Protocol Title: Alcohol Use and Chronic Pain among Primary Care Patients
NCT04958200
IRB Protocol #: 4947
Charles River Campus Institutional Review Board

Relevant Approval Dates

- Most recent IRB approval for Continuing Review Application: September 10, 2024
- Final approval date for consent form used in the trial: September 19, 2022

Study 5: Pilot Study

Consent Form

BASIC INFORMATION

Title of Project: Alcohol Use and Chronic Pain among Primary Care Patients

Sponsor: National Institutes of Health/National Institute on Alcohol Abuse and Alcoholism

BU Charles River Campus (BU-CRC) Principal Investigator: Tibor Palfai, PhD, Department of Psychological and Brain Sciences, 900 Commonwealth Ave, Boston MA 02215, 617-353-9345
palfai@bu.edu
IRB Number: 4947

BU Medical Campus (BUMC) Principal Investigator: Natalia Morone, MD, Department of Community Health Sciences, Boston University School of Public Health, Crosstown Center, 801 Massachusetts Ave, 617-414-6652, Natalia.Morone@bmc.org
INSPIR #H38310

Study Phone Number: 857-225-8843

THE PROJECT

You are invited to participate in a research study on chronic pain and alcohol use among patients in primary care. You have been selected for this study because you experience chronic pain, consume alcohol, and are currently in primary care. During this study, you will be asked a series of questions regarding your symptoms of pain, your alcohol use, and any previous treatment that you have received for these conditions. You will also be asked about your use of smartphones and the internet. The purpose of this study is to develop an intervention approach to help patients in primary care reduce their chronic pain and make informed decisions about their alcohol use.

Your participation is entirely voluntary: whether or not you choose to participate will not affect your existing relationships with Boston Medical Center (BMC), Boston University Medical Campus (BUMC), or Boston University (BU) in any way. Boston University officials and health care providers who are not part of this research study will not have access to your responses unless you voluntarily choose to share them. Any information you provide during the study will be kept confidential (except for disclosures to appropriate authorities that may be required by law as described in the CONFIDENTIALITY section of this form, below).

In this study, we will ask you questions, review your medical records, and measure your breath alcohol. The procedures in this study are for research purposes only and will not affect your normal healthcare at BMC. In addition, intervention sessions will be recorded to permit review of procedures.

Questionnaires: We will ask you questions about your use of alcohol and drugs, physical and mental health, and other personal information. Information about both legal and illegal activity

(along with alcohol and drug use) will be collected in questionnaires. All in-person interviews will be in a private space. Visits will be at the General Clinical Research Unit (GCRU) at BUMC or at the Psychological and Brain Sciences Department at Boston University which is located at 900 Commonwealth Avenue. While there are public health concerns that restrict in-person visits and to reduce risk of COVID-19 transmission, interviews will occur over videoconferencing using encrypted telecommunication technology. Interviews may be completed in person if you would be otherwise unable to participate in the study.

Health Records: For research purposes only, study staff will collect information about your use of medical services, prescription history, diagnoses, and test results relevant to your diagnoses. We will use records at BMC (including electronic records) in this study if you are a patient at BMC. If complete records are not available from BMC, the study may request and review similar records from other public or private sources regarding your health and healthcare. BMC and other health records will also be used to find you and update contact information. The records reviewed will be from one year before the first person enters the study until one year after the last person enters the study. If you leave the study, we will still collect this information unless you ask us not to. All of these records will be kept private as reported below under the section titled “Confidentiality”.

Data Repository: We will keep electronic research data on computers at the Biostatistics and Epidemiology Data Analytics Center (BEDAC). This state-of-the-art data repository safeguards research data on computers in locked rooms behind two card-access doors with access to the main door restricted to key staff in charge of computers for Boston University. Information that you provide to us (including information taken from your medical records) will be kept anonymous and will be identified by a participant number instead of your name. A master list of participant numbers linked to identifying information will be kept physically separate from the rest of the study data. Using a participant number and separate master list helps protect your privacy. If you leave the study, we will keep the information already collected from you confidential.

Study Procedures: The study consists of four parts: (1) a baseline interview and initial intervention session, (2) a series of internet-based sessions and communications with a health promotion coach over the next 8-weeks (intervention phase), 3) a 2-month follow-up assessment, and (4) a 4-month follow-up assessment. During the first visit (today), you will be asked to complete a baseline assessment interview in which we will ask you questions about your use of alcohol and drugs, physical and mental health, and other personal information. These interviews will be in a private space. Visits will be at the General Clinical Research Unit (GCRU) at BUMC, or at 900 Commonwealth Ave. at BU. While there are public health concerns that restrict in-person visits and to reduce risk of COVID-19 transmission, interviews will be conducted remotely using videoconferencing. Interviews may be completed in-person if you are otherwise unable to participate. Final determination of eligibility for the study will be based on the baseline assessment interview completed today. If you are not eligible, you will still be compensated for your time and effort but you will not be enrolled in the remainder of the study. If you are eligible after completing the baseline assessment interview, you will then meet with a coach through videoconferencing who will begin the intervention phase during this same visit (today).

The first visit today will take approximately 2.5 hours.

For this phase, you will be randomly assigned to one of two conditions. This means that you will have an equal chance of being assigned to one or the other condition:

Condition One: Some participants will be enrolled in the information condition in which they will meet with the health counselor and receive information about alcohol, its effects on pain, and referral sources for pain and alcohol use.

Condition Two: Other participants will be assigned to the Internet intervention. In addition to meeting with the health promotion coach in-person today, these participants will complete a series of video-based intervention sessions on a smartphone and communicate with the coach via text messaging and/or phone. If you are assigned to this condition, you will be asked to complete 1-2 internet sessions per week at a time of your convenience over the next 8 weeks. Each internet session will take 10-15 minutes to complete and each weekly discussion with the coach will take 15-20 minutes. The coach will communicate with you each week about your experience with the internet sessions, your chronic pain, and your alcohol use. He/she will also discuss strategies that may help you manage your pain. Participants in this condition will receive instructions on how to access the intervention and messaging app procedures.

Regardless of your assignment for the intervention phase (Condition One or Condition Two), you will be asked to return to BUMC (or 900 Commonwealth Avenue at Boston University) two months after the baseline interview to complete a follow-up interview where you will be asked questions about your pain, alcohol and substance use. You will also be asked questions about your experience with the intervention. This interview will take approximately 1.5 hours. A second follow-up interview will be scheduled four months after the baseline interview. This final interview will last approximately 1.5 hours. To reduce risk of transmission of COVID-19, interviews will take place over videoconferencing. Interviews may take place in-person pending COVID-19 restrictions and if you are otherwise unable to complete the interviews.

If you are assigned to Condition Two (Internet Intervention), you may be provided with equipment and/or resources (e.g., phone, data plan) to facilitate access to the intervention website. These materials are to be used for the purpose of the study only. All data plans and hot spots will be terminated and phones will be deactivated at the end of participation. By accepting equipment and/or resources to participate in the study, you agree to use them for study purposes only. Moreover, any equipment that is provided will be returned at the end of your study participation and will be maintained in good condition. If you are provided with equipment for this study, a separate form will need to be signed to confirm your awareness of these conditions.

Your discussions with the health coach will be digitally recorded so that there will be a record of these sessions. The purpose of these recordings is to provide information to researchers so they can understand how the intervention is being delivered and received by patients. These responses will be combined with the responses of other patients and analyzed by researchers to further refine and develop the intervention.

RISKS AND DISCOMFORTS

Possible risks and discomforts related to this study include psychological stress resulting from consideration of questions on the survey, participation in the intervention sessions, and risks to confidentiality associated with study participation. We expect any such risks or discomforts to be minimal.

Confidentiality: While study records are confidential, there is always the possibility for loss of confidentiality. We take many precautions to keep your information safe and private. While we will make reasonable efforts to maintain the confidentiality of your study records, we cannot eliminate the possibility that events beyond our control could lead to a loss of confidentiality. There is also risk of breach of confidentiality through the use of internet-based videoconferencing, internet-based content, text messaging, and other communications with the coach/interventionist, though we will also take precautions to minimize the potential for this outcome.

BENEFITS

There are no direct benefits to participating. Potential benefits that you may obtain from participation in this study include learning more about your own alcohol use patterns and factors that influence your experience of pain and learning skills to manage pain. This study may also provide benefit to society as it will inform investigators about methods of treating pain and alcohol use among patients in primary care. No special provision will be made for compensation or for payment for treatment solely because of your participation in the study.

COSTS

You may have costs related to travel or parking. If study visits are completed remotely, there will be no costs associated with transportation. It should be noted that internet-based videoconferencing and the intervention mobile application use data. If you do not use Wifi settings or do not have an unlimited data plan, you will use data from your cell phone plan.

ALTERNATIVES TO PARTICIPATION

There are no alternatives to participation apart from the study described in this consent form. You may decline to participate if you do not wish to participate.

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 described in this form.

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

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

- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
- Information collected about you as a part of this study may be used to determine your eligibility for related studies. You may be approached by study staff about your participation in these related studies. You will have the option of choosing whether or not you want to participate in these studies and will provide separate informed consent if you choose to participate.

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 or otherwise as required by law.

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

- People or groups within BU-CRC/BUMC/BMC:
    - Researchers involved in this research study.
    - The BU Institutional Review Board that oversees this research.
    - 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 outside of BUMC/BMC:
    - People or groups that we hire to do certain work for us, such as data storage companies or laboratories
    - Federal and state agencies involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.
    - Organizations that make sure hospital standards are met.
    - The sponsor(s) of the research study, and people or groups it hires to help them do the research.
    - Other researchers that are part of this research study.
    - A group that oversees the research information and safety of this study.
    - Other researchers who apply to use your data to answer other research questions.

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

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 can choose 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 this study. This is because we need to use the health information to do the research.
- You have the right to change your permission to use or share your health information in this research study. If you want to take away your permission, you must talk to staff who work on this research study. If you take away your permission, you will not be able to take back information that has already been 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 take away your permission, you cannot continue to be in the study.
- You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.
- The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

CONFIDENTIALITY

All survey and interview data will be recorded confidentially and will be accessible only to study staff and/or staff from Boston University's Institutional Review Board (IRB), who may review study data to verify the integrity of the research being conducted. Each participant will be assigned a numeric identification code for data collected in this study. These codes and names will be accessible only to the project director and individuals involved in the study. We will take a number of steps to ensure the privacy of participants. The web-based data collection and digital audio recordings will be password protected. The databases will be created using MS SQL Server and reside on a secure, password-protected server. Access to the database will be implemented by means of unique login names and passwords. Access to certain functions within the web application will be restricted by user and authenticated by username and password. Lists of patients' names and email addresses will be kept in a secure password-protected database accessible only to research staff and the PI. Eventually, following all data collection and entry, the code list will be destroyed.

For the delivery of the initial videoconferencing session with the health coach and for the text messaging components of the intervention, encrypted telecommunication technology will be used to provide real-time videoconferencing between the patient (at their chosen site) and interventionist (at Boston University). Patients are discouraged from using last names during sessions, and we will require patients to generate access ID numbers that do not include any identifying information.

To help protect your privacy, a Certificate of Confidentiality from the National Institutes of Health (NIH) is included as part of this study. The certificate does not mean that the Secretary of the Department of Health and Human Services (DHHS) approves or disapproves of the project.

This certificate allows researchers to maintain the confidentiality of your information even if a court subpoenas our records as part of any federal, state or local legal proceedings. The investigators will use the Certificate of Confidentiality to object to any requests for information that would identify you except in cases of government audit of this study. There are other limits to confidentiality of which you should be aware: Disclosures of current child abuse, senior citizen abuse, the abuse of any disabled person, or intention to inflict physical harm on yourself or any other person may be reported to appropriate authorities as required by law. It should be noted that there are no specific questions asked in this study that explicitly refer to these issues.

IN ADDITION, if you voluntarily disclose your participation in the study or if another party learns of your participation in the research study then we may not use the NIH Certificate of Confidentiality to withhold this information. All other procedures to safeguard confidentiality of responses described above, however, will be applied.

CONTACT INFORMATION

Any questions about this study should be directed to the Study Coordinator, by phone at 857-225-8843 or by email to mhealth@bu.edu. You may also contact Dr. Tibor Palfai at 617-353-9345. Any questions about your rights as a research subject should be directed to the CRC IRB office at 617-353-6115 or irb@bu.edu.

COMPENSATION

You will receive total compensation of $150 for participating in this study. Compensation for time and effort will be $50 for the baseline visit, $50 at the 2-month follow-up visit, and $50 at the 4-month follow-up visit. If you are not eligible based on the baseline assessment interview completed today, you will still be compensated $50 for your time and effort. You will be paid through check, pre-paid gift card (e.g., Visa, American Express, etc.), or cash depending on available means.

RIGHTS OF PARTICIPANT

You are free to refuse participation in the study, decline to answer any question, or withdraw from the study at any time without penalty, judgment, or loss of benefits. You should know that declining or discontinuing participation in the study will not affect your status as a patient at Boston Medical Center in any way. A copy of this consent form will be provided to you.

SIGNING STATEMENT

Participant: _____
Printed name of participant

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 Participant 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