Date: ___ / ___ /_____
Signature of Investigator

_____
Printed Name of Investigator

_____ Date: ___ / ___ /_____
Signature of Witness (or Legal Representative)

_____
Printed Name of Witness (or Legal Representative)