RESEARCH CONSENT FORM

Basic Information

Title of Project: Response to Relapse in Office-Based Opioid Treatment Trial

IRB Number: 1H79TI081600-01

Sponsor: Substance Abuse and Mental Health Services Administration

Principal Investigator: Tae Woo Park, MD
Phone: 617-414-1906
E-mail: taewoo.park@bmc.org

Study Phone Number: 617-414-1950

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. You will still receive clinical care at the ABOVE program if you do not agree to be in the study. The purpose of the **A**ddiction and **B**ehavioral health **O**utpatient reco**VE**ry clinic (ABOVE) program is to expand treatment for patients with co-occurring opioid use disorder (OUD) and mental disorders through the utilization of medications for OUD treatment, mental health services, and peer recovery support. We are doing the research to compare two different treatment approaches to help patients with OUD. The results of the study may allow people taking medications for OUD to come to the clinic less while still receiving effective treatment. There are two treatment approaches – Treatment A or Treatment B. These treatments are two different but similar ways to deal with relapse to use of illicit drugs for people taking medications for OUD.

If you agree, you will be randomized to one of two different ways to participate in the ABOVE program. Randomization is being assigned to one of the ways we can deliver the ABOVE intervention. In the Treatment A approach, if you test positive for opioids or other drugs after stabilization, you will be asked to return for clinical appointment weekly until you have 2 consecutive urine drug tests negative for opioids or other illicit drugs. You will then be asked to return every other week until you have 2 consecutive urine drug tests negative for opioids or other illicit drugs, before being asked to return every 4 weeks. In the Treatment B approach, the frequency of your clinical visits will be organized similarly as Treatment A (weekly, every other week, and every 4 weeks) but you will be able to move more freely between these steps. If you decide to stay for the whole study, you will participate in one of the ABOVE program treatment approaches for 24 weeks. After these 24 weeks have ended, the study will have

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ended but you will still be able to receive treatment in the ABOVE program. You will find more information about what will happen in this study later in this form.

If you choose not to participate in this study, you will receive the Treatment A approach in the ABOVE program as it is the approach typically used at Boston Medical Center.

The main risks of being in the study are loss of confidentiality (privacy), discomfort and stress from treatment and randomization, and others risks associated with the frequency of monitoring. You will find more information about risks later in this form.

You may benefit from being in the study because your treatment could result in a decrease in the number of visits required for treatment. You will find our more information about benefits later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. You may want to get a second opinion about being in the study. You can do so now or at any time during the study. Another doctor who is not an investigator can give you a second opinion about being in the study. You do not have to agree to be in this study even though it is offered by your doctor.

It is important for you to know that this is a research study. If at any point you decide you do not want to be in the research that is fine. You will always have access to all services at the ABOVE program even if you do not participate in the study.

Purpose

The purpose of this study is to learn whether there is a difference between Treatment A and Treatment B in keeping patients in medication treatment for co-occurring OUD and mental conditions. Treatment A and Treatment B are different ways to deal with relapse to illicit drug use in patients who are receiving medication treatment for OUD.

What Will Happen in This Research Study

If you agree to take part, after enrollment in the ABOVE program, you will be randomized to either Treatment A or Treatment B. This means that the choice of one or the other is made at random like a flip of a coin.

In both treatment approaches, after starting on MOUD, if you do not use opioids or other illicit drugs throughout the study, you will initially be asked to return weekly until you have 4 consecutive negative (drug-free) urine drug tests. This period is called initial stabilization. After initial stabilization, you will be asked to return every 2 weeks. If you then provide 2 consecutive negative urine drug tests for opioids or other illicit drugs, you will be asked to return every 4 weeks thereafter.

In Treatment A, if you test positive for opioids or other illicit drugs after initial stabilization, you will be required to return on a weekly basis beginning the process again, though this time only requiring 2 consecutive negative tests. After 2 consecutive negative tests, you will be asked to return every 2 weeks.

If you can provide 2 consecutive negative tests every 2 weeks without a positive test, you will move on to returning every 4 weeks.

In Treatment B, there are two main differences. First, if you test positive for opioids or other illicit drugs, instead of beginning the process again as in the intensive treatment arm, you will move down a "step" until you test negative for opioids or other illicit drugs. For example, if you are returning every 2 weeks for MOUD and test positive for opioids or unprescribed benzodiazepines, you will be asked to return in a week. If you then test negative for opioids or other illicit drugs, you will immediately go back to being asked to return every 2 weeks. Second, if you test positive for non-opioid or benzodiazepine illicit drugs (for example, cocaine), you will not be asked to return more frequently than every 2 weeks unless your clinician feels that you are at a particularly high risk of relapsing to opioid use. Additionally, in the initial stabilization period, you will still move to every 2 week visits as long as you can give 4 consecutive opioid-free urine tests, even if you are using other illicit drugs at the time.

If you are having to return at higher frequencies because of ongoing drug use, there will be exceptions made for emergency situations when you are unable to attend clinical appointments. These exceptions might include the death of a loved one, a court date, and work-related emergencies. Clinicians involved in the ABOVE program treatment team will determine whether an exception is made regarding increasing the frequency of visits.

All assessments will be part of your clinical care in the ABOVE program. There will be no additional assessments for this study. If you agree to participate in this study, we will review your clinical care records.

Your treatment may be discontinued if clinically indicated or treatment may be transferred to a more appropriate clinical program. For example, if you are found to be selling your medications, you may be discontinued from treatment in the ABOVE program and this research study. Or if you become pregnant, you may be transferred to an obstetrics clinic that specializes in treating pregnant women with medications for OUD. In all cases of treatment discontinuation, you are still encouraged to give assessments at 3 and 6 months for internal program evaluation purposes.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.
You will be one of approximately 197 subjects who will be asked to be in the study.

Risks and Discomforts

There are several risks to participating in the study described below.

Psychological stress from interview: All interviews and assessments will be performed for clinical purposes whether or not you agree to participate in the research study. The PI, other psychiatrists, psychiatric nurse practitioners, and addiction RNs will be available to respond to any concerns with referrals at the study site as needed should you describe any newfound psychological distress as a result of the interview. Urine drug tests will be collected at each visit. No laboratory tests will be done solely for research purposes. The results of these urine drug tests will be delivered for clinical purposes and could potentially be psychologically stressful. This information will be delivered by trained RNs, MDs, and NPs who are familiar with your care experience.

Psychological stress from randomization: You may feel distressed from the results of the randomization. This information will also be delivered by trained RNs, MDs, and NPs.

Loss of confidentiality: As with any research study, there is always a risk of loss of confidentiality. However, we will employ measures described later in this form how we will minimize the risk of breach of confidentiality.

Risks related to frequency of monitoring: You may be randomized to a treatment approach with less frequent monitoring, (i.e. fewer drug tests and visits with clinician) after illicit drug use. The consequences of less frequent monitoring are unknown, though one previous study suggests that it may lead to less drug use. There is a possibility that less monitoring could lead to a longer period of relapse to drug use. But if you do relapse, you will still have more monitoring than if you did not relapse. Also, if you and your clinician decide that you need more monitoring than described in the treatment approach you are randomized into, then you may receive more frequent monitoring equivalent to the other treatment approach.

There may be unknown risks or discomforts involved.

If you decide that you want to stop being in the study, we ask that you let us know. You are free to withdraw from the study at any point and for any reason.

If you get pregnant while you are in this study, you will be referred to an obstetrics clinic at Boston Medical Center that specializes in treatment of pregnant women with opioid use disorder.

Potential Benefits

The benefits of being in this study may be spending less time in clinic and experiencing fewer drug tests which may lead to greater satisfaction with your treatment. However, you may not receive any benefit from participating in the study.

Your being in the study may help investigators gain a deeper understanding of treatment of opioid use. Information gathered in this study will also contribute to more individuals with opioid use disorder being treated utilizing fewer resources without a loss in effectiveness. Information collected as part of this study will be made available to investigators who are part of the proposed study team or who join the study team.

Costs

Items and services done only for study purposes will be provided at no cost to you. They won't be billed to your health insurance either. You or your health insurance will be billed for all costs that are part of your normal medical care. These costs include co-payments and deductibles. There may be more insurance costs and co-pays depending on treatment arm and frequency of visit. You can ask any questions now about insurance coverage for this study or about the research activities paid for by the sponsor. You can also ask the investigator later, using the number on the first page of this form.

Payment

You will receive a $30 prepaid Clincard per assessment visit at the following time intervals: 3 months, 6 months, and discharge from ABOVE clinical program (if applicable). If you are discharged from the

ABOVE program or dropout from the research study, you will still be asked to complete the 3 and 6 month assessments. If those assessments are completed, we will continue to pay you.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.
If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- People who see your medical records. Please ask us if you have any questions about what information will be included in your medical records. We are only using information for the research study that would be collected for the purposes of your clinical treatment.
- Any people who you give us separate permission to share your information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

During this study, we may learn information from you that must be reported. If you tell study staff about any current thoughts of harming yourself, attempting suicide, or harming other people, investigators may need to break confidentiality to prevent this harm from happening. If this happens, we may refer you for an emergency evaluation at the Boston Medical Center Psychiatric Emergency Services or at the Boston Emergency Services Team (BEST) located near the hospital. We also may contacting treating health care providers to be sure they are aware of the risk identified. We would continue to reach out to you to be sure that you received the needed care and assessments.

Some study staff members are mandated reporters, including the study's Principal Investigator, Dr. Park. You should know that we are required to report information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others. If study staff learn of any current abuse or neglect of a child or elder, they must report this to the Department of Children and Families.

If you would like us to share information obtained during the study with your doctor or a mental health professional treating you, you will have the opportunity to sign a release of information allowing us to communicate with that provider. You can give consent for us to share only parts of the study information collected. If you do not want us to share this information, you do not need to sign this

release, and we will not share any information with your providers unless we learn of a safety concern as described above.

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.

Use and Disclosure of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or given out during this research includes:

- Information that is in your hospital or office health records. The records we will use or give out are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
- The health information specifically includes:
    - Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist)
    - Social work communications
    - Alcohol or drug use disorder treatment records, in particular record of prescription of controlled substances from the Massachusetts prescription monitoring program

The reasons that your health information might be used or given out to others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information. As we explained above, we also have to give out any information from you about child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others.

The people and groups that may use or give out your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study

- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research
- Government agencies in other countries that are involved in the research
- Public health and safety authorities who receive our reports about child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others.

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or giving out your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and give out your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG-privacyofficer@bmc.org or at Boston University at HIPAA@BU.EDU.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes ____No You may contact me again to ask for additional information related to this study

____Yes ____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

During this study, we may find out something that might make you not want to stay in the study. If this happens, we will tell you as soon as possible.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Kristin Parent at 617-414-1950. Also call if you need to report an injury while being in this research. Contact Kristin Parent at 617-414-1950 if there is no answer at that phone number or if you are calling after normal business hours.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and release of information that may identify you as described including your health information.

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

To be completed by witness if researcher reads this form to the subject
This consent form was read to and apparently understood by the subject in my presence.

_____
Printed name of witness (a person not otherwise associated with the study)

_____ _____
Signature of witness Date

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