

eIMPACT Trial:

Modernized Collaborative Care to Reduce the Excess CVD Risk of Older Depressed Patients
(ClinicalTrials.gov ID: NCT02458690)

Informed Consent Statement
7/13/2018

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

eIMPACT Trial: Modernized Collaborative Care to Reduce Excess CVD Risk of Older Depressed Patients

You are invited to participate in a research study examining whether a new depression treatment can help prevent cardiovascular disease (CVD). You were selected as a possible participant because your medical records showed that you are a patient at an Eskenazi Health or Indiana University Health primary care clinic, are 50 years or older, and have one or more risk factors for CVD but have not developed CVD. Your responses to our depression questions also show that you may have a depressive disorder. Before you decide if you want to be a part of this study, we want you to know about it.

The study is being conducted by Dr. Jesse C. 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.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions at any time. You will have as much time as you need to decide if you would like to participate. If you agree to participate, you will be asked to sign this consent form, and you will get a copy to keep.

STUDY PURPOSE

CVD is the leading cause of death of American men and women. Medical research has shown that people who are depressed today have a higher risk of CVD in the future, similar to people with high cholesterol. In other words, depression is a new risk factor for CVD. The main symptoms of depression are (1) feeling down, depressed, or hopeless and (2) having little interest or pleasure in doing things. The purpose of this study is to compare a new depression treatment to standard depression treatment to see if our new treatment lowers the risk of developing CVD.

People who agree to participate will be randomly assigned to one of two groups, as if a coin were flipped to decide. If you are assigned to Group A (standard depression treatment), you will be referred back to your primary care provider, and he or she will decide how to treat your depression. If you are assigned to Group B (new depression treatment), you will receive up to a year of our *eIMPACT* treatment. A licensed mental health counselor (LMHC) will work with you and your primary care provider to treat your depression. Established treatments will be available to you, like antidepressant medications 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.

We plan to use the data from this study to develop depression treatments that could be easily used in primary care clinics. We hope that these depression treatments will help prevent CVD.

STUDY PARTICIPANTS

This trial will include primary care patients who are at least 50 years old, have one or more risk factors for CVD but have not developed CVD, and screened positive for a depressive disorder.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of up to 220 men and women participating in this study locally.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will be asked to attend a pre-treatment visit, a mid-treatment call approximately 6 months later, and a post-treatment visit approximately 12 months later. For participants assigned to *eIMPACT* (Group B), you will be asked to complete additional visits and calls to receive the depression treatment. Finally, all participants will be asked to complete yearly follow-up calls. Each visit and call is described below.

Pre-Treatment Visit (All Participants)

Within two weeks, you will be asked to come to the Indiana Clinical Research Center (CRC) at Indiana University Hospital for the 3-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 after the visit.

At the pre-treatment visit, you will have your height, weight, blood pressure, heart rate, and temperature measured by a nurse. The nurse will complete a standard blood draw to collect 1½ tablespoons of blood. This is similar to what your doctor would collect for usual blood tests. You will then be asked to fill out questionnaires on a secure computer in a private room. These questionnaires will ask you for basic background information, your medical and psychiatric history, and your medications. You will also be asked about your behaviors, such as smoking, exercise, and medication taking. Finally, you will be asked about your mood and sleep.

The research assistant will then place three small sensors on your shoulder and lower ribs to measure your heart rate. You will then be asked to rest in a bed for 10 minutes. The ultrasound test will then be completed to measure your blood vessel function. An ultrasound scan, which is a standard medical test, is painless and involves bouncing sound beams off an artery in your arm so it can be seen on a computer screen. A blood pressure cuff will then be placed on your lower arm and inflated for about 5 minutes. While the cuff is inflated, your hand will be uncomfortable. This is unavoidable and expected, and it will be relieved within a few minutes after the cuff is deflated. Next, another ultrasound scan of the artery in your arm will be done.

At the end of this visit, your mid-treatment phone call and post-treatment visit will be scheduled. 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 doctors will continue to make your own treatment decisions. Neither you nor your doctors will be able to choose your group assignment. If you are assigned to Group B (new depression treatment), you will briefly speak to the depression clinical specialist over FaceTime to learn about depression treatment materials and schedule your first session.

Treatment for Group A

If you are assigned to Group A (standard depression treatment), you will be informed that you screened positive for depression, will be provided with a list of mental health services available to Eskenazi patients, and will be encouraged to follow-up with your primary care provider regarding your depression. Your primary care provider will also receive a letter from our team informing him/her of your depression and assignment to Group A. This letter will also encourage your provider to work with you to address your depression and will provide the same list of available mental health services that we will give to you. Please note that, although we will pass

along information to your primary care provider, participants in Group A do not receive any depression treatments from the study team. Instead, depression treatments that participants in Group A receive during the study are from their usual providers, like their primary care provider. Also please note that there are no restrictions on the care that you can receive during the study, meaning that you will continue to 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 (new depression treatment), you will receive up to one year of our *eIMPACT* treatment. A Master's-level licensed mental health counselor, called a depression clinical specialist (DCS), will call you within two weeks of your pre-treatment visit. During this call, the DCS will review depression materials and discuss treatment options. The DCS will then work with your primary care provider to develop a treatment plan. Initial treatment options include 2-3 months of Beating the Blues, a computerized therapy for depression, or an antidepressant medication, whichever you prefer.

If you select Beating the Blues, you will have the opportunity to complete eight 50-minute therapy sessions, one per week. Sessions will take place at Indiana University Hospital, at Dr. Stewart's office, at your primary care clinic, or at a location selected by you where you can access a computer with internet, such as your home, your work, a family member's/friend's home, or a public library. Your preference will drive the location of the sessions.

Beating the Blues is a computer program, so you will not be meeting face-to-face with a therapist. Through 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 problem solving. 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 you select an antidepressant medication, it will be prescribed by your primary care provider and monitored by the DCS and your provider.

The DCS will be in regular contact with you during the 12 months to monitor your response to treatment. 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, including adding or switching to (a) Beating the Blues or talk therapy over phone or FaceTime or (b) another antidepressant medication. If your depression still does not improve, you may be seen by the study psychiatrist to discuss other treatment options. The main idea is that, if your depression does not improve, your treatment will be changed to see if another one works better for you.

You will continue to have access to and will receive any health services that are part of your usual care. There will be no restrictions on the care you can receive, although starting new depression treatments outside of the study is discouraged during the 1-year treatment period if you are assigned to Group B.

On occasion, FaceTime will be used to make contact with the DCS. This program encrypts information that is sent and is a secure form of communication. We will not record any sessions in this study, including FaceTime contacts.

Mid-Treatment Call at 6 months (All Participants)

About 6 months after the pre-treatment visit, you will be asked to complete questionnaires over the phone for about 45 minutes. Many of the questionnaires completed at the start of the study will be repeated. You will

also be asked about whether you have experienced any CVD events since the start of the study. If you have had a CVD event, we may request medical records related to the event.

Post-Treatment Visit at 12 months (All Participants)

About 12 months after the pre-treatment visit, you will be asked to come back to the CRC at Indiana University Hospital for the 3-hour post-treatment visit. This visit will be identical to the pre-treatment visit. In addition, you will be asked about whether you have experienced any CVD events since the mid-treatment call. If you have had a CVD event, we may request medical records related to the event.

Annual Follow-up Calls (All Participants)

Depending on when you enrolled in this study, you will be asked to complete 2-4 yearly follow-up calls. These calls will be identical to the mid-treatment call.

Study Newsletters at 3 and 9 months

About 3 and 9 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 heart healthy recipe, profiles for the eIMPACT team members, and a reminder to update the study team if your contact information has changed.

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 questionnaires or interviews

The interviews and questionnaires will be completed in a private room. The research assistants 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 to not answer any question.

Risks of the standard blood draw

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

Risks of the ultrasound scan

The ultrasound scan is a painless test that has no short- or long-term risks. The test usually causes a moderate uncomfortable feeling in your arm and hand because a blood pressure cuff is tightly inflated on your arm. The cuff will be inflated to a level similar to what you would experience in your regular physician's office. The uncomfortable feeling is relieved within a few minutes after the cuff is deflated. You may terminate the ultrasound scan at any time for any reason, including if the cuff becomes too uncomfortable.

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 telephone 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 Midtown Community Mental Health Center and escort you to the Crisis Intervention Unit at Eskenazi Hospital. If you prematurely terminate a phone 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.

BENEFITS OF TAKING PART IN THE STUDY

You may receive no direct benefits from participating in this study. By taking part in the study, you will also learn about the relationship between depression and cardiovascular disease at the post-treatment visit. In addition, participants in Group A will be informed that they screened positive for depression, and their provider will be encouraged to work with participants to address their depressive symptoms. Participants in Group B will receive 12 months of our new depression treatment free of charge. Finally, participants may feel satisfied knowing that their involvement will generate knowledge that may help to treat depression and prevent cardiovascular disease in the future.

ALTERNATIVES TO TAKING PART IN THE STUDY

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 leading treatments for depression are antidepressant medications and psychotherapy. You may want to contact your primary care provider to discuss treatment options. If you choose not to participate, your decision will not affect your regular healthcare or your relationship with the study team.

CONFIDENTIALITY

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 Heart Lung and Blood Institute/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](https://www.clinicaltrials.gov), 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.

COSTS

There are no costs directly associated with participation in this study. The costs of all study-related tests 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. You or your insurance company will be responsible for all standard of care procedures, drugs, tests, etc.

PAYMENT

You will receive payment for taking part in this study: \$100 cash for completing the pre-treatment visit, a \$25 gift card for completing the mid-treatment call, \$100 cash for completing the post-treatment visit, and a \$20 gift card for completing the each of the annual follow-up calls. Gift cards will be mailed once the call is completed. If you complete all visits and calls, you will receive a total of \$265 to \$305, depending on the number of follow-up calls. You will not be paid for completing any visits or calls related to depression treatment, although if you are in Group B, treatment will be provided free of charge. You will also receive up to \$10 per assessment visit to cover parking or transportation costs.

COMPENSATION FOR INJURY

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.

CONTACTS FOR 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. If you cannot reach the Dr. Stewart during regular business hours (8:00 AM to 5:00 PM), please call the Indiana University Human Subjects Office at (317) 278-3458 or (800) 696-2949. 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 or to discuss problems, complaints, or concerns about a research study or to obtain information or offer input, contact the Indiana University Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. You may do so by notifying any member of the research team (including the principal investigator) at any time by email, telephone, 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.

SUBJECT'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 statement to keep for my records.

SUBJECT'S SIGNATURE: _____ Date: _____

(must be dated by subject)

SUBJECT'S PRINTED NAME: _____

SIGNATURE OF PERSON OBTAINING CONSENT: _____ Date: _____

PRINTED NAME OF PERSON

OBTAINING CONSENT: _____

Form date: July 13, 2018