RESEARCH CONSENT FORM

Basic Information

NCT 03698669

9-24-2023

Title of Project: Treating Opioid Patients' Pain and Sadness (TOPPS)
IRB Number: H-38056
Sponsor: National Institutes of Health (NIH)
Principal Investigator: Michael Stein, MD
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715 Albany Street
Boston, MA 02118
Study Phone Number: (617) 358-3643

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. We are doing the research to compare two interventions for people who have pain and sadness and take buprenorphine. If you agree, you will meet one-on-one with a study counselor and receive either the Life Goals program, or the Healthy Living program. You will be in the study for 9 months if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are the potential loss of confidentiality, or your discomfort with a question about your personal background and mental health. You will find more information about risks later in this form.

You might benefit from being in the study because you will receive some form of health education. You will find more information about benefits later in this form.

You could get these benefits without being in the study by seeking alternative treatment. You will find more information about alternatives later in this form.

If you agree to take part in this study, you will complete an initial survey that will take approximately 60 minutes. The entire meeting however may take up to 3 hours.

During your first survey, you will answer questions about several different areas of your life, like your alcohol and substance use, pain, your medical history, and mental health. During your first survey, we will also ask you some questions about mental health to confirm your eligibility. If you are not an active member of the OBAT or SSTAR clinic and you are not receiving buprenorphine (Suboxone) from the OBAT or SSTAR clinic at the time of enrollment, you will be asked to confirm that you are receiving an active buprenorphine (Suboxone) prescription from another clinic to confirm your eligibility. A prescription may be confirmed by showing study staff an active script or pill bottle with your name on it, by allowing the study team to communicate with your MOUD provider, or by answering a series of questions. Study staff will only retain whether or not the prescription was confirmed and if you meet eligibility criteria for active buprenorphine (Suboxone) prescription. If we find that the study is not a good fit for you after completing this survey, you will still receive compensation for your time, but you will not be asked to continue on in the study.

At the completion of the first survey, we will tell you if you are in the Healthy Living program or the Life Goals program. Which program you are in will be decided randomly. Random means that the program you are assigned to is pure chance, like flipping a coin. You have an equal chance of being in the Healthy Living program or the Life Goals program and our study staff have no control over which intervention you are assigned to.

Program 1: Healthy Living

If you are in the Healthy Living program, you will meet with a study behavioral health specialist, either in person or by phone, after the first survey to discuss which health education topics are most relevant for you. You will choose from a list of topics, including nutrition, sleep, and exercise. The second, third, fourth, fifth, and sixth meetings with the study behavioral health specialist will be conducted mainly by phone at approximately week 2, week 4, week 6, week 8, and week 11 and will last approximately 30-45 minutes. All sessions will be audio-recorded. At each meeting, you will discuss one of the health education topics you have chosen.

Program 2: Life Goals

If you are in the Life Goals program, you will meet with a study behavioral health specialist, either in person or by phone, after the first survey to briefly discuss the relationship between pain, sadness, and buprenorphine treatment for you. The second, third, fourth, fifth, and sixth meetings will be conducted mainly by phone at approximately week 2, week 4, week 6, week 8, and week 11 and will last approximately 30-45 minutes. All sessions will be audio-recorded. At each meeting, you will talk about your own specific goals and ways to live your life to the fullest while coping with chronic illness.

Follow-up appointments

The study lasts for 9 months. Regardless of which program you receive, you will also complete six follow-up surveys at 1-, 2-, 3-, 4-, 6-, and 9-months with a member of the study team. Each survey will last approximately 60 minutes and will take place primarily at BMC, but may also be conducted by telephone or at a safe community location of your choosing. You will answer similar questions about your alcohol and substance use, pain, your medical history, and mental health. All surveys will be audio-recorded.

FitBit D___

All study participants will receive a FitBit to collect the number of steps taken per day. You will be asked to wear the FitBit continuously for 7 days after your baseline survey. You will

need to return your FitBit either in person or through the mail.We will provide you with a prepaid envelope and ask you return it 7 days after you receive the FitBit.

Medical Records

If you agree to be in the study, we will review your medical records at Boston Medical Center starting 6 months before you are enrolled in the study, as well as during the period you are enrolled in the study.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Risks and Discomforts

A possible risk from these surveys is your discomfort or unease with a question about your personal background and mental health. You have the right not to answer any question that makes you feel uncomfortable.

Potential Benefits

The benefits of being in this study may be that you will receive some form of health education. However, you may not receive any benefit. Your being in the study may help the investigators learn more about treating patients with pain and sadness who receive buprenorphine.

Alternatives

The following alternative procedures or treatments are available if you choose not to be in this study: you may seek alternative treatment and we can also provide you with a referral for treatment that is suitable to you. Counseling and health education for pain management is also available through clinical services.

Costs

There is no cost to you for being in the study.

Payment

You will receive up to $370 total in gift cards for completing surveys and returning the FitBit. The study may also cover local transportation costs. Participants will be paid for each study activity as outlined below.

Time Point	Activity	Amount
Baseline	Assessment	$60
7 days after Baseline	FitBit return	$20
1 Month	Assessment	$40
2 Month	Assessment	$40
3 Month	Assessment	$50
4 Month	Assessment	$50
6 Month	Assessment	$50
9 Month	Assessment	$60
	Total	**$370**

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 paperfiles in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC**.** The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information. We will record some information from this study in your medical record, such as information related to your medical care. We will not record any of your answers to the survey questions in your medical record. Please ask us if you have any questions about what information will be included in your medical records. You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protectedin other ways.

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.
- Any people who you give us separate permission to share your information.

You should know that we are required to report information about child abuse or neglect, elder abuse, or if you intend to harm yourself or others.

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 medical book orjournal.

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

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:
  - HIV/AIDS information
  - Sexually transmitted disease information
  - Communicable disease information
  - Alcohol or drug use disorder treatment records about buprenorphine treatment

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, or if you intend to harm yourself 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, Stanley Street Treatment and Resources, 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
- Public health and safety authorities who receive our reports about child abuse or neglect, elder abuse, or if you intend to harm yourself 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 may occur during study participation, after your participation has ended, or 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 ask for additional biological samples 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.

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 Dr. Michael Stein at 617-358-1956. Also call if you need to report an injury while being in this research.

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.

Project Title: Treating Opioid Patients' Pain and Sadness (TOPPS)
Principal Investigator: Michael Stein, MD

Communication method (check one):

In-person
Phone
BMC Zoom
BU Zoom Meetings for HIPAA
BU Teams

In-Person Signature Page

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

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

Remote Consent Signature Page

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

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 the participant is a limited/non-reader or cannot electronically sign the consent form

By directing the witness to sign 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 are providing consent for yourself:
- 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.

Subject: _____
Printed name of subject

The subject has confirmed that they have signed and dated a copy of the consent form, and they have directed me to sign this consent form on their behalf.

The subject did not need the consent form read to them

The subject is a limited- or non-reader. The consent form was read to and apparently understood by the subject in my presence.

_____
Printed name of witness

_____ _____
Signature of witness Date